

As filed with the Securities and Exchange Commission on January 29, 2024.

Registration No. 333-276046

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

**AMENDMENT NO. 1
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

FRACTYL HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3841
(Primary Standard Industrial
Classification Code Number)

27-3553477
(I.R.S. Employer
Identification No.)

**17 Hartwell Avenue
Lexington, MA 02421
Telephone: (781) 902-8800**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Harith Rajagopalan, M.D., Ph.D.
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**Approximate date of commencement of proposed sale to the public:
As soon as practicable after this Registration Statement is declared effective.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion
Preliminary Prospectus dated January 29, 2024.

PROSPECTUS

7,333,333 Shares



Common Stock

This is Fractyl Health, Inc.'s initial public offering. We are selling 7,333,333 shares of our common stock.

We expect the initial public offering price to be between \$14.00 and \$16.00 per share. Currently, no public market exists for our common stock. We have applied to list our common stock on the Nasdaq Global Market ("Nasdaq") under the symbol "GUTS." The closing of this offering is conditioned upon Nasdaq's final approval of our listing application. We cannot assure you that our listing application will be approved. If our common stock is not approved for listing on Nasdaq, we will not consummate this offering.

We are an "emerging growth company" and a "smaller reporting company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves risks. See "[Risk Factors](#)" beginning on page 18 of this prospectus.

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) We refer you to "Underwriting" beginning on page 240 for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 1,099,999 shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The shares will be ready for delivery on or about _____, 2024.

BofA Securities

Morgan Stanley

Evercore ISI

The date of this prospectus is _____, 2024

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus, any amendment or supplement to this prospectus, or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

BASIS OF PRESENTATION

Except where the context otherwise requires or where otherwise indicated, the terms “Fractyl,” “Fractyl Health,” “we,” “us,” “our,” “our company,” “Company” and “our business” refer to Fractyl Health, Inc and its subsidiary.

The consolidated financial statements include the accounts of Fractyl Health, Inc. Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. Our fiscal year ends on December 31 of each year. References to 2022 refer to the year ended December 31, 2022. Our most recent fiscal year ended on December 31, 2022.

Certain monetary amounts, percentages and other figures included in this prospectus have been subject to rounding adjustments. Percentage amounts included in this prospectus have not in all cases been calculated on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this prospectus may vary from those obtained by performing the same calculations using the figures in our consolidated financial statements included elsewhere in this prospectus. Certain other amounts that appear in this prospectus may not sum due to rounding.

TRADEMARKS AND TRADENAMES

This prospectus includes our trademarks and trade names, including, without limitation, REVITA, REJUVA and our logo, which are our property and are protected under applicable intellectual property laws. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we or the applicable owner will not assert, to the fullest extent permitted under applicable law, our or its rights or the right of any applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

INDUSTRY AND OTHER DATA

This prospectus contains industry, market and competitive position data from our own internal estimates and research as well as industry and general publications and research surveys and studies conducted by independent third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believe to be reliable. Our internal data and estimates are based upon information obtained from trade and business organizations and other contacts in the markets in which we operate and our management’s understanding of industry conditions. Management is responsible for the accuracy of our internal company research and believes such information is reliable and the market definitions are appropriate. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors”. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent third parties and by us.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read the entire prospectus carefully, including “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Some of the statements in this prospectus constitute forward-looking statements. See “Cautionary Note Regarding Forward-Looking Statements.”

Overview

We are a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including type 2 diabetes and obesity. Despite advances in treatment over the last 50 years, type 2 diabetes, or T2D, and obesity continue to be principal and rapidly growing drivers of morbidity and mortality. According to the Centers for Disease Control and the International Diabetes Federation, approximately 100 million people in the United States have prediabetes and/or obesity, and an additional 25 million people have T2D on medical therapy. In 2022, there was an estimated \$65 billion in annual pharmaceutical spending on drugs aimed at controlling glucose and body weight, all attributable to medicines requiring chronic administration, none of which modifies underlying disease progression. Highly potent drugs in the GLP-1RA class are now available to lower blood sugar, lower weight, and prevent cardiovascular mortality. However, a retrospective study conducted by Polonsky *et al.* analyzing medical claims data between July 2012 and January 2019 demonstrated that a majority of patients on a weekly GLP-1RA (i.e., semaglutide, dulaglutide or exenatide extended release) discontinued therapy at 12 months. Discontinuation of these agents typically leads to an immediate loss of metabolic benefit and weight rebound, as seen in Eli Lilly’s SURMOUNT-4 study with tirzepatide and Novo Nordisk’s STEP-1 extension study with semaglutide. We believe the unmet need has now shifted from temporary glucose lowering and weight loss strategies to approaches that can enable durable maintenance of metabolic health without daily or weekly pharmacotherapy. Our goal is to develop durable disease-modifying therapies that are designed to provide long-term maintenance of metabolic health without requiring lifetime treatment by targeting the organ-level root causes of T2D and obesity. We believe there is significant clinical and economic opportunity for new approaches to achieve a major leap forward by enabling long-term control over T2D and obesity without the burden of chronic therapies.

Emerging consensus on the role of the gut in driving human metabolic disease led our founders to design novel, differentiated disease-modifying therapies aiming to advance patient care from management into prevention and remission of underlying disease. The Revita DMR System, or Revita, our lead product candidate, is an outpatient procedural therapy designed to durably modify duodenal dysfunction, a major pathologic consequence of a high fat and high sugar diet, which can initiate T2D and obesity in humans. The duodenum regulates the human metabolic response to food intake, and modern diets drive dysfunctional hyperplasia of the duodenal mucosa. This results in alterations to physiologic signaling that affect glucose control and satiety. The Revita system is designed to enable durable and repeatable metabolic improvement via hydrothermal ablation of the dysfunctional duodenal mucosa to address duodenal pathology and consequent metabolic disease progression directly. We have observed the Revita DMR Procedure to be generally well tolerated and to have demonstrated durable blood glucose lowering and weight maintenance for two years post-procedure in controlled studies of patients with T2D who are inadequately controlled despite already taking certain ADAs and receiving lifestyle counseling. We have initiated a broad clinical program designed to evaluate Revita in multiple clinical studies across a range of patient populations from prediabetes and obesity to advanced T2D patients on long-acting insulin. We have obtained Breakthrough Device designation from the U.S. Food and Drug Administration, or the FDA, for Revita to perform hydrothermal ablation of the duodenal mucosa, or the Revita DMR Procedure, to improve glycemic control and eliminate insulin needs in T2D patients who are inadequately controlled on long-acting insulin.

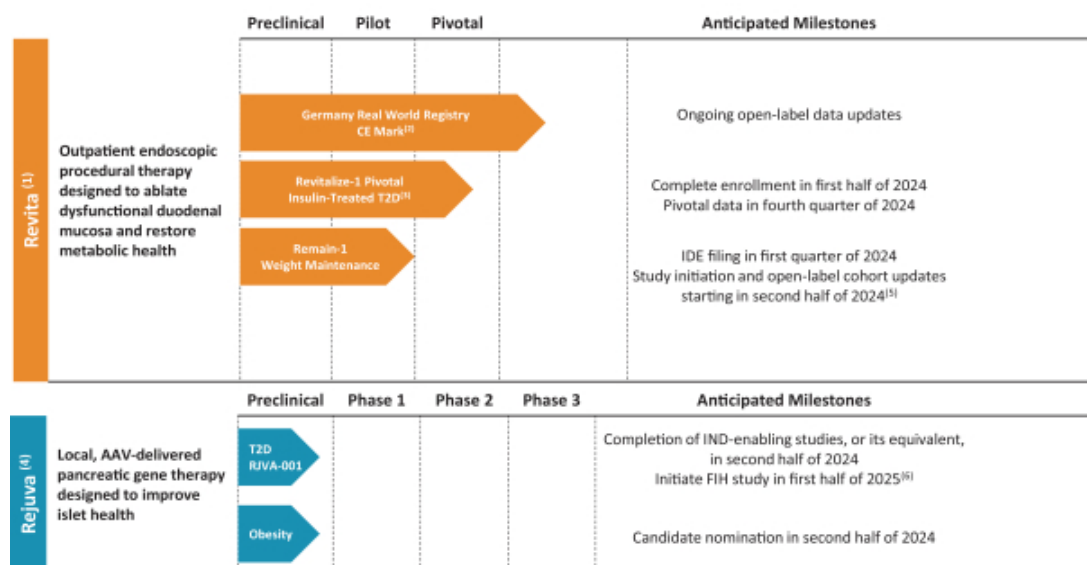
We are currently enrolling our pivotal Revitalize-1 study in patients with inadequately controlled T2D despite being on up to three anti-diabetic agents, or ADAs, and daily insulin. We anticipate completing enrollment in the first half of 2024 and expect to report topline data in the fourth quarter of 2024. We are also planning to evaluate Revita in a two-part, parallel cohort, randomized, open-label clinical study, which we refer to as the Remain-1 study, for weight maintenance in patients with obesity who have lost at least 10% total body weight on GLP-1RA therapy and wish to discontinue their GLP-1RA without weight regain. We expect to submit an IDE and comparable documents to the FDA and comparable foreign regulatory authorities or notified bodies in the first quarter of 2024 for a potentially pivotal Remain-1 study. If the IDE for Remain-1 is approved, we plan to initiate the study and begin reporting updates for the open-label cohort, which we refer to as the Reveal-1 cohort, in the second half of 2024. Revita is already approved for patients with inadequately controlled T2D in Europe. After securing reimbursement for Revita Germany in the first half of 2023, we initiated our pilot commercial launch along with a Real World Registry study. We believe Revita has the potential to serve as a backbone therapy to prevent progression of T2D and for the prevention of weight gain, working in concert with behavioral therapies and standard of care pharmacology.

We are also developing Rejuva, a novel, locally administered, adeno-associated virus, or AAV, delivered pancreatic gene therapy, or PGTx, platform. Rejuva is designed to enable long-term remission of T2D and obesity by durably altering metabolic hormone function in the pancreatic islet cells of patients. In a preclinical head-to-head study, a glucagon-like peptide 1, or GLP-1, PGTx candidate demonstrated improvement in glycemic control, delayed T2D progression and reduction in weight compared to semaglutide (the active agent in Ozempic and Wegovy), an FDA-approved GLP-1RA. We believe these results highlight the potential benefits of metabolic treatment at the locus of disease in the pancreas. Our approach to pancreatic gene therapy is enabled by our expertise in developing proprietary delivery systems that target the gut locally and precisely. We plan to complete Investigational New Drug application, or IND, or IND-equivalent, enabling studies for RJVA-001, our first nominated GLP-1 PGTx candidate designed for the treatment of T2D, in the second half of 2024. If the IND, or IND-equivalent, for RJVA-001 is approved, we plan to initiate a first-in-human study in the first half of 2025.

We believe Revita and Rejuva, if approved, have the potential to revolutionize treatment across the spectrum of T2D and obesity, align the clinical and economic interests of key stakeholders around the long-term regression of metabolic disease, and, at their fullest potential, significantly reduce the burden of metabolic disease globally.

Our Development Pipeline

Our development pipeline for Revita and Rejuva PGTx candidates target large market indications in T2D and obesity and aim to transform treatment from chronic symptom management to disease-modifying therapies that target the organ-level root causes of metabolic disease. The following table summarizes our development pipeline and potential clinical opportunities across the spectrum of metabolic disease, from advanced T2D on insulin to obesity and prediabetes:



(1) Revita has been granted Breakthrough Device designation for the hydrothermal ablation of the duodenal mucosa to improve glycemic control and eliminate insulin needs in T2D patients inadequately controlled on long-acting insulin; and CE mark obtained from EU and UK in 2016 for Revita for the improvement of glycemic control in patients with inadequately controlled T2D despite oral and/or injectable glucose lowering medications and/or long-acting insulin.
 (2) The Germany Real World Registry study is a post-market, clinical follow-up study in real-world patients with inadequately controlled T2D on at least one ADA.
 (3) The Revitalize-1 study is a pivotal study in patients with inadequately controlled T2D despite being on up to three ADAs and daily insulin.
 (4) Product candidates under our Rejuva gene therapy platform will undergo Phase 1, Phase 2 and Phase 3 clinical trials.
 (5) If IDE is approved.
 (6) If IND is approved.
 * IND = Investigational New Drug Application with FDA or comparable regulatory body; IDE = Investigational Device Exemption with FDA or comparable regulatory body; FIH = first-in-human.

Our Team

We were founded by our Chief Executive Officer, Harith Rajagopalan, M.D., Ph.D., and our President and Chief Product Officer, Jay D. Caplan, with the goal of developing innovative procedures and novel therapeutics to improve the lives of patients with metabolic diseases, initially targeting T2D. Before starting Fractyl Health, Dr. Rajagopalan was a physician scientist and cardiovascular fellow at Brigham and Women’s Hospital. During his M.D./Ph.D. training at Johns Hopkins, Dr. Rajagopalan did award winning research on mechanisms of colorectal cancer formation with significant implications on cancer metabolism and published in leading scientific journals, including *Nature* and *Science*. Dr. Rajagopalan’s background in intestinal biology, cardiovascular medicine and stem cell research has contributed to the founding scientific insight behind Fractyl Health: intestinal stem cell biology fundamentally helps to explain one of the root causes of obesity and metabolic disease in humans, along with the attendant health consequences, including T2D, cardiovascular disease, or CVD, and colorectal cancer. Mr. Caplan is an electrical engineer by training and an experienced life sciences executive with an extensive track record of developing transformational medical products, including at ThermoCardio with the development of the HeartMate 2 Left Ventricular Assist Device. Our multi-disciplinary

team consists of both seasoned biopharmaceutical and medical device professionals with deep industry experience. Our team brings together experts across multiple areas, including endocrinology (particularly in metabolic diseases), gastroenterology, endoscopy, engineering and medical device development. Members of our team have worked with well-regarded biopharmaceutical and medical technology companies, such as Pfizer, AbbVie and Abbott, and we are supported by a leading group of life sciences investors.

What Sets Us Apart

Our vision is to develop transformative therapies that can prevent and eliminate metabolic disease. Our culture of scientific rigor and innovation is entrenched in all aspects of our organization and informs our goal of disrupting the current, inadequate chronic care model in T2D and obesity. We are focused on developing disease-modifying therapies to treat metabolic diseases by targeting the gut and pancreas, driving widespread adoption of our novel approach, delivering on the promise of improved experience for patients and health systems, and also potentially reducing costs for the healthcare system. We believe our vision is supported by the following strengths:

- ***Pioneering New Approaches Based on Deep Understanding of Metabolic Diseases.*** We are pioneering the development of disease-modifying therapies targeting the organ level root cause of metabolic disease. Our approach builds on over a decade of our research and the accumulation of independently published, supportive clinical evidence, all implicating the gut and pancreas as validated, untapped targets in T2D and obesity. We aim to restore and preserve the health of the key organs required for metabolic fitness and reduce the burden of metabolic disease for patients.
- ***Developing Disease-Modifying Therapies that Provide Long-Term Metabolic Benefits and the Potential to Shift the Treatment Paradigm in T2D and Obesity.*** Our Revita and Rejuva programs are designed to target dysfunction in the duodenum and pancreas, respectively, to provide long-term metabolic benefits from a single administration. For this reason, Revita and Rejuva offer the potential to target T2D and obesity in a manner that we believe is not addressed with currently available therapies, including the prevention and remission of the disease. Specifically, Revita has the potential to play a significant role in preventing T2D onset and weight gain, while Rejuva has the potential to drive remission of T2D and achieve durable weight loss. We believe Revita and Rejuva's unique features can provide significantly differentiated and compelling solutions to address the large unmet need in these metabolic diseases. If approved, we believe these programs can fundamentally disrupt the chronic care model for patients with or at risk for T2D and obesity, and could offer several key advantages, including sustained clinical benefit in glucose control and weight loss and reduced long-term disease management burden for patients.
- ***Rigorous Approach to Clinical Development.*** The Revita clinical program is designed to advance the development of Revita to potentially become a backbone procedural therapy across the spectrum of T2D and obesity. To date, we have evaluated Revita in over 300 patients across multiple clinical studies and we have observed over 500 patient-years of exposure data, favorable tolerability data, as well as favorable glycemic control and weight maintenance data. Our Rejuva platform with GLP-1 PGTx candidates has been evaluated in small and large animal models, as well as *ex vivo* murine and human islets. In a head-to-head preclinical study in a *db/db* mouse model, a GLP-1 PGTx candidate demonstrated improved glucose control, prevention of T2D progression and prevention of weight gain compared to semaglutide, an FDA-approved GLP-1 receptor agonist, or GLP-1RA. We plan to leverage our extensive clinical experience with Revita to inform our clinical plans with our Rejuva PGTx candidates.
- ***Aligning Interests of Key Stakeholders: Patients, Referring Physicians, Providers and Payors.*** We believe Revita and Rejuva, if approved, have the potential to offer clinical and economic

benefits while reducing the burden of disease management compared to the current standard of care in T2D and obesity. We believe both programs have the potential to broadly align interests across key stakeholders involved in the treatment of T2D and obesity, and may have the following benefits to these groups:

- *Patients.* Improving weight and glycemic control while reducing the number and burden of therapies required to adequately control T2D and obesity.
- *Referring Physicians.* Preventing weight gain and lowering HbA1c for specific patient populations with a procedural therapy that reduces the workload in disease management (i.e., rigorous patient medication, diet adherence) and improves quality metrics associated with the disease.
- *Providers.* Straightforward, easy to train outpatient procedures, which we believe could be safely deployed at scale across a large patient population. Intended to seamlessly integrate into existing endoscopist workflows and provide a new, potentially profitable service line for hospitals with a patient-friendly therapeutic option for a significant portion of their patients.
- *Payors.* Significant health economic benefits for payors who are currently struggling with the increasing expenses of T2D and obesity, driven primarily by unchecked disease progression and the lack of disease-modifying therapies.
- ***Purpose-Built Leadership Team with Shared Mission to Advance Patient Care in Metabolic Disease.*** Our diverse team, combining marketing, product development and therapeutic expertise, has over 150 years of collective experience in therapeutic development. We are mission-driven to develop novel disease-modifying therapies that can potentially reverse metabolic diseases for patients and for health systems. Our team aims to continuously advance and expand upon our body of knowledge in order to establish and maintain a scientific leadership position in our therapeutic areas of focus. We do so by collaborating with expert advisors who are leaders in metabolic disease, endocrine signaling and endoscopy. As part of these ongoing efforts, we have also convened the Erase T2D Task Force, a group of academic and scientific experts in the metabolic disease space, to serve as key advisors as we develop our understanding of the role of the gut in T2D. The Erase T2D Task Force is co-chaired by our CEO, Harith Rajagopalan, M.D., Ph.D., and Alan Cherrington, Ph.D., the former President of the American Diabetes Association and the winner of its Banting Medal for Scientific Achievement. Other members of the Erase Task Force include Geltrude Mingrone, M.D., Ph.D., David D'Alessio, M.D., and Randy Seeley, Ph.D.

Our Approach

We design and develop novel, differentiated, disease-modifying therapies that precisely target and alter the function of the diseased organs responsible for T2D and obesity. Despite the development of highly potent medicines that can improve glucose control and weight, significant unmet needs remain in these diseases due to high rates of drug discontinuation over time, the loss of metabolic benefit upon drug discontinuation, and the inability of medicines to arrest the progressive nature of these conditions. Our vision is to develop transformative therapies that have the potential to prevent and eliminate metabolic diseases (as depicted in the image below).

Our product candidates have the potential to offer a major advance in healthcare because they are designed to be disease-modifying treatments that provide long-term metabolic benefits from a single administration, and are therefore potentially positioned to target the *prevention* and *remission* of disease, critically important categories in T2D and obesity treatment that cannot be addressed with current pharmacology.

In order to be maximally impactful, these therapies must also be delivered at a scale that can match the incidence and prevalence of metabolic disease around the world. We believe our product candidates are not only unique in their potential for disease modification, but also in their design for broad accessibility for large populations. Accordingly, we believe our candidates have the capacity to revolutionize treatment of T2D and obesity and, at their fullest potential, significantly reduce the burden of metabolic disease globally.

ADA Mission Statement: "To prevent and cure diabetes..."

	T2D	Obesity
Revita Targeting the duodenum Designed for prevention	T2D Prevention	Weight Maintenance
Rejuva Targeting the pancreas Designed for remission	T2D Remission	Obesity Remission

Our Solutions

We believe there is a significant market opportunity for disease-modifying treatments that provide long-term metabolic benefits across the spectrum of T2D and obesity and we are developing a suite of product candidates that will target all phases of these diseases. Our Revita clinical development program is designed to evaluate Revita in multiple concurrent clinical studies across a range of patient populations from advanced T2D on insulin to obesity and prediabetes. We are also developing Rejuva to enable long-term remission of T2D and obesity by potentially restoring pancreatic metabolic function in patients with these diseases.

ADA Mission Statement: "To prevent and cure diabetes..."

	T2D	Obesity
Revita Targeting the duodenum Designed for prevention	T2D Prevention	Weight Maintenance
Rejuva Targeting the pancreas Designed for remission	T2D Remission	Obesity Remission

Overview of Revita

Revita is an outpatient procedural therapy designed to durably modify duodenal dysfunction, a major pathologic consequence of a high fat high sugar diet, which can initiate T2D and obesity in humans. The duodenum is the first segment of the small intestine and the first site of nutrient absorption within the body. The duodenal mucosa regulates the human metabolic response to food intake, and chronic exposure to modern diets high in fat and sugar drive a functional maladaptation of stem cells in the duodenum and lead to dysfunctional hyperplasia of the duodenal mucosa. These diet-induced changes to the structure and function of the duodenal mucosa disrupt physiologic nutrient sensing and signaling mechanisms from the gut to the brain, with resulting alterations to systemic metabolic activity that affect glucose control and satiety through multiple downstream organ systems. Emerging scientific consensus has identified this dysfunction in the gut as a root cause of obesity and metabolic dysfunction and therefore propose targeting gut dysfunction to address downstream metabolic diseases. There are no therapies approved today that target the duodenal mucosa for regeneration and renewal.

The Revita system is designed to enable durable and repeatable metabolic improvement by targeting duodenal dysfunction with an outpatient, endoscopic procedural therapy. Revita uses heat energy to ablate the dysfunctional duodenal mucosa, including the duodenal stem cells residing at the base of the mucosa, to enable regeneration and renewal of the duodenum and restore normal metabolic signaling from the gut. The Revita procedure provides thermal protection to the duodenum before ablating the superficial mucosa by (1) isolating the mucosa from the deeper muscle layer of the duodenum and then (2) hydrothermally ablating the superficial layer of the duodenal lining with a proprietary balloon catheter and control console. The procedure takes less than 45 minutes and can be conducted in an outpatient setting in a manner that allows immediate return to daily life for patients. In the days following the ablation procedure, the duodenal mucosa regenerates, which we believe leaves the duodenal lining revitalized and better able to properly coordinate the gut's metabolic signaling mechanisms.

Revita is designed to treat patients ranging from those who have advanced T2D who have exhausted medical therapies and require insulin therapy to those with prediabetes and obesity. For people with T2D treated with medicines and insulin, Revita is intended to improve glucose control and prevent or delay further progression of their disease. For individuals with prediabetes and obesity, Revita is designed to address upstream metabolic dysfunction that puts them at risk for the progression of T2D and obesity.

Potential Benefits of Revita

We believe that Revita's unique individual features combine to provide a significantly differentiated solution to T2D and obesity, offering the following potential benefits:

- ***Durable and Repeatable Benefit.*** Revita is designed to improve metabolic health, blood glucose levels, and weight in patients with inadequately controlled T2D. Based on a long-term follow-up study of the per protocol, or PP, population in our Revita-1 study, we observed that Revita, in combination with at least one ongoing oral anti-diabetic agent, or OAD, and lifestyle counseling, had a statistically significant mean HbA1c reduction of 1.0% (n=27) and a statistically significant raw change in weight of -3.1 kg (n=25) compared to sham patients at 24 months. A pooled analysis of data collected on secondary endpoints assessing weight in all of our controlled clinical studies across the United States and Europe demonstrated a 3.4% (n=100) mean reduction in total body weight loss at four weeks in patients with T2D on multiple ADAs after undergoing a single Revita DMR Procedure and showed a sustained mean body weight loss of 4.0% (n=94) at 48 weeks. We believe this is an important and differentiated therapeutic profile in obesity management. In addition, we believe our Revita system has the potential to enable repeat Revita procedures over time.
- ***Tolerability.*** In clinical studies to date, Revita has been observed to be generally well tolerated, with most patients resuming normal daily activities one day after the procedure and none requiring

prescription pain medications. Our proprietary Revita technology is designed to provide thermal protection before ablation, enabling isolation of the mucosa from deeper tissue structures and sparing pain fibers in the muscle while reducing risk of tissue injury.

- **Broad Implementation.** Revita is a modular system that can potentially be incorporated into the endoscopist workflow by leveraging familiar skillsets of advanced endoscopists. Revita is intended to fit into most endoscopy suites and typically requires fewer than four cases for the endoscopist to acquire proficiency. It is designed to be an outpatient procedure that can be performed by a trained therapeutic endoscopist in less than an hour. Today, over 20,000,000 endoscopies are performed each year in the United States, including over 600,000 advanced endoscopic procedures, by nearly 10,000 gastroenterologists. The Revita DMR Procedure is designed to be a simple add-on procedure to the 4.7 million endoscopies already performed on T2D patients annually.
- **Real World Outcomes.** Because it is a procedural therapy, Revita does not rely on perfect patient adherence or persistence to chronic therapy for its anticipated clinical effects. Unlike diet and lifestyle interventions or pharmacologic management, the benefits of Revita are intended to be conferred at the time of the procedure and not reliant upon ongoing therapeutic maintenance. This allows a shift in patient focus from escalating chronic disease management burden to ongoing health maintenance after the procedure.
- **Patient Friendly.** Revita is designed to offer a straight-forward, outpatient experience requiring less than a half-day visit, and allowing patients to typically return to their normal daily lives the very next day. Furthermore, the Revita DMR Procedure has thus far been observed to be compatible with other current interventions for T2D and obesity in broad use, including diet and lifestyle, as well as existing and emerging pharmacologic therapies.

Overview of Rejuva

Rejuva is a novel, locally administered, AAV-delivered PGTx platform designed to enable long-term remission of T2D and obesity by durably altering metabolic hormone function in the pancreatic islet cells of patients with T2D and obesity. Pancreatic islets are tiny clusters of cells distributed throughout the pancreas that play a crucial role in endocrine function and glucose metabolism. There are several cell types within the pancreatic islet, including alpha cells responsible for glucagon production and beta cells responsible for insulin production. Metabolic dysfunction in obesity and prediabetes can lead to progressive beta cell dysfunction and eventual failure, loss of insulin production and secretion, and the development of T2D. There are no therapies approved today that target the pancreatic islet in T2D for repair or replacement.

Our Rejuva PGTx platform utilizes our novel investigational pancreatic delivery device to administer gene therapy candidates to target the dysfunctional pancreatic beta cells that are a root cause of insulin insufficiency in T2D. Rejuva is a modular, physiologic gene therapy platform with three key elements designed to enable successful pancreatic gene therapy: (1) a proprietary delivery catheter designed to enable local, low dose therapeutic delivery directly to the pancreas via endoscopic access, (2) vectors with tropism for the pancreatic islet to enable successful transduction and gene delivery with limited biodistribution via this route of administration, and (3) transgenes with tissue-restricted promoters and metabolically active peptides that can durably impact glucose and weight control. Rejuva is designed to directly administer a gene therapy into the body and tail of the pancreas via mechanical confinement of virus with local administration and molecular confinement of transgene expression with tissue-specific promoters. These hormones are intended to rejuvenate beta cell health and restore the body's natural ability to produce insulin. The first gene therapy candidate for Rejuva will be a locally administered AAV9 viral vector that expresses a full-length GLP-1 hormone from the insulin promoter.

Potential Benefits of Rejuva

We believe that Rejuva's individual features combine to provide a significantly differentiated solution to T2D and obesity, offering the following potential benefits:

- **Novel Approach to a Highly Validated Target.** *Our Rejuva platform candidates are being developed as an investigational pancreatic delivery device and local, AAV-delivered PGTx to durably improve islet health in the pancreas. Our first Rejuva PGTx candidate is intended to augment intra-islet GLP-1 receptor activation, leveraging well established biology on GLP-1 signaling and potentially leading to improved beta cell health and glucose control in patients with T2D and obesity.*
- **Precise Local Delivery.** Our Rejuva gene therapy platform is designed to provide precise local delivery of gene therapy to the pancreas in a single endoscopic procedure. Our Rejuva platform leverages standard-of-care techniques for pancreatic tissue access and possesses key proprietary device elements and procedure steps, thereby reducing procedural risk. We believe our Rejuva gene therapy candidates will benefit from localized administration, potentially avoiding the risk of high dose systemic administration that has been observed with other gene therapy candidates or GLP-1 receptor analogs.
- **Preclinical Pharmacology and Toxicology Profile.** In preclinical studies, we observed that a single administration of a GLP-1 PGTx candidate achieved durable and statistically significant improvements in blood glucose control and weight loss in *db/db* mice. In a preclinical proof-of-concept head-to-head study in a *db/db* model, after a single administration of a GLP-1 PGTx candidate, we observed (compared to chronic semaglutide at 10 nmol/kg daily):
 - statistically significant average reduction of fasting plasma glucose, or FPG, levels of 50.9% ($p < 0.0001$) at eight weeks;
 - non-statistically significant decrease in fasting insulin of 48.6% ($p=0.374$) during a glucose tolerance test at eight weeks; and
 - statistically significant decrease in total body weight of 19.6% ($p<0.0001$) at four weeks.

Additionally, no adverse events related to the pancreas, liver or other tissues were observed in our rodent or large animal studies.

- **Building Upon Clinical and Real-World Experience with Revita.** The gene therapy candidates from our Rejuva platform benefit from the extensive clinical and real-world experience that we have accumulated through our Revita program. Rejuva PGTx candidates can be delivered by the same treating physicians and in the same setting as the DMR procedure, utilizing the same Revita console and leveraging the same distribution network. Moreover, we believe the metabolic benefits of Rejuva PGTx candidates have the potential to be complementary to, and perhaps synergistic with, the Revita DMR Procedure.
- **Rigorous Development Plan.** We anticipate completing IND-enabling studies, or its equivalent, for RJVA-001 in the second half of 2024. If the IND, or IND-equivalent, for RJVA-001 is approved, we plan to initiate a first-in-human study in the first half of 2025.
- **Interchangeable Platform for Metabolic Therapy.** The Rejuva platform enables selection of multiple metabolically active peptide hormones (GLP-1, GIP, PYY, amylin, glucagon, etc.), either individually or combinatorially, with the same local delivery and plasmid construct for differential therapeutic profiles over time.

By employing Revita and Rejuva to target the prevention and remission of T2D and obesity, we believe it is possible to provide a step change in outcomes for patients above and beyond the current chronic management strategies that exist today. If we are able to obtain approval for these product candidates in the United States, we believe these therapies will enable us to chart a course towards significantly reducing the burden of T2D and obesity globally.

Growth Strategies

Our mission is to develop transformative therapies that prevent and eliminate metabolic disease. In order to achieve this goal, we plan to employ the following strategies:

- *Establish Practice-Changing Levels of Evidence for Revita Across the Spectrum of T2D and Obesity*
- *Develop Rejuva Gene Therapy Platform to Enable Long-Term Remission of T2D and Obesity*
- *Execute Targeted and Efficient Go-to-Market Strategy*
- *Broaden the Indication and Use of Revita*
- *Expand Application of Rejuva Platform to Other Metabolic Targets Beyond GLP-1*

Summary Risk Factors

Investing in our common stock involves substantial risk. Our ability to execute our strategy is also subject to certain risks. The risks described under the heading “Risk Factors” included elsewhere in this prospectus may cause us not to realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our strategy. Some of the most significant challenges and risks include the following:

- We have a limited operating history in developing medical devices and biopharmaceutical products, have not completed any pivotal clinical studies and have no products approved for commercial sale in the United States, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future and may never achieve or sustain profitability.
- Conditions in the banking system and financial markets, including the failure of banks and financial institutions, could have an adverse effect on our operations and financial results.
- Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Our management has expressed substantial doubt about our ability to continue as a going concern.
- Our credit agreement contains restrictive and financial covenants that may limit our operating flexibility.
- The regulatory approval process of the FDA, comparable foreign regulatory authorities and notified bodies, are lengthy, time-consuming and inherently unpredictable, and even if we complete the

necessary clinical studies, we cannot predict when, or if, we will obtain regulatory approval or certification for any of our product candidates, and any such regulatory approval or certification may be for a more narrow indication than we seek.

- We may not be able to file IDEs or IDE supplements or comparable documents in foreign jurisdictions to commence additional clinical studies on the timelines we expect, and even if we are able to, the FDA or comparable foreign regulatory authorities may not permit us to proceed.
- Our product candidates may cause serious adverse events or undesirable side effects or have other properties which may cause us to suspend or discontinue clinical studies, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- We are substantially dependent on the success of our lead product candidate, Revita. If we are unable to obtain marketing approval or certification for and commercialize any of our current or future product candidates in a timely manner, our business will be harmed.
- We may not be able to gain the support of leading hospitals and key thought leaders, or to publish the results of our clinical studies in peer-reviewed journals, which may make it difficult to establish the Revita DMR Procedure and/or our Rejuva gene therapy candidates as a standard of care, if approved, and may limit our revenue growth and ability to achieve profitability.
- We have not yet studied the ability of Revita to be used in repeated procedures and we are uncertain as to whether patients will need additional procedures in the future. If we are unable to demonstrate the safety and improved glycemic effects of Revita for repeat use, it could have a material adverse effect on the on the clinical utility and commercial adoption of the device.
- We have never obtained marketing approval for a product candidate in the United States or abroad and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate in the United States.
- Although Revita has received Breakthrough Device designation, there can be no guarantee that the designation will benefit the development and regulatory approval process.
- If we are unable to obtain a billing code from the U.S. Department of Health and Human Services so that procedures using Revita, if approved, are covered under Medicare and Medicaid, this could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results.
- The training required for endoscopists to use Revita could reduce the market acceptance of our products, when and if approved.
- We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies, and clinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain marketing authorization of or commercialize our product candidates and our business could be substantially harmed.
- We contract with third parties for the manufacture of sub-assembly components for Revita and for the materials for our Rejuva gene therapy platform for preclinical studies and our ongoing clinical

studies, and expect to continue to do so for additional clinical studies and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

- We rely on a variety of intellectual property rights, and if we are unable to obtain, maintain or protect our intellectual property, our business, financial situation, results of operations, and prospects will be harmed. If we are unable to obtain and maintain patent protection for our current product candidate, any future product candidates we may develop and our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our current product candidate, any future product candidates we may develop and our technology may be adversely affected.

Corporate History and Information

We were incorporated under the laws of the state of Delaware on August 30, 2010 under the name MedCatalyst, Inc. On January 12, 2012, we changed our name to Fractyl Laboratories Inc. On June 9, 2021, we changed our name to Fractyl Health, Inc. Our principal executive offices are located at 17 Hartwell Avenue, Lexington, Massachusetts 02421 and our telephone number is (781) 902-8800. Our principal website address is www.fractyl.com. The information on or accessed through our website is not incorporated in this prospectus or the registration statement of which this prospectus forms a part.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. As an “emerging growth company” we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- the option to present only two years of audited financial statements and only two years of related “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- not being required to comply with any requirements that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if any of the following events occur prior to the end of such five-year period, (i) our annual gross revenue exceeds \$1.235 billion, (ii) we issue more than \$1.0 billion of non-convertible debt in any three-year period, or (iii) we become a “large accelerated filer,” (as defined in

Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act), we will cease to be an emerging growth company prior to the end of such five-year period. We will be deemed to be a “large accelerated filer” at such time that we (a) have an aggregate worldwide market value of common equity securities held by non-affiliates of \$700.0 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act, for a period of at least 12 months, and (c) have filed at least one annual report pursuant to the Exchange Act. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. In particular, we have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company, or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. If we were to subsequently elect instead to comply with these public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

We are also a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

THE OFFERING

Common stock offered by us	7,333,333 shares
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to 1,099,999 additional shares of common stock.
Common stock to be outstanding immediately after this offering	47,607,201 shares (or 48,707,200 shares if the underwriters exercise their option to purchase additional shares in full)
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$99.0 million (or approximately \$114.3 million if the underwriters exercise their option to purchase additional shares in full), based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds of this offering to complete the ongoing Revitalize-1 pivotal clinical study of Revita and fund the Remain-1 study; fund the continued preclinical development of our Rejuva gene therapy candidates; and for working capital and other general corporate purposes, including medical education and other commercial readiness activities. For a more complete description of our intended use of the proceeds from this offering, see “Use of Proceeds.”</p>
Risk factors	You should read the section titled “Risk Factors” beginning on page 18 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	“GUTS.”

The number of shares of our common stock to be outstanding after this offering is based on 40,273,868 shares of our common stock outstanding as of December 31, 2023, after giving effect to (i) the conversion of all outstanding shares of our convertible preferred stock into 36,343,909 shares of our common stock immediately prior to the closing of this offering and (ii) the issuance of 1,824,144 shares of common stock upon the automatic settlement of our convertible promissory notes issued in January 2022, as amended, or the 2022 Convertible Notes, including accrued interest, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, in connection with the closing of this offering, and excludes:

- 8,721,884 shares of common stock issuable upon exercise of outstanding stock options granted under the Fractyl Health, Inc. Amended and Restated 2011 Incentive Stock Plan, or the 2011 Plan, as of December 31, 2023, at a weighted average exercise price of \$5.34 per share;
- 604,509 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units, or RSUs, granted under the 2011 Plan, as of December 31, 2023, at a weighted average grant date fair value of \$11.20 per share.

- 4,298,825 shares of common stock that will become available for future issuance under the 2024 Incentive Award Plan, or the 2024 Plan, which will become effective in connection with the completion of this offering (which number includes (i) 1,517,600 shares of common stock issuable upon the exercise of stock options granted in connection with this offering under the 2024 Plan to certain of our executive officers, directors and employees, at an exercise price per share equal to the initial public offering price in this offering and (ii) 645,785 shares of common stock available for future issuance under the 2011 Plan), as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the 2024 Plan;
- 487,070 shares of common stock that will become available for future issuance under the 2024 employee stock purchase plan, or the ESPP, which will become effective in connection with the completion of this offering, and shares of our common stock that become available pursuant to provisions in the ESPP that automatically increase the share reserve under the ESPP;
- 216,827 shares of common stock issuable upon the exercise of outstanding warrants held by entities affiliated with SVB Financial Group as of December 31, 2023, at a weighted average exercise price of \$3.28 per share; and
- 1,673,276 shares of common stock issuable upon the exercise of outstanding warrants issued in July and September 2023, as of December 31, 2023, at an assumed exercise price of \$15.00.

Unless we indicate otherwise or the context otherwise requires, all information in this prospectus assumes or gives effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the closing of this offering;
- the conversion of all outstanding shares of our convertible preferred stock into 36,343,909 shares of our common stock immediately prior to the closing of this offering;
- the conversion of outstanding warrants to purchase 118,483 shares of Series B Preferred Stock into warrants to purchase 55,211 shares of common stock immediately prior to the closing of this offering;
- the conversion of outstanding warrants to purchase 600,858 shares of Series F Preferred Stock into warrants to purchase 279,999 shares of common stock immediately prior to the closing of this offering, at an assumed exercise price of \$15.00;
- a 1-for-2.146 stock split of our common stock, effected on January 26, 2024;
- no exercise of the outstanding stock options or warrants described above after December 31, 2023;
- no vesting and settlement of the outstanding RSUs described above after December 31, 2023; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated financial data for the periods indicated. We have derived the summary consolidated statements of operations data for the nine months ended September 30, 2023 and 2022 and the summary consolidated balance sheet data as of September 30, 2023 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. We have derived the consolidated statements of operations data for the years ended December 31, 2022 and 2021 from our audited consolidated financial statements included elsewhere in this prospectus. We have prepared the unaudited interim consolidated financial statements on a basis substantially consistent with our audited consolidated financial statements as of and for the year ended December 31, 2022, and the unaudited interim consolidated financial statements include all normal recurring adjustments necessary for a fair statement of the financial information set forth in those unaudited interim consolidated financial statements. Our historical results are not necessarily indicative of the results that should be expected for any future period. You should read the following summary consolidated financial data together with the more detailed information contained in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of our future results, and our operating results for the nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 or any other interim periods or any future year or period.

	Nine Months Ended September 30,		Year Ended December 31,	
	2023	2022	2022	2021
	(unaudited) (in thousands, except for share and per share information)			
Consolidated Statements of Operations Data:				
Revenue	\$ 113	\$ —	\$ —	\$ —
Cost of goods sold	75	—	—	—
Gross profit	38	—	—	—
Operating expenses:				
Research and development	27,872	25,737	34,354	26,435
Selling, general and administrative	10,021	12,235	15,031	10,493
Total operating expenses	37,893	37,972	49,385	36,928
Loss from operations	(37,855)	(37,972)	(49,385)	(36,928)
Other income (expense), net	(20,056)	2,377	2,932	(1,807)
Net loss and comprehensive loss	\$ (57,911)	\$ (35,595)	\$ (46,453)	\$ (38,735)
Accretion of dividends on convertible preferred stock	(12,850)	(12,850)	(17,180)	(14,486)
Net loss attributable to common stockholders	(70,761)	(48,445)	(63,633)	(53,221)
Net loss per share attributable to common stockholders, basic and diluted	\$ (34.11)	\$ (24.61)	\$ (31.97)	\$ (28.62)
Weighted average number of common stock, basic and diluted	2,074,223	1,968,521	1,990,419	1,859,582
Pro Forma net loss per share, basic and diluted (unaudited) ⁽¹⁾	\$ (1.76)		\$ (1.59)	
Pro Forma weighted average shares of common stock outstanding, basic and diluted (unaudited)	40,198,377		40,065,800	

(1) The unaudited pro forma net loss per share for the nine months ended September 30, 2023 and for the year ended December 31, 2022 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of our convertible preferred stock into shares of common stock and the automatic settlement of the 2022 Convertible Notes, including accrued interest, into shares of our common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates, if later.

	As of September 30, 2023		
	Actual	Pro	Pro Forma
		Forma ⁽¹⁾	As Adjusted ⁽²⁾⁽³⁾
(unaudited, in thousands)			
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 44,500	\$ 44,500	\$ 143,527
Working capital ⁽⁴⁾	38,414	38,963	139,277
Total assets	56,782	56,782	154,455
Total liabilities	76,627	35,366	34,079
Accumulated deficit	(327,436)	(326,915)	(326,915)
Convertible preferred stock	287,330	—	—
Total stockholders' equity (deficit)	(307,175)	21,416	120,376

- (1) Gives effect to (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 36,343,909 shares of common stock immediately prior to the closing of this offering, as if such conversion had occurred on September 30, 2023, (ii) the automatic settlement of the 2022 Convertible Notes, including accrued interest, into 1,780,245 shares of our common stock in connection with the closing of this offering, assuming an initial public offering price per share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, and (iii) an aggregate decrease to accumulated deficit of \$0.5 million relating to the change in fair value of debt recorded as a result of the settlement of the 2022 Convertible Notes, assuming an initial public offering price per share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus.
- (2) Gives further effect to the sale of 7,333,333 shares of our common stock in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) A \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by \$6.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A 1.0 million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity (deficit) by \$14.0 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. This information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.
- (4) We define working capital as current assets less current liabilities. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this prospectus, including our consolidated financial statements and related notes appearing elsewhere in this prospectus and in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. See “Cautionary Note Regarding Forward-Looking Statements.” Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to Our Financial Condition and Capital Requirements

We have a limited operating history in developing medical devices and biopharmaceutical products, have not completed any pivotal clinical studies and have no products approved for commercial sale in the United States, which may make it difficult for you to evaluate our current business and predict our future success and viability.

Medical device and biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are an organ-editing metabolic therapeutics company with a limited operating history in developing medical devices and biopharmaceutical products, which makes it difficult to evaluate our business and prospects in future product development. We have no products approved for commercial sale in the United States and have not generated any revenue from product sales. We obtained a CE mark for Revita in Europe in 2016 and have received reimbursement authorization in Germany. To date, we have devoted substantially all of our resources and efforts to increasing our manufacturing capacity, raising capital, discovering, identifying and developing potential product candidates, securing related intellectual property rights and undertaking preclinical and clinical studies of our product candidates, including the ongoing Revitalize-1 pivotal clinical study of Revita in patients with inadequately controlled T2D despite being on up to three ADAs and 20 to 100 units of insulin daily. We have not yet demonstrated our ability to successfully complete any pivotal clinical studies, submit a Premarket Approval application, or PMA, a new drug application, or NDA, or biologic license application, or BLA, or similar marketing authorization application, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability to develop new medical devices and biopharmaceutical products than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by medical device and biopharmaceutical companies developing products in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future and may never achieve or sustain profitability.

We have incurred net losses since inception, have not generated any significant revenue from product sales to date and have financed our operations primarily through the sale of our convertible preferred stock and debt financing. We have incurred a net loss of approximately \$46.5 million and \$38.7 million for the years ended December 31, 2022 and December 31, 2021, respectively, and a net loss of approximately \$57.9 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of approximately \$327.4 million. Our losses have resulted principally from expenses incurred in research and

development of our product candidates, as well as management and administrative costs and other expenses that we have incurred while building our business infrastructure. Our lead product candidate, Revita, is currently undergoing a pivotal clinical study in patients with inadequately controlled T2D despite being on up to three ADAs and 20 to 100 units of insulin daily. We expect that it will be several years, if ever, before we have a commercialized product in the United States and generate significant revenue from product sales. Even if we succeed in receiving marketing approval or certification for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop and market additional potential product candidates.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- advance the development of our lead product candidate, Revita, and our Rejuva gene therapy candidates through preclinical and clinical development, and, if approved or certified by the FDA, other comparable foreign regulatory authorities or notified bodies, commercialization;
- incur manufacturing costs for our product candidates;
- increase our manufacturing capacity;
- seek regulatory approvals or certifications for any of our product candidates that successfully complete clinical studies;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- invest in measures to protect and expand our intellectual property;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize;
- expand our manufacturing and develop our commercialization efforts; and
- operate as a public company.

To date, we have generated insignificant revenue. To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical and clinical studies of our product candidates, obtaining regulatory approval, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate any revenue in the United States or revenue that is significant enough to achieve profitability.

The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing medical devices or biopharmaceutical products, including conducting preclinical and clinical studies, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we initiate and conduct clinical studies of, and seek marketing approval or certification for our current and any future product candidates. Even if one or more of the product candidates that we develop is approved or certified for commercial sale, we anticipate incurring significant costs associated with commercializing any approved or certified product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other comparable foreign regulatory authorities or notified bodies to perform clinical studies or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval or certification for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Because the design and outcome of our anticipated clinical studies are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. Following this offering, we also expect to incur additional costs associated with operating as a public company. Accordingly, it is likely that we will need to obtain substantial additional funding in order to maintain our continuing operations in the future.

As of September 30, 2023, we had approximately \$44.5 million in cash and cash equivalents. Based on our current business plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditures requirements through December 2025. Our estimate as to how long we expect the net proceeds from this offering, together with our existing cash and cash equivalents, to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timeline, cost and results of our clinical studies for our product candidates;
- the initiation, progress, timeline, cost and results of additional research and preclinical studies related to pipeline development and other research programs we initiate in the future;
- the cost and timing of manufacturing activities as we advance our product candidates through clinical development and commercialization;
- the potential expansion of our current development programs to seek new indications;
- the potential negative impact of future health crises, including epidemics and pandemics, on our business;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities or notified bodies;

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- the ability of healthcare providers to obtain coverage and adequate reimbursement by third-party payors for procedures using our products, if approved (or certified), and any additional products we commercialize, as well as any future changes to coverage or reimbursement policies that may increase our competition or reduce reimbursement for procedures using our products, if approved (or certified);
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, in-licensed or otherwise;
- the effect of competing technological and market developments;
- the payment of licensing fees, potential royalty payments and potential milestone payments;
- the cost of general operating expenses;
- the cost and timing of completion of commercial-scale manufacturing and product development activities;
- market acceptance of our product candidates, if cleared, approved or certified;
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive regulatory approval or certification in regions where we choose to commercialize our products, if approved (or certified), on our own; and
- the cost of operating as a public company.

We plan to use the net proceeds from this offering to complete the ongoing Revitalize-1 pivotal clinical study of Revita and fund the Remain-1 study; fund the continued preclinical development of our Rejuva gene therapy candidates; and for working capital and other general corporate purposes, including medical education and other commercial readiness activities. Advancing the development of our product candidates will require a significant amount of capital. The net proceeds from this offering and our existing cash and cash equivalents will not be sufficient to fund all of the activities that are necessary to complete the development and commercialize our product candidates, if approved (or certified).

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Other than our credit agreement, we do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Additionally, the impact of global macroeconomic events on the capital markets may affect the availability, amount and type of financing available to us in the future. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical studies or future commercialization efforts.

Our management has expressed substantial doubt about our ability to continue as a going concern.

The consolidated financial statements have been prepared as though we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have incurred operating losses and negative cash flows from operations since inception. As of September 30, 2023, we had an accumulated deficit of approximately \$327.4 million. Management expects to continue to incur operating losses and negative cash flows from operations in 2024. We have financed our operations to date primarily through sales of our convertible preferred stock and debt financing.

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If we are unable to successfully complete this offering, we will need to create alternate financing or operational plans to continue as a going concern. There can be no assurance that such alternate financing, if available, can be obtained on acceptable terms. If we are unable to obtain such alternate financing, future operations would need to be scaled back or discontinued.

Accordingly, these factors raise substantial doubt about our ability to continue as a going concern within one year after the date the consolidated financial statements are issued. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Our credit agreement contains restrictive and financial covenants that may limit our operating flexibility.

Our credit agreement contains certain restrictive covenants that either limit our ability to, or require a mandatory prepayment in the event that we (i) engage in businesses other than businesses in which we are currently engaged or businesses reasonably related or complementary thereto, or (ii) subject to certain baskets and exceptions, incur additional indebtedness or liens, make certain investments, make certain payments of indebtedness, pay dividends or make any other distributions, merge with other companies or consummate certain changes of control, acquire other companies, transfer or dispose of certain assets, and enter into transactions with affiliates, among other things. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of all or a majority of the lenders under the credit agreement or prepay our outstanding obligations under the credit agreement. The credit agreement contains the following financial covenants: (i) a minimum liquidity covenant requiring us to maintain a minimum \$10.0 million balance in cash and cash equivalents on deposit in accounts, subject to certain exceptions, and (ii) a financing milestone covenant requiring that (a) we have received proceeds from an equity financing or series of financings (including the net proceeds from this offering) of at least \$40.0 million during the period commencing on September 7, 2023, or the Closing Date, and ending on or prior to February 15, 2024, and (b) we have received equity financing or series of financings of at least \$100.0 million (inclusive of such equity financing or series of financings in the preceding clause (a)) during the period commencing as of the Closing Date and prior to June 30, 2024. Our obligations under the credit agreement are collateralized by substantially all of our assets, including our intellectual property, but excluding certain customary and agreed upon assets. Additionally, we may not be able to generate sufficient cash flow or sales to pay the principal and interest under the credit agreement. Furthermore, our future working capital, borrowings or equity financings could be unavailable to repay or refinance the amounts outstanding under the credit agreement. In the event of a liquidation, the lenders and the agent under the credit agreement would be repaid all outstanding principal and interest prior to distribution of assets to unsecured creditors, and the holders of our common stock would receive a portion of any liquidation proceeds only if all of our creditors then existing, including the agent and lenders under the credit agreement, were first repaid in full. If we do not raise at least \$100.0 million in net proceeds in connection with this offering, we will need to raise additional capital to satisfy the financing milestone covenant in our credit agreement.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity offerings, debt financings, including our credit agreement, or other sources, including up-front payments and milestone payments from strategic collaborations. In addition, if we do not raise at least \$100.0 million in net proceeds in connection with this offering, we will need to raise additional capital to satisfy the financing milestone covenant in our credit agreement. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product

candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, including the conflict between Ukraine and Russia, the conflict between Israel and Hamas, and recent bank failures affecting the financial services industry, have affected and could further adversely affect our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical studies.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. A severe or prolonged economic downturn, or additional global financial or political crises, could result in a variety of risks to our business, including delayed clinical studies or preclinical studies, delayed approval (or certification) of our product candidates, delayed ability to obtain patents and other intellectual property protection, weakened demand for our product candidates, if approved (or certified), or our ability to raise additional capital when needed on acceptable terms, if at all. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership, and on May 1, 2023, First Republic Bank was also swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of Silicon Valley Bank would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with Silicon Valley Bank, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of the banks which hold our cash deposits were to be placed into receivership, we may be unable to access such funds. As of December 31, 2023, substantially all of our cash on deposit was maintained at two financial institutions in the United States, and our current deposits are in excess of federally insured limits. If further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash, cash equivalents and short-term investments would adversely affect our business. In addition, if any of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to fulfill their obligations to us could be adversely affected.

Our ability to utilize our net operating loss carryforwards, research and development tax credit carryforwards, and certain other tax attributes to offset taxable income or taxes may be limited.

As of December 31, 2022, we had U.S. federal and state net operating loss carryforwards of approximately \$215.3 million and \$207.8 million, respectively, which begin to expire at various dates beginning in 2030. Portions of these net operating loss carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the legislation enacted in 2017, commonly referred to as the Tax Cuts and Jobs Act, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security, or the CARES Act, U.S. federal net operating losses incurred in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in taxable years beginning after December 31, 2020, is limited. It is uncertain how various states will respond to the Tax Act and the CARES Act.

In addition, as of December 31, 2022, we had U.S. federal and state research and development tax credit carryforwards of \$8.5 million and \$3.6 million, respectively. The federal research and development tax credit carryforwards will expire at various dates beginning in 2031. The state research and development tax credit carryforwards will expire at various dates beginning in 2027. We may not be able to utilize these credits for federal and state income tax purposes before they expire.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. The completion of this offering, together with other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. To date, we have not completed an analysis under Section 382. We may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future results of operations by effectively increasing our future tax obligations.

Risks Related to Development, Regulatory Approval and Commercialization

The regulatory approval process of the FDA, comparable foreign regulatory authorities and notified bodies, are lengthy, time-consuming and inherently unpredictable, and even if we complete the necessary clinical studies, we cannot predict when, or if, we will obtain regulatory approval or certification for any of our product candidates, and any such regulatory approval or certification may be for a more narrow indication than we seek.

The research, testing, manufacturing, labeling, approval, certification, selling, import, export, marketing, and distribution of medical devices and biopharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities in and outside the United States. We are currently in clinical-stage development of Revita, which is an investigational medical device, and are conducting preclinical development of our Rejuva PGTx candidates along with a device delivery system, which together with the gene therapy candidate, we anticipate will be regulated as a combination biologic-device.

In the United States, before we can market a new medical device, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a PMA, from the FDA, unless an exemption applies. We expect Revita to be subject to the requirement for approval of a PMA. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life sustaining, life supporting or implantable devices. We plan to seek approval of a PMA from the FDA for the Revita DMR Procedure to improve glycemic control and eliminate insulin needs in T2D patients who are inadequately controlled on insulin.

Modifications to products that are approved through a PMA generally require FDA approval. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The process of obtaining a PMA is costly and uncertain and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical studies. Despite the time, effort and cost, a device may not be approved by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

Similarly, we are not permitted to market any biological product in the United States or in foreign jurisdictions until we receive approval of a biologics license application, or BLA, from the FDA or approval of similar foreign applications from comparable foreign authorities. We anticipate that each of our Rejuva gene therapy candidates will be regulated as a biological product or biological product-device combination product, requiring approval of a BLA or a similar approval from comparable foreign authorities, and as the case may be, certification from a notified body. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA and similar approval filings must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, including with respect to chain of identity and chain of custody of the product. Similar requirements may apply in foreign jurisdictions.

To the extent we intend to sell medical devices in member states of the European Union, or EU, our products must comply with the general safety and performance requirements of the Medical Devices Regulation, or MDR (Regulation (EU) No 2017/745), which repeals and replaces the Medical Devices Directive, or the MDD. Compliance with these requirements is a prerequisite to be able to affix the European conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the MDR, including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low risk medical devices (Class I), where the manufacturer can self-assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. The notified body would typically audit and examine the technical file and the manufacturer's quality system (notified bodies must presume that quality systems which implement the relevant harmonized standards—ISO 13485:2016 for Quality Management Systems—conform to these requirements), design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues an EU certificate, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. See “Government Regulations—Regulation of Medical Devices in the European Union” for more information.

The CE mark for Revita was issued under the MDD, which has now been superseded by the MDR and we are currently working on obtaining MDR certification. Under the recently extended MDR transitional provisions, both (i) devices lawfully placed on the market pursuant to the MDD prior to May 26, 2021 and (ii) legacy devices lawfully placed on the market after May 26, 2021, in accordance with the transitional provisions of the MDR, may generally continue to be made available on the market or put into service, provided that the requirements of the transitional

provisions are fulfilled. In particular, no substantial change must be made to the device as such a modification would trigger the obligation to obtain a new certification under the MDR and therefore to have a notified body conducting a new conformity assessment of the devices. Once our devices are certified under the MDR, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU, of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the MDR or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the MDR. If the assessment is favorable, the notified body will issue a new certificate or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the MDR. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland). Non-compliance with the above requirements would therefore also prevent us from selling our products, if approved, in Norway, Liechtenstein and Iceland. We cannot be certain that transitioning towards the MDR will not have any material impact on our sales in the EU and EEA and, if we were considered noncompliant and unable to sell our products in the EU and EEA, it could harm our business, operating results, prospects and financial condition.

As a result of the UK leaving the EU, since January 1, 2021, the regulatory framework and regimes for medical devices in the UK and EU have diverged. Northern Ireland has adopted a hybrid approach as a result of the divergence in accordance with the Northern Ireland Protocol. Great Britain's national legislation remains based on the (EU) MDD as implemented nationally, however, amendments to the existing legislation are being drawn up by the Government, the core elements of which are expected to apply from July 1, 2025. The Medicines and Healthcare products Regulatory Agency, or MHRA, has stated that specific rules relating to post-market surveillance will be introduced in advance of the broader legislative overhaul, with such changes expected to apply from mid-2024. The MHRA has also recently confirmed that, subject to certain conditions, general medical devices compliant with the (EU) MDD or EU active implantable medical devices directive, or AIMDD, with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of expiry of certificate or June 30, 2028. The MHRA has indicated that the legislative amendments will include a requirement for newly certified devices to carry a UKCA mark.

The UKCA mark is not recognized in the EU, EEA or Northern Ireland markets, so relevant products require a CE mark for sale in these markets.

Our product candidates could fail to receive regulatory approval or certification from the FDA, a comparable foreign regulatory authority or notified body for many reasons, including:

- disagreement with the design or conduct of our clinical studies;
- failure to demonstrate to the satisfaction of regulatory agencies or notified bodies that our product candidates are safe and effective, or have a positive benefit/risk profile for its proposed indication;
- serious and unexpected adverse device effects experienced by participants in our clinical studies;
- failure of clinical studies to meet the level of statistical significance required for approval or certification;
- disagreement with our interpretation of data from preclinical or clinical studies;
- the insufficiency of data collected from clinical studies of our product candidates to support the submission and filing of a IND, PMA or BLA or other submission or to obtain regulatory approval or certification;

- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval or certification policies or regulations that render our preclinical and clinical data insufficient for approval or certification.

This lengthy approval process as well as the unpredictability of future clinical study results may result in our failing to obtain regulatory approval or certification to market our product candidates, which would significantly harm our business, results of operations and prospects. The FDA, a comparable foreign regulatory authority or notified body may require more information, including additional preclinical or clinical data to support approval or certification, which may delay or prevent approval or certification and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval or certification, regulatory authorities or notified bodies may approve or certify any of our product candidates for fewer or more limited indications than we request (including failing to approve or certify the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve or certify a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical studies, the regulatory authorities or notified bodies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval or certification.

We expect the novel nature of certain of our product candidates to create further challenges in obtaining regulatory approval or certification. The FDA may also require a panel of experts to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the panel, although not binding, may have a significant impact on our ability to obtain approval of the product candidates based on the completed clinical studies, as the FDA often adheres to the panel's recommendations. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical studies and the review process. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

In addition, the FDA and comparable foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council (not expected before early 2025) and may have a significant impact on the biopharmaceutical industry in the long term.

Clinical studies are expensive, time-consuming, difficult to design and implement, and have an uncertain outcome. Further, we may encounter substantial delays in our clinical studies.

Before obtaining regulatory approvals or certification for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical and clinical studies that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and takes many years to complete, and is subject to uncertainty. Our clinical studies may not be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical study process. Even if our clinical studies are completed as planned, their results may not support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Our future clinical study results may not be successful.

In addition, even if our planned studies are successfully completed, the FDA or foreign regulatory authorities or notified bodies may not interpret the results as we do, and more studies could be required before we submit our product candidates for approval or certification. To the extent that the results of the studies are not satisfactory to the FDA or foreign regulatory authorities or notified bodies for support of a marketing application or certification, we may be required to expend significant resources, which may not be available to us, to conduct additional studies in support of potential approval of our product candidates.

We may experience delays in conducting any clinical studies and we do not know whether our clinical studies will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient data to support the initiation of clinical studies;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical studies;
- delays in reaching agreement with the FDA or other regulatory authorities as to the design or implementation of our clinical studies;
- delays in or failure to obtain regulatory clearance to commence a clinical study;
- delays in or failure to reach an agreement on acceptable terms with clinical study sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical study sites;
- delays in or failure to obtain IRB or ethics committee approval at each site;
- delays in or failure to recruit suitable patients to participate in a clinical study;
- delays in or failure to have patients complete a clinical study or return for post-treatment follow-up;
- clinical sites, CROs or other third parties deviating from study protocol or dropping out of a study;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements, or applicable regulatory guidelines in other countries;
- failure in addressing patient safety concerns that arise during the course of a study, including occurrence of adverse events associated with the product candidate;
- failure to add a sufficient number of clinical study sites; or
- failure to manufacture sufficient quantities of product candidates for use in clinical studies.

If we are required to conduct additional clinical studies or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical studies of our product candidates or other testing, if the results of these studies or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval or certification for our product candidates or not obtain marketing approval or certification at all;

- obtain marketing approval or certification in some countries and not in others;
- obtain marketing approval or certification for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval or certification with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval or certification.

We could encounter delays if a clinical study is suspended or terminated by us, by the IRBs of the institutions in which such studies are being conducted, by the Data Safety Monitoring Board, or DSMB, for such study or by the FDA or other regulatory authorities. These authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols, inspection of the clinical study operations or study site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical study. We may also seek feedback from the FDA or other regulatory authorities on our clinical development program, and the FDA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

We also cannot with any certainty whether or when we might complete a given clinical study. If we experience delays in the commencement or completion of our clinical studies, or if we terminate a clinical study prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed. In addition, any delays in our clinical studies could increase our costs, slow down the development and approval or certification process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

We currently conduct and may in the future conduct clinical studies for our product candidates outside the United States, and the FDA or comparable foreign regulatory authorities may not accept data from such studies.

We are currently engaging in clinical studies that involve clinical sites in the United States and EU. We could also in the future plan to conduct one or more future clinical studies of our product candidates outside the United States, including in Europe. The acceptance of study data from clinical studies conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities or notified bodies may be subject to certain conditions or may not be accepted at all. In cases where data from clinical studies conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; (ii) the studies were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical study requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance that

the FDA or any comparable foreign regulatory authority or notified body will accept data from studies conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable regulatory authority or notified body does not accept such data, it would result in the need for additional studies, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

We may not be able to file IDEs or IDE supplements or comparable documents in foreign jurisdictions to commence additional clinical studies on the timelines we expect, and even if we are able to, the FDA or comparable foreign regulatory authorities may not permit us to proceed.

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, if necessary, for a PMA, 510(k) premarket notification or de novo classification request, a company must, among other things, apply for and obtain institutional review board, or IRB, approval of the proposed investigation. In addition, if the clinical study involves a “significant risk” (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an IDE application and follow applicable IDE regulations. Unless IDE-exempt, nonsignificant risk devices are still subject to certain abbreviated IDE requirements; however, an IDE application is not required if such abbreviated requirements are met. We may not be able to obtain any necessary FDA and/or IRB approval to undertake clinical studies in the United States for future devices we develop and intend to market in the United States. If we do obtain such approvals, the FDA may find that our studies do not comply with the IDE or other regulations governing clinical investigations or the data from any such studies may not support marketing authorization of the investigational device. Moreover, certainty that clinical studies will meet desired endpoints or produce meaningful or useful data and be free of unexpected adverse effects cannot be assured, and such uncertainty could preclude or delay marketing authorization resulting in significant financial costs and reduced revenue. Similar requirements may apply in jurisdictions outside the United States.

While we plan to submit IDEs or comparable documents for Revita, we may not be able to file such IDEs or comparable documents on the timeline we expect. For example, we may experience manufacturing delays or other delays. Moreover, we cannot be sure that submission of an IDE or comparable document will result in the FDA or other comparable foreign regulatory authorities allowing further clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate clinical studies. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical studies set forth in an IDE, we cannot guarantee that such regulatory authorities will not change their requirements in the future. In addition, the FDA may disapprove of our IDE or withdraw approval of a previously-approved IDE if it finds that:

- we have not complied with certain requirements of the IDE regulations, any other applicable regulations or statutes, or any condition of approval imposed by an IRB or the FDA;
- the application or a report contains untrue statements or omits required material information;
- we fail to respond to a request for additional information within the time prescribed by the FDA;
- there is reason to believe that the risks to the human subjects are not outweighed by the anticipated benefits to the subjects or the importance of the knowledge to be gained;
- the informed consent is inadequate;
- the investigation, as proposed, is scientifically unsound;
- there is reason to believe that the device as used is ineffective; or

- it is unreasonable to begin or to continue the investigation due to the way in which the device is used or the inadequacy of:
 - (i) the report of prior investigations or the investigational plan;
 - (ii) the methods, facilities, and controls used for the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device; or
 - (iii) the monitoring and review of the investigation.

Although we would expect to submit a compliant, truthful and complete application, we cannot guarantee that the FDA would approve it. If the FDA were to disapprove our IDE application or propose to withdraw prior approval, we would have the right to request a regulatory hearing. However, we cannot guarantee what the outcome of such a hearing would be. If we are required and fail to obtain approval of an IDE, the FDA may prohibit us from conducting our investigation, or place us on a “clinical hold,” which could result in significant delay to our clinical studies or prevent us from completing them at all.

We may not be able to file INDs or IND amendments or comparable documents in foreign jurisdictions to commence additional clinical studies on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

While we plan to submit INDs or comparable documents for our Rejuva gene therapy candidates, we may not be able to file such INDs or comparable documents on the timeline we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND or comparable document will result in the FDA or other comparable foreign regulatory authorities allowing further clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate clinical studies. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical studies set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical studies we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our study may prevent us from completing our clinical studies or commercializing our product candidates on a timely basis, if at all.

Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical and clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical and clinical studies. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our product candidates may cause serious adverse events or undesirable side effects or have other properties which may cause us to suspend or discontinue clinical studies, delay or prevent regulatory approval or certification, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label than anticipated or the delay or denial of regulatory approval or certification by the FDA or comparable foreign regulatory authorities or notified bodies. Results of our clinical studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable side effects or deaths arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted, DSMB or other regulatory authorities could suspend or terminate our clinical studies or the FDA or other regulatory authorities could order us to cease clinical studies or deny approval or certification of our product candidates for any or all targeted indications. Undesirable side effects or deaths in clinical studies with our product candidates may cause the FDA or comparable foreign regulatory authorities to place a clinical hold on the associated clinical studies, to require additional studies, or otherwise to delay or deny approval or certification of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the study or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical studies and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval or certification and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities or notified bodies may suspend, limit or withdraw approvals or certifications of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities or notified bodies may require additional warnings on the label, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical studies or post-approval studies;
- we may be required to create a risk evaluation and mitigation strategy, or REMS, or similar mitigation plans in the case of our Rejuva gene therapy candidates, which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved or certified, and could seriously harm our business.

In previous clinical studies conducted by third parties involving viral vectors for gene therapy, some patients experienced serious adverse events, including the development of leukemia due to vector-related insertional oncogenesis. If our vectors demonstrate a similar effect, we may be required to halt or delay clinical development of our Rejuva gene therapy candidates or future gene therapy candidates.

A significant risk in any gene therapy product based on viral vectors is that the vector will insert in or near cancer-causing oncogenes leading to uncontrolled clonal proliferation of mature cancer cells in the patient. For example, in 2003, clinical studies using early versions of murine gamma-retroviral vectors, which integrate with, and thereby alter, the host cell's DNA, have led to several well-publicized adverse events, including reported cases of leukemia. The cause of these adverse events was shown to be insertional oncogenesis, which is the process whereby the corrected gene inserts in or near a gene that is important in a critical cellular process like growth or division, and this insertion results in the development of a cancer, often leukemia. Using molecular diagnostic techniques, it was determined that clones from these patients showed retrovirus insertion in proximity to the promoter of the *LMO2* proto-oncogene. Earlier generation retroviruses like the one used in these two studies have been shown to preferentially integrate in regulatory regions of genes that control cell growth.

These well-publicized adverse events led to the development of new viral vectors, such as AAV vectors, which is what we use for our planned Rejuva gene therapy candidates, with the goal of potentially improved safety profiles, as well as the requirement of enhanced safety monitoring in gene therapy clinical studies, including routine performance of vector copy number analysis on all production lots to monitor the number of insertion events per cell. Notwithstanding the potential safety improvements of AAV vectors, the risk of insertional oncogenesis remains a significant concern for gene therapy, and we cannot be certain that it will not occur in any of our clinical studies. There is also the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biological activity of the genetic material or other components of products used to carry the genetic material. The FDA has stated that AAV vectors possess characteristics that may pose risks of delayed adverse events. If any such adverse events occur, advancement of our preclinical and clinical studies could be halted or delayed, which would have a material adverse effect on our business and operations.

Although Revita has received Breakthrough Device designation, there can be no guarantee that the designation will benefit the development and regulatory approval process.

Revita has received Breakthrough Device designation from the FDA for the hydrothermal ablation of the duodenal mucosa to improve glycemic control and eliminate insulin needs in T2D patients who are inadequately controlled on long-acting insulin therapy. Breakthrough Device designation is available to medical devices that meet certain eligibility criteria, including that there is a reasonable expectation that the device will provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. In granting breakthrough device designation to Revita, the FDA found the following: there is a reasonable expectation that Revita will provide for more effective treatment or T2D patients who are inadequately controlled on long-acting insulin therapy; Revita represents a breakthrough technology; Revita, if found to be safe and effective, could offer significant advantages over existing approved or cleared alternatives; and the availability of Revita, if found to be safe and effective, would be in the best interest of patients. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of post-market data collection, when

scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and prioritized review of premarket submissions.

However, we may not experience a faster development process or review, and Breakthrough Device designation has no bearing on whether or not we will obtain approval, as compared to conventional FDA procedures. Breakthrough Device designation does not alter or convey any advantage in the regulatory review and approval standard for medical devices. Further, the FDA may rescind Breakthrough Device designation if it believes that the designation is no longer supported by data from our clinical development program.

If healthcare providers are unable to obtain coverage or adequate reimbursement for procedures performed with our products, if approved, such products will not likely be widely used.

In the United States, the commercial success of Revita and any future products will depend, in part, on the extent to which governmental payors at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for procedures utilizing our products, if approved.

Hospitals and other healthcare providers that purchase our product, if approved, for treatment of their patients generally rely on third-party payors to pay for all or part of the costs and fees associated with our products, if approved, as part of a “bundled” rate for the associated procedures. The existence of coverage and adequate reimbursement for our products, if approved, and the procedures performed with them by government and private payors is critical to market acceptance of our existing and future products. Neither hospitals nor physicians are likely to use our product, if approved, and any future products if they do not receive adequate reimbursement for the procedures utilizing such products.

Many private payors currently base their reimbursement policies on the coverage decisions and payment amounts determined by the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program. Others may adopt different coverage or reimbursement policies for procedures performed with our products, if approved, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for the procedures performed with our products in an adequate amount, if at all. A Medicare national or local coverage decision denying coverage for our products or for procedures using our products could result in private and other third-party payors also denying coverage for our products or procedures using our products. Third-party payors also may deny reimbursement for our products or procedures using our products if they determine that a product used in a procedure was not medically necessary, was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved use. Unfavorable coverage or reimbursement decisions by government programs or private payors underscore the uncertainty that our product face in the market and could have a material adverse effect on our business.

Many hospitals, clinics and other health care providers in the United States participate in group purchasing organizations, or GPOs, which may incentivize their members to make a relatively large proportion of purchases of medical technology from a limited number of vendors of similar products that have contracted with the GPO to offer discounted prices to the GPO’s members. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key group purchasing organizations and/or persuade hospitals and clinics to purchase our product “off contract.” The healthcare industry in the United States has experienced a trend toward cost containment as government and private payors seek to control healthcare costs by paying service providers lower rates. While we believe that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Private payors frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payors are adopting pay-for-performance programs that differentiate payments to healthcare providers based on the achievement of documented quality-of-care metrics, cost efficiencies, or patient outcomes.

These programs are intended to provide incentives to providers to deliver the same or better results while consuming fewer resources. Because of these programs, and related payor efforts to reduce payment levels, hospitals and other providers are seeking ways to reduce their costs, including the amounts they pay to medical device manufacturers. We may not be able to sell our product profitably if third-party payors deny or discontinue coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. Adverse changes in payment rates by payors to hospitals could adversely affect our ability to market, sell our products, and negatively affect our financial performance.

In international markets, medical device regulatory requirements and healthcare payment systems vary significantly from country to country, and many countries have instituted price ceilings on specific product lines. We cannot assure you that our products will be considered cost-effective by international third-party payors, that reimbursement will be available or, if available, that the third-party payors' reimbursement policies will not adversely affect our ability to sell our product profitably. Any failure to receive regulatory or reimbursement approvals would negatively affect market acceptance of our products in any international markets in which those approvals are being sought.

Additional time may be required to develop and obtain regulatory approval or certification for our Rejuva gene therapy candidates because we expect it to be regulated as a combination product.

We expect our Rejuva gene therapy candidates to require the development of a drug delivery device, such that the gene therapy candidate and drug delivery device may be regulated as a biologic-device combination product that requires coordination within the FDA and similar foreign regulatory agencies and notified bodies for review of its device and biologic components. Although the FDA and similar foreign regulatory agencies and notified bodies have systems in place for the review and approval or certification of combination products such as our Rejuva gene therapy candidates, we may experience delays in the development, approval or certification, and commercialization of our Rejuva gene therapy candidates due to regulatory timing constraints and uncertainties in the product development and approval or certification process.

Obtaining and maintaining regulatory approval or certification of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval or certification of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval, clearance, or certification of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval, clearance, or certification in any other jurisdiction, while a failure to obtain or delay in obtaining regulatory approval, clearance, or certification in one jurisdiction may have a negative effect on the regulatory approval, clearance, or certification process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval or certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical or clinical studies as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities or notified bodies in other jurisdictions. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval.

We may also submit marketing applications or certifications in other countries. Regulatory authorities and notified bodies in jurisdictions outside of the United States have requirements for approval and certification of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals or certifications and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products, if approved, in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals and/or certifications, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval or certification of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper approval or certification to market a device, biological product, or combination product, we will have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations.

Any regulatory approvals or certifications that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable foreign regulatory authority or notified body approves or certifies our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice requirements, or cGMPs, or similar foreign requirements, good clinical practice requirements, or GCPs, for any clinical studies that we conduct post-approval, and applicable product tracking and tracing requirements for certain drug and biological products. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP or similar foreign requirements and adherence to commitments made in any marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA and foreign regulatory authorities could require us to conduct another study to obtain additional safety or biomarker information.

Further, we will be required to comply with FDA and other regulatory authorities' promotion and advertising rules, which include, among others, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Although the FDA and other regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance or certification has not been issued. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS or similar program for our gene therapy candidates, if approved.

Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or product recalls;
- fines, untitled letters, warning letters or holds on clinical studies;
- refusal by the FDA or similar foreign authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or similar approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval or certification of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval or certification that we may have obtained and we may not achieve or sustain profitability.

For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Since January 31, 2023, submissions for all new clinical trials must be made under the CTR. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments.

The EU landscape concerning medical devices recently evolved. On May 25, 2017, the MDR entered into force, which repeals and replaces the MDD and the AIMDD. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member States.

The MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU and EEA for medical devices and to ensure a high level of safety and health while supporting innovation. See "Government Regulations—Regulation of Medical Devices in the European Union" for more information.

These modifications may have an effect on the way we intend to develop our business in the EU and EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed or canceled, which could adversely affect our ability to grow our business.

We expect our Rejuva gene therapy candidates will be, and future gene therapy candidates may be, regulated as biological products, or biological product-device combination products, and therefore may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA.

In addition, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA, if any, should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the approval of a biologic product biosimilar to one of our product candidates could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

Disruptions at the FDA and other government agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA, similar foreign regulatory authorities and notified bodies to review and authorize or certify new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the European Medicines Agency, or the EMA, following its relocation to Amsterdam and corresponding staff changes, may also slow the time necessary for new products or modifications to cleared or approved products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic manufacturing facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities or notified bodies from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities or notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

For instance in the EU, notified bodies must be officially designated to certify products and services in accordance with the MDR. However, the COVID-19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests with the new regulation

and notified body review times have lengthened. This situation could impact our ability to grow our business in the EU and EEA and the ability of the notified body to timely review and process our regulatory submissions and perform its audits.

A recall of our products, if approved, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized medical devices in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Further, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which a commercialized medical device product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, results of operations and financial condition.

In the EU, we must comply with the EU medical device vigilance system. Under this system, serious incidents and Field Safety Corrective Actions, or FSCAs must be reported to the relevant authorities of the EU. These reports will have to be submitted through EUDAMED—once functional—and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until EUDAMED is fully functional, the corresponding provisions of the MDD continue to apply. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices, or FSNs. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

Any adverse event involving our products, whether in the United States or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

If we obtain approval or certification of any of our product candidates, we may be subject to enforcement action if we engage in the off-label promotion of our products.

If we obtain approval or certification for any product candidates, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of off-label use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. For example, we are pursuing market authorization for Revita to improve glycemic control and eliminate insulin needs in T2D patients inadequately

controlled on insulin, but physicians may decide to use Revita for other, non-approved, T2D patient populations. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

Risks Related to Our Business and Strategy

We are substantially dependent on the success of our lead product candidate, Revita. If we are unable to obtain marketing approval or certification for and commercialize any of our current or future product candidates in a timely manner, our business will be harmed.

Our future success is dependent on our ability to timely advance and complete clinical studies, obtain marketing approval or certification for and successfully commercialize Revita. In 2016, Revita was CE marked under the MDD. The certificate was renewed under the MDD on March 8, 2021. However, we have only received reimbursement authorization for this product in Germany. We are investing significant efforts and financial resources in the research and development of Revita as well as our Rejuva gene therapy candidates. We are currently conducting a pivotal clinical study of Revita in patients with inadequately controlled T2D despite being on up to three ADAs and 20 to 100 units of insulin daily. Revita will require additional clinical development, evaluation of clinical manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we can generate any revenues from product sales in the United States. We are not permitted to market or promote Revita or any other product candidate, before we receive marketing approval or certification from the FDA or comparable foreign regulatory authorities or notified bodies, and we may never receive such marketing approvals or certifications.

The success of Revita will depend on several factors, including the following:

- the successful and timely completion of our ongoing or planned clinical studies;
- the initiation and successful patient enrollment and completion of additional clinical studies on a timely basis;
- maintaining and establishing relationships with CROs and clinical sites for clinical development, both in the United States and internationally;
- the frequency and severity of adverse events in the clinical studies;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA or any comparable foreign regulatory authority or notified bodies for marketing approval or certification;
- the timely receipt of marketing approvals or certifications from applicable regulatory authorities or notified bodies;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;

- maintaining our manufacturing facility and certain regulatory requirements thereof;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of our product candidates, if approved or certified;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval or certification;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize Revita, which would materially harm our business. If we do not receive marketing approvals or certification under the MDR for Revita, we may not be able to continue our operations.

Our long-term prospects depend in part upon discovering, developing and commercializing product candidates, which may fail in development or suffer delays that adversely affect their commercial viability. We intend to identify and develop novel product candidates, which makes it difficult to predict the time, cost and potential success of our current product candidates, and other product candidates we may develop in the future.

Our future results of operations are dependent on our ability to successfully discover, develop, obtain regulatory approval or certification for and commercialize product candidates beyond those we currently have in preclinical studies and clinical development. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical or early clinical studies of a product candidate may not be predictive of the results that will be obtained in later stage clinical studies of the product candidate.

The success of the product candidates we have or may develop will depend on many factors, including the following:

- the success of our research methodology in identifying potential indications or product candidates;
- generating sufficient data to support the initiation or continuation of clinical studies;
- obtaining regulatory permission to initiate clinical studies;
- contracting with the necessary parties to conduct clinical studies;
- successful enrollment of patients in, and the completion of, clinical studies on a timely basis;

- the timely manufacture of sufficient quantities of the applicable product candidate for use in clinical studies;
- the possible occurrence of adverse events in our clinical studies; and
- any potential interruptions or delays resulting from factors related to the COVID-19 pandemic or any future public health crises, including epidemics and pandemics.

In addition, our strategy includes identifying, developing and commercializing our Rejuva gene therapy candidates by using an AAV vector for endoscopic delivery of transgenes, such as GLP-1 receptor analog, to the pancreas to enable long-term remission of T2D by potentially restoring insulin production in patients with advanced disease. Our future success depends on the successful development of our Rejuva gene therapy platform. To date, very few products that utilize gene transfer have been approved in the United States or Europe and no gene therapy products that utilize an endoscopic method of administration have been approved. In addition, there have been a limited number of clinical studies of gene transduction technologies as compared to other, more conventional forms of therapy.

Although several AAV vectors have been tested in numerous clinical studies and are currently used in FDA-approved products, we cannot be certain that our Rejuva gene therapy candidates will successfully complete preclinical and clinical studies, or that it will not cause significant adverse events or toxicities. We also cannot be certain that we will be able to avoid triggering toxicities in our future preclinical or clinical studies or that our endoscopic method of administration will not cause unforeseen side effects or other challenges. Any such results could impact our ability to develop a product candidate, including our ability to enroll patients in our clinical studies. As a result of these factors, it is more difficult for us to predict the time and cost of our Rejuva gene therapy candidates' development, and we cannot predict whether the application of our approach to gene therapy, or any similar or competitive programs, will result in the identification, development, and regulatory approval of Rejuva, or that other gene therapy programs will not be considered better or more attractive. There can be no assurance that any development problems we experience in the future related to our Rejuva gene therapy candidates or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. We may also experience delays and challenges in achieving sustainable, reproducible, and scalable production. Any of these factors may prevent us from completing our preclinical or clinical studies or commercializing any gene therapy candidates we may develop on a timely or profitable basis, if at all.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval or certification of, commercialize or generate significant revenue from our other product candidates.

We may not be able to gain the support of leading hospitals and key thought leaders, or to publish the results of our clinical studies in peer-reviewed journals, which may make it difficult to establish the Revita DMR Procedure and/or our Rejuva gene therapy candidates as a standard of care, if approved, and may limit our revenue growth and ability to achieve profitability.

Our strategy includes developing relationships with leading hospitals and key thought leaders in the industry. If these hospitals and key thought leaders determine that the Revita DMR Procedure and/or our Rejuva gene therapy candidates are not clinically effective, or that alternative technologies or products are more effective, or if we encounter difficulty promoting adoption of or establishing the Revita DMR Procedure and/or our Rejuva gene therapy candidates as a standard of care, once approved or certified, our revenue growth and our ability to achieve profitability could be significantly limited.

We believe that the successful completion of our clinical studies of the Revita DMR Procedure and our Rejuva gene therapy candidates, publication of scientific and medical results in peer-reviewed journals, and

presentation of data at leading conferences are critical to the broad adoption of the Revita DMR Procedure and our Rejuva gene therapy candidates. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving the Revita DMR Procedure and/or our Rejuva gene therapy candidates sufficiently novel or worthy of publication.

We have not yet studied the ability of Revita to be used in repeated procedures. If we are unable to demonstrate the safety and improved glycemic effects of Revita for repeat use, it could have a material adverse effect on the on the clinical utility and commercial adoption of the device.

We have not yet studied the ability of Revita to be used in repeat procedures. Although, in a long-term follow-up study of the PP population in our Revita-1 study, we observed a statistically significant mean HbA1c reduction of 1.0% (n=27) at 24 months in patients who underwent the Revita DMR Procedure, in combination with at least one ongoing OAD and lifestyle counseling, we cannot be certain that patients will be able to have repeat procedures in the future. If we are unable to demonstrate the safety of Revita for repeat use, it could have a material adverse effect on the clinical utility and commercial adoption of Revita because providers, referring physicians, payors and patients may not find the product to be a compelling treatment option for T2D patients. To the extent any of the aforementioned groups do not accept Revita as a compelling treatment option for T2D patients, it could significantly harm our business, financial condition and prospects.

We have never obtained marketing approval for a product candidate in the United States and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate in the United States.

We have never obtained marketing approval for a product candidate in the United States. It is possible that the FDA may refuse to accept for substantive review any PMAs, BLAs or similar applications that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. We believe our proposed approach of treating T2D and obesity through the Revita DMR Procedure and our Rejuva gene therapy candidates is novel and, as a result, the process for, and the outcome of, our efforts to seek FDA approval is especially uncertain. If the FDA does not accept or approve our PMAs or BLAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any PMA or BLA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our PMAs or BLAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

If we are unable to obtain a billing code from the U.S. Department of Health and Human Services so that procedures using Revita, if approved, are covered under Medicare and Medicaid, this could have a negative impact on our intended sales and would have a material adverse effect on our business, financial condition and operating results.

We plan to submit an application to the U.S. Department of Health and Human Services for a billing code so that procedures using Revita, if approved, are covered under Medicare and Medicaid. However, there can be no assurance that our application will be successful, or that we will be able to obtain a code in a timely manner. In the event that we do not obtain a billing code for Revita, our customers may be unable to obtain reimbursement to cover the cost of their purchases under private or government-sponsored insurance plans, which could have a negative impact on our sales and have a material adverse effect on our business, financial condition and operating results. In addition, Medicare and its administrative contractors as well as other insurers

must find that Revita meets their medical necessity requirements for the treatment of patients with T2D on long-acting insulin or they will not pay for the treatment. In addition, there is a risk that the payment amount for Revita could be too low or too high to incentivize customer adoption.

If Revita, our Rejuva gene therapy candidates or any of our other future product candidates is approved or certified and fail to achieve and sustain sufficient market acceptance, we will not generate expected revenue and our business may be harmed.

Commercialization of Revita, our Rejuva gene therapy candidates and any of our other future product candidates in the United States and other jurisdictions in which we intend to pursue marketing approval or certification for such product candidates is a key element of our strategy. To be commercially successful, we must establish through clinical studies and convince physicians, hospitals and other healthcare providers, as well as potential patients, that the Revita DMR Procedure and our Rejuva gene therapy candidates are superior and attractive alternatives to currently available treatment options. Acceptance of our Rejuva gene therapy candidates and the Revita DMR Procedure depends on establishing their safety and effectiveness, including the Revita DMR Procedure's durability in treating T2D, and educating our target audience about their distinct characteristics, potential benefits, safety and ease-of-use. If we are not successful in establishing safety, effectiveness and ease of use, and conveying that our product candidates, if approved or certified, or the procedures and treatment they enable, provide superior results compared to existing technologies, practices and/or therapies, or that these product candidates improve patient outcomes, we may experience reluctance or refusal on the part of physicians, hospitals and other healthcare providers to accept and order, and third-party payors to pay for the treatment or procedures performed with, our product candidates, or patients may elect not to undergo the Revita DMR Procedure or take our Rejuva gene therapy candidates.

We believe that physicians, hospital and other healthcare providers will not widely accept our product candidates unless they are able to determine that our product candidates provide a benefit to patients and are a superior alternative to currently available interventions and easily integrated into their current endoscopy suite. Physicians, hospitals and other healthcare providers may be hesitant to change their medical treatment practices for the following reasons, among others:

- comfort and experience with current treatment regimens;
- long-standing relationships with competitors and distributors that sell other products and such parties' negative selling efforts;
- perceived liability risks generally associated with the use of new products and procedures;
- lack or perceived lack of long-term clinical data relating to safety or effectiveness, including durable effectiveness;
- difficulty in using Revita;
- higher cost or perceived higher cost of our product candidate compared to currently available treatments; and
- the additional time commitment that may be required for training.

These hurdles may make it difficult to demonstrate to physicians, hospitals and other healthcare providers that the Revita DMR Procedure and our Rejuva gene therapy candidates are an appropriate option for treating metabolic diseases, such as T2D and obesity, may be superior to available treatments and may be more cost-effective than alternative technologies. Furthermore, we may encounter significant difficulty in gaining inclusion in metabolic disease treatment guidelines and gaining broad market acceptance by healthcare providers, third-party payors and patients for our products, if approved, or procedures in which our products are used.

In addition, patient satisfaction with the Revita DMR Procedure and our Rejuva gene therapy candidates will be an important factor in providers' decisions to use our products. The success of any particular procedure using our products, and a patient's satisfaction with the procedure, is dependent on the technique and execution of the procedure by the endoscopist. Even if our products are manufactured exactly to specification, there is a risk that the endoscopist may not perform the procedure to specifications, leading to patient dissatisfaction with the procedure. If patients do not have a good outcome following procedures conducted using our products, providers' views of our products may be negatively impacted.

If we fail to successfully commercialize our products, if approved or certified, we may never receive a return on the significant investments in product development, sales and marketing, regulatory, manufacturing and quality assurance we have made, or further investments we intend to make, and we may fail to generate revenue or gain economies of scale from such investments.

Our future growth depends on physician awareness and adoption of the Revita DMR Procedure.

We intend to focus our sales, marketing and training efforts on diabetologists, gastroenterologists and interventional endoscopists. However, the initial point of contact for many patients suffering from T2D may be primary care physicians, or PCPs, or other referring medical professionals, such as nurse practitioners or physician assistants, who commonly see patients who have, or who are at risk of developing, T2D. We believe that education of PCPs, and other medical professionals caring for patients with metabolic diseases, about the clinical merits and patient benefits of the Revita DMR Procedure and our Rejuva gene therapy candidates is an important element of the adoption and market acceptance of our product candidates. If we fail to educate PCPs and other medical professionals, or if we educate them but they disagree with the clinical merits, patient benefits and ease-of-use of the DMR procedure using Revita and/or our Rejuva gene therapy candidates, or do not modify their current referral pattern to refer T2D and/or obesity patients to diabetologists, gastroenterologists and interventional endoscopists to perform the DMR procedure using Revita, our ability to achieve our projected revenues may be impaired.

The training required for endoscopists to use Revita could reduce the market acceptance of our products.

As with any new method or technique, endoscopists must undergo a training program before they are qualified to perform DMR procedure using Revita and administer our Rejuva gene therapy candidates. Endoscopists may not achieve the technical competency necessary to perform the procedure. We could also experience difficulty in meeting expected levels of endoscopists' completing our training program. This could happen due to there being less demand than expected, the length of time necessary to train each endoscopist being longer than we anticipate and/or the capacity of our future sales representatives to train endoscopists being lower than expected.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. We will have to develop our own sales, marketing and supply organization or outsource these activities to a third party to commercialize our products. If we decide to license our product candidate to others, we may need to rely on the marketing assistance and guidance of those collaborators.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization. If we are unable to build our own

distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

The medical device, diabetes management and biopharmaceutical markets are highly competitive. We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.

If our device product candidates receive marketing authorization or are cleared, approved or certified by regulatory authorities or notified bodies, when we commercialize our products we will compete with commercial medical device and diabetes management companies that offer a wider variety of products, services and procedures within the diabetic care categories. Some of these product offerings include: lifestyle and diet services, pharmaceuticals, and bariatric surgeries, in particular gastric bypass surgeries. Most of our expected competitors are either publicly traded or are divisions of publicly traded companies and have a number of competitive advantages over us, including:

- greater name and brand recognition, and financial and human-capital resources;
- longer commercial histories and better-established, broader operations and product lines and pipelines;
- larger sales forces and more established distribution networks;
- greater experience in conducting research and development, manufacturing, clinical studies, preparing regulatory submissions and obtaining regulatory clearance, approval or certification for product candidates;
- substantial intellectual property portfolios;
- larger and better-established customer bases and more extensive relationships with physicians, including diabetologists and endoscopists, providing them with more opportunities to interact with stakeholders involved in purchasing decisions; and
- better-established, larger-scale and lower-cost manufacturing capabilities and supplier relationships.

We believe that the principal competitive factors in our target markets include:

- safety and impact of products and procedures on the health of the patient;
- acceptance by diabetologists, endoscopists, endocrinologists, PCPs and other healthcare providers;
- reputation among physicians, hospitals and other healthcare providers;
- effectiveness, ease-of-use and reliability of the Revita DMR Procedure;
- capital and per-procedure economics of the DMR procedure using Revita;
- capital and per-treatment economics of our Rejuva gene therapy candidates;
- ability to implement a consumables-based model for product candidates;
- innovation in product candidate offerings;

- effective manufacturing, sales, marketing and distribution channels; and
- technical superiority of the Revita DMR Procedure in comparison to current treatment options.

We cannot assure you that we will effectively compete or that we will be successful in the face of increasing competition from existing and new products and technologies introduced by competitors, including pharmaceutical therapies to treat the same metabolic diseases as those targeted by our product candidates. We cannot assure you that our future competitors do not have or will not develop products or technologies that enable them to produce competitive products with greater capabilities or at lower costs than our product candidates. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize, such as our Rejuva gene therapy candidates, will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates.

In particular, there is intense competition in the field of gene therapy we are pursuing. We have competitors both in the United States and internationally, including major multinational biopharmaceutical companies, established biotechnology companies, specialty biopharmaceutical companies, emerging and start-up companies, universities and other research institutions. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical study sites, enrolling subjects for clinical studies and in identifying and in-licensing new product candidates.

We have chosen to initially address a well-validated biochemical target, and therefore expect to face competition from existing products and products in development for each of our product candidates. There are a large number of companies developing or marketing gene therapies, including many major pharmaceutical and biotechnology companies. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established biopharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may succeed in obtaining approval from the FDA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could

result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

We may not be able to develop new product candidates or enhance the capabilities of our existing product candidates to keep pace with our industry's rapidly changing technology and customer requirements, which could have a material adverse impact on our revenue, results of operations and business.

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements and evolving industry standards. Our success depends on our ability to develop new product candidates and applications for our technology in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our existing product candidates. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we plan to sell. Existing markets for our intended product candidates are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage our introduction of new product candidates. If potential customers believe that such product candidates will offer enhanced features or be sold for a more attractive price, they may delay purchases until such product candidates are available. We may also have excess or obsolete inventory of older products as we transition to new product candidates, and we have no experience in managing product transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines or manage the transitions of our technology to new product offerings, our revenue, results of operations and business will be adversely impacted.

Competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face strong competition in the future as expected competitors develop new or improved products and as new companies enter the market with new technologies.

If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, our internal estimates are based in large part on current patterns of treatment selection by diabetologists. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we develop could be significantly diminished and have an adverse material impact on our business.

If the quality of our product candidates does not meet the expectations of diabetologists, gastroenterologists, interventional endoscopists, endocrinologists, PCPs or other referring physicians, or patients, then our brand and reputation could suffer and our business could be adversely impacted.

In the course of conducting our business, we must adequately address quality issues that may arise with our product candidates, as well as defects in third-party components included in our product candidates.

Although we have established internal procedures to detect and address quality issues, there can be no assurance that we will be able to eliminate or mitigate risks that may arise from these issues. If the quality of our product candidates does not meet the expectations of diabetologists, gastroenterologists, interventional endoscopists, endocrinologists, PCPs or other referring physicians, or patients, then our brand and reputation could suffer, and our business could be adversely impacted.

Our sales cycle will be lengthy and variable, which makes it difficult for us to forecast revenue and other operating results.

If Revita is approved, we expect that our sales process will involve numerous interactions with multiple individuals within an organization and will often include in-depth analysis by potential customers of our products, performance of proof-of-concept studies, preparation of extensive documentation and a lengthy review process. As a result of these factors and the budget cycles of our potential customers, the time from initial contact with a customer to our receipt of a purchase order will vary significantly and could be up to 12 months or longer. Given the length and uncertainty of our anticipated sales cycle, we likely will experience fluctuations in our product sales on a period-to-period basis. Expected revenue streams are highly dependent on adoption of our consumables-based business model, and we cannot assure you that our potential clients will follow a consistent purchasing pattern. Moreover, it is difficult for us to forecast our revenue from product candidates that are not yet approved for commercialization, as such revenue is dependent upon our ability to establish, and then convince the medical community and third-party payors of, the clinical utility and economic benefits of our product candidates.

Third-party payors may choose not to cover the DMR procedure using Revita or they may require extensive and/or independently performed clinical studies prior to covering or maintaining coverage of the DMR procedure using Revita.

Our success depends on the medical and third-party payor communities' acceptance of our product candidates as tools and/or therapies that are useful to diabetologists, gastroenterologists and interventional endoscopists in treating patients with T2D and other metabolic diseases. The safety and effectiveness of the Revita DMR Procedure and our Rejuva gene therapy candidates have not been established, and we cannot assure you that any data that we or others generate will be consistent with the preclinical and clinical studies we have completed, or those we intend to complete. Even if our clinical studies demonstrate safety and effectiveness sufficient to gain regulatory approval for Revita or our Rejuva gene therapy candidates, certain diabetologists, gastroenterologists, interventional endoscopists, hospitals, ambulatory surgery centers and third-party payors may not find data from our clinical studies compelling or may prefer to see longer-term effectiveness data before adopting or covering the DMR procedure using Revita and/or our Rejuva gene therapy candidates. If providers do not adopt or third-party payors do not provide coverage for the DMR procedure using Revita and/or our Rejuva gene therapy candidates, our business will be materially and adversely affected.

We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology systems for significant elements of our operations, including the storage of data and retrieval of critical business information. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including systems handling human resources, financial controls and reporting, contract management, regulatory compliance and other infrastructure operations. These information technology systems may support a variety of functions, including storage of clinical data, laboratory operations, test validation, quality control, customer service support, billing and reimbursement, research and development activities and general administrative activities.

Information technology systems are vulnerable to damage from a variety of sources, including network failures, malicious or accidental human acts and natural disasters. Despite network security and back-up

measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Failures or significant downtime of our information technology systems or those used by our third-party service providers could prevent us from conducting our general business operations. Any disruption or loss of information technology systems on which critical aspects of our operations depend could have an adverse effect on our business. Further, we store highly confidential information on our information technology systems, including information related to clinical data, product designs and plans to create new products. If our systems are compromised by a physical or electronic break-in, computer virus or other malicious or accidental human action, our confidential information could be compromised, stolen or destroyed.

Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of our Rejuva gene therapy candidates, and any of our potential future gene therapy candidates, and adversely affect our ability to conduct our business or obtain regulatory approvals for our Rejuva gene therapy candidates.

Our Rejuva PGTx candidate involves introducing genetic material into a patient's pancreas via endoscopic administration. Gene therapy remains a novel technology, with only a limited number of gene therapy approved to date. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of metabolic diseases targeted by our current or future gene therapy candidates, prescribing treatments that involve the use of our current or future gene therapy candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development, commercialization or demand of our current and future gene therapy candidates we develop. Potential serious adverse events in our clinical studies, or other clinical studies involving gene therapy or our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our current and future gene therapy candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

Risks Relating to Our Dependence on Third Parties

We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies, and clinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain marketing authorization of or commercialize our product candidates and our business could be substantially harmed.

We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and to monitor and manage data for our ongoing preclinical programs. We rely on these parties for execution of our preclinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We, our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of study sponsors, principal investigators and study sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical studies may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations.

In addition, our clinical studies must be conducted with product produced under cGMP or similar foreign regulations. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations.

In addition, the FDA or comparable foreign regulatory authority may conclude that our financial relationships with principal investigators, some of whom we engage as consultants, have created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical study site and the utility of the clinical study itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Further, there is no guarantee that any such CROs, investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

Our CROs have the right to terminate their respective agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical studies warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we decide to establish new collaborations in the future, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We may face significant competition in seeking appropriate collaborators and the related negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

Those factors may include the design or results of clinical studies, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large companies in our industry that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We may enter into collaborations in the future with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators in the future for the development and commercialization of one or more of our product candidates. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical study results, changes in the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study or abandon a product candidate, repeat or conduct new clinical studies or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive

products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA or foreign regulations, provide accurate information to the FDA or comparable foreign regulatory agencies or notified bodies, comply with federal, state and foreign health care fraud and abuse and compliance laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, submission of false claims, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting/rebating, marketing and promotion, consulting, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Risks Related to Manufacturing

We contract with third parties for the manufacture of sub-assembly components for Revita and for the materials for our Rejuva gene therapy platform for preclinical studies and our ongoing clinical studies, and expect to continue to do so for additional clinical studies and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of sub-assembly components for Revita and for the materials for our Rejuva gene therapy platform for preclinical and clinical studies under the guidance of members of our organization. We do not have long-term supply agreements. We manage the final assembly and testing of Revita at our headquarters located in Lexington, Massachusetts, except for the sterilization of the Revita DMR catheter, which is outsourced to a third party. Furthermore, the materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical studies. For example, the extent to which any future public health crises, including epidemics and pandemics, such as COVID-19, impact our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the disease and the actions undertaken to contain the disease or treat its effects.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical study interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP or similar foreign regulations for manufacturing both active drug substances and finished drug products. For example, we are dependent on our contract manufacturing partners for the production of sub-assembly components of Revita, such as the Revita DMR catheter and Revita console. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

If we or our suppliers fail to comply with the FDA's good manufacturing practice regulations, this could impair our ability to market our products in a cost-effective and timely manner.

We and our third-party suppliers and manufacturers are required to comply with the FDA's cGMPs, which in the case of medical devices is known as the Quality System Regulation, or QSR. The QSR covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our device product candidates. The FDA audits compliance with the QSR and similar cGMPs for biologics through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time. If we or our suppliers or manufacturers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying approval of a PMA, BLA or supplements thereto for new products or modified products;
- withdrawing approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition.

Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies, such as the International Organization for Standardization, or ISO. Foreign bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign bodies. We intend to comply with the standards enforced by such foreign bodies as needed to commercialize our products. If we fail to adequately comply with any of these standards, a foreign body may take adverse actions similar to those within the power of the FDA. Any such action may harm our reputation and business, and could have an adverse effect on our business, results of operations and financial condition.

We depend on third-party sole-source suppliers for certain sub-assembly components of Revita, and any interruption in our relationship with such third-party sole-source suppliers may materially adversely affect our business.

We rely upon third-party suppliers for the manufacture of sub-assembly components of Revita. We do not have long-term supply agreements with any of our suppliers, some of which are single- or sole-source suppliers of the relevant sub-assembly component. For example, we order sub-assembly components on a purchase-order basis from several key suppliers. We have not yet identified and qualified second-source replacements for many of our critical single-source suppliers. Thus, in the event that our relationship with any of our single- or sole-source suppliers terminates in the future, we may have difficulty maintaining sufficient supplies of key sub-assembly components of our product candidate. We may also have difficulty obtaining similar sub-assembly components from other suppliers that are acceptable to the FDA or other regulatory agencies or notified bodies, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. Where practicable, we are currently seeking, or intend to seek, second-source manufacturers for our single-source components.

Changes in methods of our Rejuva gene therapy candidate manufacturing or formulation may result in additional costs or delay.

As gene therapy candidates proceed through preclinical studies to late-stage clinical studies towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such alterations can also occur due to changes in manufacturers. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our Rejuva gene therapy candidates to perform differently and affect the results of planned clinical studies or other future clinical studies conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical studies, require the conduct of bridging clinical studies or the repetition of one or more clinical studies beyond those we currently anticipate, increase clinical study costs, delay approval of our Rejuva gene therapy candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of any future gene therapy candidates.

Any contamination or interruption in our Rejuva gene therapy candidates' manufacturing process, shortages of raw materials or failure of our suppliers of plasmids and viruses to deliver necessary components could result in delays in our Rejuva gene therapy candidates' preclinical and clinical development or marketing schedules.

Given the nature of gene therapy manufacturing, there is a risk of contamination. Any contamination could adversely affect our ability to produce our Rejuva gene therapy candidates or future gene therapy candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Additionally, although our Rejuva gene therapy candidates will be tested for contamination prior to release, if a

contaminated product was administered to a patient in any future clinical studies, it could result in harm to the patient. Some of the raw materials required in the manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our Rejuva gene therapy candidates could adversely impact or disrupt the commercial manufacturing or the production of preclinical and clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

If our facilities are damaged or become inoperable, we will be unable to continue to research, develop and manufacture our product candidates and, as a result, there will be an adverse impact on our business until we are able to secure a new facility.

We do not have redundant facilities. We currently perform substantially all of our research and development, manufacturing and back office activity and maintain most of our raw material and finished goods inventory in a single location in Lexington, Massachusetts. Our facility and equipment would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, tornadoes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development, manufacturing and commercialization activities for some period of time. The inability to perform those activities, combined with our limited inventory of reserve raw materials and finished product candidates, may result in the inability to manufacture our product candidates during such periods and the delay of our ongoing or future clinical studies, including our ongoing Revitalize-1 pivotal clinical study of Revita. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

Risks Related to Legal and Regulatory Compliance Matters

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our product candidates may contain undetected defects. Any such defects may prevent or impair our customers' ability to use our product candidates, if approved, and may damage our customers' businesses and could harm our reputation. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise. We may also be subject to warranty and liability claims for damages related to defects in our product candidates. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our product candidates could harm our business and operating results.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices or biopharmaceutical products. This risk exists even if a device is cleared, approved or certified for commercial sale by the FDA, foreign regulatory authorities or notified bodies and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future products will be designed to affect, important bodily functions and processes and may contain undetected defects. Any side effects, manufacturing defects, misuse or abuse associated with our products or our products in development could result in patient injury or death. The medical device and biopharmaceutical industries have historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if Revita or other products or product candidates cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with sub-assembly components necessary to manufacture Revita, may be the basis for a claim against us. Product liability claims may be brought against us by consumers, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend

ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our product candidates;
- decreased demand for our products or, if cleared, approved or certified, products in development;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical study participants;
- substantial monetary awards to patients or other claimants; or
- loss of revenue.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have an adverse impact on our business.

In addition, although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have an adverse impact on our business.

We are subject to applicable fraud and abuse, transparency, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with physicians, hospitals and other healthcare providers are subject to scrutiny under these laws. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibit any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific

intent to violate it in order to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including significant criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payors. Private individuals can bring FCA “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil FCA, the government may impose significant civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children’s Health Insurance Program to report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician’s immediate family members;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- state and foreign laws that require companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report pricing, gifts, compensation and other remuneration provided to physicians and other health care providers or marketing expenditures; and state and local laws that require the registration of medical device sales representatives.

These laws and regulations, among other things, constrain our business, marketing and other promotional and research activities by limiting the kinds of financial arrangements we may have with hospitals, physicians, and other healthcare providers and potential purchasers of our products, when approved. We have entered into consulting agreements with physicians, including some who have ownership interests in us, which could be viewed as influencing the purchase of or use of our products in procedures they perform. Compensation under some of these arrangements includes the provision of stock or stock options. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between medical device and pharmaceutical manufacturers and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, manufacturers may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to.

Any action brought against us for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private qui tam actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties.

If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputation harm and disgorgement and we could be required to curtail, restructure or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

Healthcare reform initiatives and other administrative and legislative proposals in the United States may adversely affect our business, financial condition, results of operations and cash flows.

There have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the United States healthcare system. Outside of the United States, foreign governments and regulatory authorities may implement new requirements that could impact our business and market acceptance. Certain of these

proposals could limit the prices we are able to charge for our products or limit coverage of, or lower reimbursement for, procedures associated with the use of our products, once approved, and could limit the acceptance and availability of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products. The Affordable Care Act, or ACA, made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA:

- imposed a new federal excise tax on the sale of certain medical devices, which was suspended, effective January 1, 2016, and permanently repealed in December 2019;
- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expanded the eligibility criteria for Medicaid programs.

Certain provisions of the ACA have been subject to judicial and Congressional challenges. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law, including the Tax Cuts and Jobs Act, enacted on December 22, 2017, or TCJA), which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Additionally, earlier in 2021, President Biden issued an executive order to initiate a special enrollment period to allow people to obtain health insurance coverage through the ACA marketplace, and instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, among others. We cannot predict how the Supreme Court ruling, other litigation, or the healthcare reform measures of the Biden administration will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of, on average, 2% per fiscal year, which went into effect on April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, unless additional congressional action is taken.

Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians’ participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations, or cash flows. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, once approved, and accordingly, our financial operations. We cannot assure you that the ACA, as currently enacted or as amended in the future, will not harm

our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our approved products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement and downward pressure on the price that we receive for our products, once approved. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products, once marketing clearance is obtained.

We may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.

Patients who receive treatment for their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those treatments. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our product candidates. Therefore, coverage and adequate reimbursement are critical to a new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products or procedures using these products. In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval processes apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product or procedures that use the product.

Coverage and reimbursement by a governmental and other third-party payors may depend upon a number of factors, including the third-party payor's determination that use of a product or service and its use for a particular patient is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product or procedure from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our product candidates to the payor. We may not be able to provide data sufficient to satisfy governmental and third-party payors that procedures using our products should be covered and reimbursed. There may be significant delays in obtaining such coverage and reimbursement for newly approved product candidates or the related procedures, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities.

Reimbursement may not be available for procedures using any product that we commercialize and, if coverage and reimbursement are available, the level of reimbursement may not be adequate. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for procedures using any approved product candidates that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical study that compares the cost-effectiveness of our product candidate to other available therapies. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

Changes in and actual or perceived failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.

We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that govern data privacy and security). The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and may increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations, including state security breach notification laws, federal and state health information privacy laws (including HIPAA), and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues. If

we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or applicable state laws.

We are subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, the European Union General Data Protection Regulation, or the EU GDPR, governs certain collection and other processing activities involving personal data about individuals in the European Economic Area, or the EEA, and the UK General Data Protection Regulation and UK Data Protection Act 2018, or the UK GDPR, governs similar collection and other processing activities involving personal data about individuals in the United Kingdom. References to the GDPR in this prospectus include both the EU GDPR and the UK GDPR. Among other things, the GDPR imposes requirements regarding processing health and other sensitive data, obtaining informed consent of individuals, providing notice to individuals regarding data processing activities, responding to data subject requests, taking certain measures when engaging third-party processors, notifying data subjects and regulators of data breaches, implementing safeguards to protect the security and confidentiality of personal data, and strict rules and restrictions on the international transfers of personal data. The GDPR imposes substantial fines for breaches and violations, which can be up to the greater of €20 million (£17.5 million for the UK) or 4% of our annual global revenue and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Further, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States in certain circumstances, unless a valid GDPR transfer mechanism (e.g., the European Commission approved Standard Contractual Clauses, or the EU SCCs, and the UK International Data Transfer Agreement/Addendum, or the UK IDTA) has been put in place. Where relying on the EU SCCs or UK IDTA for data transfers, we may also be required to carry out transfer impact assessments to assess whether the recipient is subject to local laws which allow public authority access to personal data. The efficacy and longevity of current transfer mechanisms between the EEA and the United States remains uncertain. The international transfer obligations under the EEA and UK data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA and UK personal data is located and which service providers we can utilize for the processing of EEA and UK personal data. If we are unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Although the UK is regarded as a third country under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EEA member states to the UK without additional safeguards. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. Further, the UK Government has introduced a Data Protection and Digital Information Bill (“UK Bill”) into the UK legislative process. The aim of the UK Bill is to reform the UK’s data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime and threaten the UK adequacy decision from the European Commission. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the UK and the EEA.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners’ or suppliers’ ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations.

If we fail to comply with any such laws, rules or regulations, we may face government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity that could adversely affect our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

We rely on a variety of intellectual property rights, and if we are unable to obtain, maintain or protect our intellectual property, our business, financial situation, results of operations, and prospects will be harmed. If we are unable to obtain and maintain patent protection for our current product candidate, any future product candidates we may develop and our technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our current product candidate, any future product candidates we may develop and our technology may be adversely affected.

Our commercial success will depend, in part, on our ability to obtain and maintain intellectual property protection for our product candidates and related technologies, including Revita, both in the United States and elsewhere, successfully defend our intellectual property rights against third-party challenges and successfully enforce our intellectual property rights to prevent third-party infringement. As with other medical device companies, we rely primarily upon a combination of patents, trademarks and trade secret protection, as well as nondisclosure, confidentiality and other contractual agreements, to protect the intellectual property related to our brands, products and other proprietary technologies.

We cannot provide any assurances that any of our pending patent applications will mature into issued patents and, if they do, that such patents will include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. Our patents and any patent issuing from any of our patent applications would not prevent third-party competitors from creating, making and marketing alternative systems, devices and/or methods capable of performing similar procedures that fall outside the scope of our patent claims. There can be no assurance that any such alternative systems, devices and methods will not be equally effective as ours or that we will be able to obtain or maintain patent protection at all. Moreover, other parties have developed technologies that may be related to or competitive with our approach, and may have filed or may file patent applications and may have received or may receive patents that may overlap or conflict with our patents or patent applications. Such third-party patent positions may limit or even eliminate our ability to obtain or maintain patent protection for certain inventions. Additionally or alternatively, such third-party patent rights may represent alternative or pre-existing technologies not protected by our own intellectual property that could be used to compete with us.

Our success depends, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our patent portfolio or other intellectual property rights, including the amount and timing of any payments we may be required to make in connection with the filing, defense and enforcement of any patents or other intellectual property rights. The process of obtaining patent protection is expensive and time-consuming, and we may not be able to file or prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or product candidates and may choose not to pursue patent protection in certain jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. For example, under the laws of many jurisdictions, patent protection is not available or is limited for surgical methods and certain other medical procedures. As a result, some of our product candidates may not be protected by patents in one or more jurisdictions, or, possibly, in any jurisdiction. We generally apply for patents in those countries where we intend to make, have made, use or sell product candidates and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not and will not seek protection in all countries where we intend to sell product candidates and we may not accurately predict all the countries where patent protection

would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities. Several of our pending patent applications are in the early stages, and the deadline for deciding whether and in which jurisdictions to pursue protection has not yet expired for those applications. Prior to the applicable deadlines, we will need to decide whether and where to pursue protection, and we will not have the opportunity to obtain protection in jurisdictions where we elect not to seek protection. For other of our pending applications, the applicable timelines for deciding where to seek protection have passed, and we have made decisions, on an application-by-application basis, to pursue protection for each of those applications in a limited number of jurisdictions.

Furthermore, we cannot guarantee that any patents will be issued from any pending or future patent applications, or that any current or future patents, will provide us with any meaningful protection or competitive advantage. Even if issued, patents may be challenged, including with respect to ownership, narrowed, invalidated, held unenforceable or circumvented, any of which could limit our ability to prevent competitors and other third parties from developing and marketing similar products or limit the duration of patent protection we may have for our product candidates and technologies. Other companies may also design around technologies we have patented or developed. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our product candidates or practicing our own patented technology, including Revita. The risks described herein with respect to patents and patent applications we own similarly apply to any patents or patent applications that we may license in the future. These and other factors may prevent us from realizing any competitive advantage from patents.

The strength of patent rights generally, and particularly the patent positions of medical device companies, can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. The standards that the United States Patent and Trademark Office, or the USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for protection of the inventions set forth in our applications. We can give no assurance that all of the potentially relevant prior art relating to our patents or patent applications has been found; overlooked prior art could be used by a third-party to challenge the validity, enforceability and scope of our patents, or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability and scope of our patents in the United States, Europe and in other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability. Third parties may challenge any existing patent or future patent we own or license through adversarial proceedings in the issuing offices or in court proceedings, including as a response to any assertion of our patents against them. In any of these proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable, or even if valid and enforceable, insufficient to provide protection against competing products and services to achieve our business objectives. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third-party asserts a

substantial question of patentability against any claim of a U.S. patent we own or license. The adoption of the Leahy-Smith America Invents Act, or the Leahy-Smith Act, in September 2011 established additional opportunities for third parties to invalidate U.S. patent claims, including *inter partes* review and post-grant review proceedings. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. Competitors may claim that they invented the inventions claimed in our patents or pending applications prior to the inventors of our intellectual property, or may have filed for protection for certain inventions before we did. We may need to participate in interference or derivation proceedings, which may result in the loss of some or all of the patent protection at issue. Furthermore, an adverse decision in an interference or derivation proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. Any of these proceedings may be very complex and expensive, and may divert our management's attention from our core business. If any of our patents, should they issue, are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of our product candidates, and if we do not own or have exclusive rights to other enforceable patents protecting our product candidates or other technologies, competitors and other third parties could market products and use processes that are substantially similar or identical to, or superior to, ours and our business would suffer.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates or the related technologies in all countries and jurisdictions throughout the world would be prohibitively expensive, and we will only pursue patent protection in selected jurisdictions outside the United States. The requirements for patentability differ in various countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and the laws of some foreign countries do not provide patent protection for certain types of inventions that are patentable in the United States. As a result, certain aspects of our technology may not be protectable by patents or may be difficult to protect in certain jurisdictions outside the United States, including in Europe, and our intellectual property rights outside the United States could be less extensive than those in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For some of the patent families owned by us, the relevant statutory deadlines have not yet expired, and we will need to decide whether and where to pursue protection outside the United States before expiration of the applicable deadlines. For other of the patent families owned by us, the relevant statutory deadlines have expired, and thus, we will only have the opportunity to pursue protection in the limited jurisdictions previously selected.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, if approved, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection,

especially those relating to medical technology. For example, an April 2021 report from the Office of the United States Trade Representative identified a number of countries, including India and China, where challenges to the procurement and enforcement of patent rights have been reported. Several countries, including India and China, have been listed in the report every year since 1989. This could make it difficult for us to stop the infringement of our patents or the misappropriation or other violation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We may choose not to initiate lawsuits because the expected benefit is not sufficient. Accordingly, our efforts to enforce our intellectual property rights outside the United States may be inadequate to obtain a significant commercial advantage from the intellectual property.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. Litigation or other legal proceedings related to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming. Competitors may infringe our patents, should they issue, or other intellectual property, or we may be required to defend against claims of infringement, misappropriation or other violation of third party intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that our patents are invalid or unenforceable or that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, which could adversely affect our competitive business position, business prospects and financial condition.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual

property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, or otherwise violating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation or continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the intellectual property rights of third parties.

The medical device industry is subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use, market and sell our product candidates and technology.

Numerous third-party patents exist in the fields relating to our product candidates, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our product candidates and technologies. There may be issued U.S. or European patents of which we are not aware, held by our competitors or third parties that, if found to be valid and enforceable, could be alleged to be infringed by some of our product candidates or technologies, including Revita. There may be patents of which we are not aware, that if they result in issued patents, could be alleged to be infringed by some of our product candidates or technologies, including Revita. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our product candidates and technologies.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates or technology because database searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our product candidates or technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not-infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates and technologies. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. Our determination of the expiration date of any patent in the United States, the European Union or elsewhere that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates.

Patents could be issued, now or in the future, to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition, results of operations and prospects. Furthermore, we would be exposed to a threat of litigation. In addition, we may be required or choose to enter into a license agreement to avoid or settle litigation.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our product candidates, components of our product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our product candidates, technologies, or processes do not infringe those third parties' patents;
- we may participate at substantial cost in International Trade Commission proceedings to abate importation of products or product candidates that would compete unfairly with our product candidates;
- if our competitors file patent applications that claim technology also claimed by us, we may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third-party with a dominant patent position;
- if third parties initiate litigation claiming that our processes or product candidates infringe their patent or misappropriate or otherwise violate other intellectual property rights, we will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings seeking to invalidate patents owned by us or to obtain a declaratory judgment that their product or technology does not infringe our patents, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of employees or consultants or others who are involved in developing our product candidates; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or product candidates infringe their patent or misappropriate or otherwise violate other intellectual property rights and/ or that we breached our obligations under the license agreement, and we would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force use to do one or more of the following:

- incur substantial monetary liability for infringement, appropriation or other violations of intellectual property rights, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third party's attorneys' fees;
- pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non-infringing technology;

- stop manufacturing, selling, using, exporting or licensing the product candidate or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product candidate or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our product candidates and technology so they do not infringe, misappropriate or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with our competitors, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing product candidates and technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims, if our claims are held invalid or unenforceable.

The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights. As we continue to develop and, if approved, commercialize our current product candidates and future product candidates, competitors may claim that our products, product candidates or technology infringe, misappropriate or otherwise violate their intellectual property rights as part of business strategies designed to impede our successful commercialization. As we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or technologies may be subject to claims of infringement, misappropriation or other violation of the intellectual property rights of third parties. There may be third-party patents or patent applications with claims related to a product candidate or our technology, such as to Revita. Because patent applications can take many years to issue, third parties may have currently pending patent applications that may later result in issued patents that our product candidates may infringe, or which such third parties claim are infringed by our technologies. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, to prevail, we would need to demonstrate that our product candidates, products, technologies or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause shipment delays of product candidates, or prohibit us from manufacturing, marketing or otherwise commercializing our product candidates and technology. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates or technologies. Third parties may assert

infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our product candidates.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition, prospects or cash flows.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future product candidates and technologies.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents. On September 16, 2011, the Leahy-Smith America Invents Act or the Leahy-Smith Act was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and may also affect patent litigation. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, including switching the United States patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. For example, a third party that files a patent application before us at the USPTO could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Additional provisions of the Leahy-Smith Act allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent through various proceedings, including post-grant review and inter partes review proceedings, administered by the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents, should they issue, all of which could have a material adverse effect on our business, results of operation, financial condition or cash flows.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Periodic maintenance fees, renewal fees, annuity fees and various government fees are due to be paid to governmental patent agencies over the lifetime of a patent. Future maintenance fees will also need to be paid on other patents that may be issued to us. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our licensor to pay annuity fees due to patent agencies on our patents and pending patent applications. In certain cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business, results of operation, financial condition, prospects or cash flows.

Patent terms may not be sufficient to effectively protect our product candidates and business for an adequate period of time.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the term of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent has expired, we may be open to competition, which may harm our business prospects. In addition, although upon issuance in the United States a patent's term can be extended based on certain delays caused by the USPTO, this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. If we do not have sufficient patent terms to protect our products, proprietary technologies and their uses, our business would be seriously harmed. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our reduced patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We rely on trademarks and tradenames to distinguish our product and technology from the products of our competitors. Our registered or unregistered trademarks or trade names may be challenged, opposed, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we rely on to build name recognition among potential partners and customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks, such as those that incorporate variations of our registered or unregistered trademarks or trade names. An adverse decision in a trademark or trade name suit may subject us to damages, and may result in the need to redesign or rename the infringing brand, which could be costly and time-consuming. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair

competition, defamation or other violation of our rights, our business could be materially adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks and trade names, may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on confidential proprietary information, including trade secrets and know-how, to develop and maintain our competitive position. However, trade secrets and other proprietary information can be difficult to protect and some courts are less willing or unwilling to protect trade secrets and proprietary information. We seek to protect our confidential proprietary information, in part, by entering into confidentiality agreements with our employees, consultants, vendors, collaborators and others, upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential. Our agreements with employees, business consultants, and our personnel policies, also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, the assignment of intellectual property rights may not be self-executing, and individuals with whom we have these agreements may not comply with their terms or may have preexisting or competing obligations to third parties of which we are not aware. Thus, despite such agreements, such inventions may become assigned to third parties. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third-party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all, and the failure to obtain rights in such intellectual property by assignment or license could have a material adverse effect on our business.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. We and our contractors and partners operate in certain countries that are at heightened risk of theft of technology, data and intellectual property through direct or indirect intrusion by private parties or international actors, including those affiliated with or controlled by state actors. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures

may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

We may also employ individuals, such as employees, consultants or advisors, who were previously or are concurrently employed at or providing consulting services for research institutions and/or other medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that these employees, consultants or advisors, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former or concurrent employers, or that patents and applications we have filed to protect inventions of these employees, consultants or advisors, even those related to one or more of our product candidates or technologies, are rightfully owned by their former or concurrent employer. Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees, consultants or advisors have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable personnel or intellectual property rights. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our product candidates. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would have an adverse effect on our business, results of operations and financial condition.

We may enter into licenses to intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing a product candidate, if approved, that relied on such licensed intellectual property.

We may in the future be party to license agreements under which we are granted rights to material intellectual property that is important to our business. We would expect any such license agreements to impose various obligations on us, including but not limited to, diligence obligations and the payment of milestones and/or royalties. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Our business could suffer, for example, if any material licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents or other forms intellectual property do not exist that might be enforced against our current product candidates or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors

access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the drug candidates that we license from third parties. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject of such licensed rights could be adversely affected.

Licensing of intellectual property involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our right to transfer or assign the license;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of patented technology; and
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

In addition, license agreements are often complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or broaden what we believe to be the scope of a licensor's rights to our intellectual property and technology, or increase what we believe to be our financial or other obligations under a relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. If

disputes over intellectual property impair our ability to maintain any future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Furthermore, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain any competitive advantage. Moreover, if a third party has intellectual property rights that cover a product candidate or the practice of our technology, such as Revita, we may not be able to fully exercise or extract value from our intellectual property rights. We cannot ensure that:

- any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our product candidates or otherwise provide any competitive advantage;
- any of our pending patent applications will issue as patents at all;
- we were the first to make inventions covered by any of our existing patent applications;
- we were the first to file patent applications for our inventions;
- we have not omitted that should be listed as inventors or included individuals that should not be listed as inventors in our patents and patent applications, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- others will not develop similar or alternative technologies that do not infringe our intellectual property, incorporate technology from the public domain, or will otherwise be able to design around our patents, should they issue;
- others will not use preexisting technology to effectively compete against us;
- any of our patents, if issued, will ultimately be found to be valid and enforceable;
- there are no prior public disclosures that could invalidate our patents, or parts of our patents;
- that there are no unpublished, third-party patent applications or applications maintained in secrecy that may later issue with claims covering our product candidate or technology;
- third parties will not compete with us in jurisdictions where we do not pursue and obtain patent protection;
- the laws of foreign countries will protect our proprietary rights to the same extent as the laws of the United States;
- the inventors of our patents or patent applications will not become involved with competitors to develop products or processes that design around our patents;
- any patents issued to us will provide a basis for an exclusive market for our commercially-viable products, if approved, or provide us with any competitive advantages, or will not be challenged by third parties; or

- our commercial activities or products will not infringe upon the patents or proprietary rights of others.

Should any of these events occur, they could significantly harm our business and results of operations.

Risks Related to Employee Matters and Managing Our Growth

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval or certification to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or certification or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. In particular, we are highly dependent on the management and business expertise of Harith Rajagopalan, M.D., Ph.D., our Chief Executive Officer, Jay D. Caplan, our President and Chief Product Officer, and Lisa A. Davidson, our Chief Financial Officer, each of whom is employed by us at will. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our results of operations. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the medical device and pharmaceutical industries is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other medical device and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry

than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2023, we have 94 full-time employees, including 78 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory agencies' or notified bodies' review process of our current product candidates and any other product candidate we develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize Revita and any other product candidate will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical studies may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize Revita and any other current or future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Risks Related to This Offering and Ownership of Our Common Stock

There has been no prior public market for our common stock. We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to this offering, no public market for shares of our common stock existed and an active trading market for our common stock may never develop or be sustained following this offering. We determined the

initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. The trading prices for common stock of other pharmaceutical and biotechnology companies have also been highly volatile as a result of the COVID-19 pandemic.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, these factors include:

- the timing and results of preclinical and clinical studies of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our product candidates or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of the COVID-19 pandemic, or any future public health crises, including epidemics and pandemics, and actions taken to slow their spread; and
- general economic, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our common stock.

Our management team has broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the net proceeds from this offering in ways with which investors disagree.

We plan to use the net proceeds from this offering to complete the ongoing Revitalize-1 pivotal clinical study of Revita and fund the Remain-1 study; fund the continued preclinical development of our Rejuva gene therapy platform; and for working capital and other general corporate purposes, including medical education and other commercial readiness activities. See “Use of Proceeds.” However, within the scope of our plan, and in light of the various risks to our business, including those discussed in this “Risk Factors” section and elsewhere in this prospectus, our management will have broad discretion over the use of net proceeds from this offering, and could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply the net proceeds from this offering in ways that improve our results of operations, we may fail to achieve expected financial results, which could cause our stock price to decline.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 68% of our voting stock and, upon the closing of this offering, that same group will beneficially own approximately 63% of our outstanding voting stock. Therefore, even after this offering these stockholders will be able to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or

approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

If you purchase shares of our common stock in our initial public offering, you will experience substantial and immediate dilution.

The initial public offering price of our common stock is substantially higher than the net tangible book value (deficit) per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on the assumed initial public offering price of \$15.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$12.47 per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the assumed initial public offering price. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. In addition, as of December 31, 2023, we had outstanding stock options to purchase an aggregate of 8,721,884 shares of common stock at a weighted-average price of \$5.34 per share. To that extent, you will experience additional dilution when those holding stock options exercise their right to purchase common stock under our equity incentive plans or when we otherwise issue additional shares of common stock. See “Dilution.”

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock after this offering or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Upon the completion of this offering, 47,607,201 shares of common stock will be outstanding (48,707,200 shares if the underwriters exercise their option to purchase additional shares from us in full), based on the number of shares outstanding as of December 31, 2023.

All shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our “affiliates” as defined in Rule 144 under the Securities Act. The resale of the remaining 40,273,868 shares, or approximately 85% of our outstanding shares of common stock following this offering, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning 181 days after the date of this prospectus. Shares issued upon the exercise of stock options, RSUs and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see “Shares Eligible for Future Sale.”

Upon the completion of this offering, the holders of approximately 36,343,909 shares, or approximately 76.3% of our outstanding shares following this offering, of our common stock will have rights, subject to some

conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to the lock-up agreements described under “Underwriting.”

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our common stock, which is not certain. Furthermore, we are a party to a credit agreement that contains negative covenants that limit our ability to pay dividends. For more information, see the section of this prospectus captioned “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

Provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our certificate of incorporation and bylaws, as we expect they will be in effect upon closing of the offering, will contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan (also known as a “poison pill”);
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;

- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause or causes of action against any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any part of this prospectus. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in

the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risks

Our information technology systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures, our information technology systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party service providers, are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. The size and complexity of our information technology systems make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious third parties. Such attacks are increasing in their frequency, levels of persistence, levels of sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise, especially given increased vulnerability of corporate information technology systems as distributed work environments have become prevalent. In addition to unauthorized access to or acquisition of personal data, confidential information, intellectual property or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial-of-service attacks, social engineering and other means, to attain such unauthorized access or acquisition or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. Like many other companies, we experience attempted cybersecurity actions on a frequent basis, and the frequency of such attempts could increase in the future. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent or quickly identify service interruptions or security breaches. The techniques used by cybercriminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot assure that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages or breaches in our systems or those of our third-party services providers or partners.

If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to health-related or other personal information, it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical study data from completed or future clinical studies could result in delays in our regulatory approval or certification efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further

development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Our operations are vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity, future pandemics and other events beyond our control, which could harm our business.

Our facilities are located in regions which experience severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major tornado, flood, fire, earthquake, power loss, terrorist activity, future pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on financial statements;
- reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue; (2) the date we qualify as a “large accelerated

filer,” with at least \$700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are a “smaller reporting company” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a “smaller reporting company.” We are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as an exemption from providing selected financial data and executive compensation information. If we qualify as a smaller reporting company because we meet the revenue limits under the definition of a smaller reporting company, we will be a “low-revenue smaller reporting company.” Low-revenue smaller reporting companies are not required to obtain an external audit on the effectiveness of their internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404. These exemptions and reduced disclosures may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

The requirements of being a public company may strain our resources, result in more litigation and divert management’s attention.

As a public company, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management’s attention may be diverted from other business concerns, which could adversely affect our business and results of operations. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If our efforts to

comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this prospectus and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are a smaller reporting company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

Changes in our effective tax rate or tax liability may have an adverse effect on our results of operations.

We are subject to income taxes in the United States. Our effective tax rate could be adversely affected due to several factors, including:

- changes in the relative amounts of income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates;
- changes in the United States tax laws and regulations or the interpretation of them, including the Tax Act, as modified by the CARES Act;
- changes to our assessment about our ability to realize our deferred tax assets that are based on estimates of our future results, the prudence and feasibility of possible tax planning strategies, and the economic and political environments in which we do business;

- the outcome of current and future tax audits, examinations, or administrative appeals; and
- limitations or adverse findings regarding our ability to do business in some jurisdictions.

New income or other tax laws or regulations could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws and regulations could be interpreted, modified, or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax Laws. Future guidance from the IRS and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act and the Inflation Reduction Act modified and introduced certain provisions to the Tax Act. Changes in corporate tax rates, the realization of net operating losses, and other deferred tax assets relating to our operations, the taxation of foreign earnings, the deductibility of expenses under the Tax Act, the corporate minimum tax and excise tax under the Inflation Reduction Act or future reform legislation could have a material impact on the value of our deferred tax assets and could increase our future U.S. tax expense.

If our product candidates are approved, we expect to generate a portion of our future revenue internationally and are subject to various risks relating to international operations, which could adversely affect our operating results.

We believe that a portion of our future revenue will come from international sources as we plan to seek regulatory approvals of our product candidates in international markets and, if approved, to establish overseas operations. Engaging in international business involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio-hazardous waste;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- foreign exchange controls;
- difficulties and costs of staffing and managing foreign operations;
- difficulties protecting or procuring intellectual property rights; and
- existence of additional third-party intellectual property rights of potential relevance.

If the value of the U.S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U.S. dollars.

If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer.

New tax legislation may impact our results of operations and financial condition.

The U.S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate and the imposition of minimum taxes or surtaxes on certain types of income. For example, the recently enacted Inflation Reduction Act, among other changes, introduced a 15% corporate minimum tax on certain U.S. corporations and a 1% excise tax on certain stock redemptions by U.S. corporations. If such changes are enacted or implemented, we are currently unable to predict the ultimate impact on our business.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, value added or similar taxes, and any such assessments could adversely affect our business, financial condition, and results of operations.

Sales and use, value added and similar tax laws and rates vary greatly by jurisdiction. Certain jurisdictions in which we do not collect such taxes may assert that such taxes are applicable or that our presence in such jurisdictions is sufficient to require us to collect taxes, which could result in tax assessments, penalties and interest, and we may be required to collect such taxes in the future. Such tax assessments, penalties and interest or future requirements may adversely affect our financial condition and results of operations. Further, in June 2018, the Supreme Court held in *South Dakota v. Wayfair, Inc.* that states could impose sales tax collection obligations on out-of-state sellers even if those sellers lack any physical presence within the states imposing the sales taxes. Under the *Wayfair* decision, a person requires only a “substantial nexus” with the taxing state before the state may subject the person to sales tax collection obligations therein. An increasing number of states (both before and after the publication of the *Wayfair* decision) have considered or adopted laws that attempt to impose sales tax collection obligations on out-of-state sellers. The Supreme Court’s *Wayfair* decision has removed a significant impediment to the enactment and enforcement of these laws, and it is possible that states may seek to tax out-of-state sellers on sales that occurred in prior tax years, which could create additional administrative burdens for us, put us at a competitive disadvantage if such states do not impose similar obligations on our competitors, and decrease our future sales, which could adversely affect our business, financial condition, and results of operations.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” , “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the timing, progress and results of preclinical and clinical studies for our current and future product candidates, including statements regarding the timing of initiation and completion of studies and related preparatory work, the period during which the results of the studies will become available and our research and development programs;
- the timing, scope or likelihood of regulatory submissions, filings, clearances and approvals, including final regulatory approval or clearance of our product candidates;
- our ability to develop and advance product candidates into, and successfully complete, clinical studies;
- our expectations regarding the size of the patient populations for our product candidates, if approved or cleared for commercial use;
- the implementation of our business model and our strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy, as well as our product development strategy;
- the pricing and reimbursement of our product candidates, if approved or cleared;
- the scalability and commercial viability of our manufacturing methods and processes, including our plans to maintain our in-house manufacturing facility, even after commercialization of any of our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our competitive position;
- the scope of protection we and/or any future licensors are able to establish and maintain for intellectual property rights covering our product candidates;

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- developments and projections relating to our competitors and our industry;
- our expectations related to the use of proceeds from this offering;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- our expectations regarding the time during which we will be an emerging growth company and smaller reporting company under the JOBS Act; and
- the impact of adverse macroeconomic conditions, geopolitical events, the recent COVID-19 pandemic and potential future public health crises, including epidemics and pandemics.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

USE OF PROCEEDS

We estimate that the net proceeds to us from in this offering will be approximately \$99.0 million, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares from us is exercised in full, we estimate that our net proceeds will be approximately \$114.3 million.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share would increase (decrease) the net proceeds to us from this offering by approximately \$6.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, by \$14.0 million, assuming the assumed initial public offering price stays the same.

We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$15.0 million to complete the ongoing Revitalize-1 pivotal clinical study;
- approximately \$23.0 million to fund the planned Remain-1 study;
- approximately \$28.0 million to fund the continued preclinical development of our Rejuva gene therapy candidates; and
- the remainder for working capital and other general corporate purposes, including medical education and other commercial readiness activities.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates can be difficult and we anticipate that we will need additional funds to complete the development of any product candidates we identify. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from preclinical studies and any ongoing clinical studies or studies we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through 2025. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect. We may satisfy our future cash needs through the sale of equity securities, debt financings, working capital lines of credit, corporate collaborations or license agreements, grant funding, interest income earned on invested cash balances or a combination of one or more of these sources.

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Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities. We cannot predict whether the proceeds invested will yield a favorable return.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to fund the development, commercialization and growth of our business, and therefore we do not anticipate declaring or paying any cash dividends on any class of our common stock in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to compliance with contractual restrictions and covenants in the agreements governing our current and future indebtedness. Any such determination will also depend upon our business prospects, results of operations, financial condition, cash requirements and availability and other factors that our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Accordingly, you may need to sell your shares of our common stock to realize a return on your investment, and you may not be able to sell your shares at or above the price you paid for them. See “Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock.”

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2023, as follows:

- on an actual basis;
- on a pro forma basis to give effect to (i) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 36,343,909 shares of our common stock, as if such conversion had occurred on September 30, 2023, (ii) the automatic settlement of the 2022 Convertible Notes, including accrued interest, into 1,780,245 shares of our common stock in connection with the closing of this offering, assuming an initial public offering price per share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, (iii) an aggregate charge to accumulated deficit of \$0.5 million relating to the change in fair value of debt recorded as a result of the settlement of the 2022 Convertible Notes, assuming an initial public offering price per share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, and (iv) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 7,333,333 shares of our common stock in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our consolidated financial statements and the related notes included elsewhere in this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections and other financial information contained in this prospectus.

	As of September 30, 2023		
	Actual	Pro Forma	Pro Forma As Adjusted⁽¹⁾
	(unaudited, in thousands, except share and per share amounts)		
Cash and cash equivalents	\$ 44,500	\$44,500	\$ 143,527
Convertible notes payable, long-term	27,225	—	—
Non-convertible notes payable, long-term	27,518	27,518	27,518
Convertible preferred stock or common stock warrant liabilities	14,036	—	—
Convertible preferred stock, par value \$0.00001 per share: 78,112,639 shares authorized, 77,994,156 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	287,330	—	—
Stockholders’ equity (deficit):			
Preferred stock, \$0.00001 par value per share: no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, pro forma and pro forma as adjusted; no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.00001 par value per share: 107,000,000 shares authorized, 2,095,129 shares issued and outstanding, actual; 300,000,000 shares authorized, pro forma and pro forma as adjusted; 40,219,283 shares issued and outstanding, pro forma; 47,552,616 shares issued and outstanding, pro forma as adjusted	—	—	—

	As of September 30, 2023		
	Actual	Pro Forma	Pro Forma As Adjusted ⁽¹⁾
	(unaudited, in thousands, except share and per share amounts)		
Additional paid-in capital	20,261	348,331	447,291
Accumulated deficit	(327,436)	(326,915)	(326,915)
Total stockholders' equity (deficit)	(307,175)	21,416	120,376
Total capitalization	\$ 48,934	\$ 48,934	\$ 147,894

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders' equity (deficit) and total capitalization by \$6.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders' equity (deficit) and total capitalization by approximately \$14.0 million.

The information in the table above excludes:

- 9,217,769 shares of common stock issuable upon exercise of outstanding stock options granted under the 2011 Plan as of September 30, 2023, at a weighted average exercise price of \$4.95 per share;
- 40,829 shares of common stock issuable upon the vesting and settlement of outstanding RSUs granted under the 2011 Plan, as of September 30, 2023, at a weighted average grant date fair value of \$11.21 per share;
- 4,298,825 shares of common stock that will become available for future issuance under the 2024 Plan, which will become effective in connection with the completion of this offering (which number includes (i) 1,517,600 shares of common stock issuable upon the exercise of stock options granted in connection with this offering under the 2024 Plan to certain of our executive officers, directors and employees, at an exercise price per share equal to the initial public offering price in this offering and (ii) 724,262 shares of common stock available for future issuance under the 2011 Plan), as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the 2024 Plan;
- 487,070 shares of common stock that will become available for future issuance under the ESPP, which will become effective in connection with the completion of this offering, and shares of our common stock that become available pursuant to provisions in the ESPP that automatically increase the share reserve under the ESPP;
- 216,827 shares of common stock issuable upon the exercise of outstanding warrants held by entities affiliated with SVB Financial Group as of September 30, 2023, at a weighted average exercise price of \$3.28 per share; and
- 1,673,276 shares of common stock issuable upon the exercise of outstanding warrants issued in July and September 2023, as of September 30, 2023, at an assumed exercise price of \$15.00.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of September 30, 2023 was \$(308.5) million, or \$(147.26) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 2,095,129 shares of our common stock outstanding as of September 30, 2023.

Our pro forma net tangible book value (deficit) as of September 30, 2023 was \$20.1 million, or \$0.5 per share of our common stock. Pro forma net tangible book value per share is determined by subtracting our total liabilities from the total book value of our tangible assets and dividing the difference by the number of shares of common stock deemed to be outstanding, after giving effect to (i) the automatic settlement of the 2022 Convertible Notes, including accrued interest, into 1,780,245 shares of our common stock in connection with the closing of this offering, assuming an initial public offering price per share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, and (ii) the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 36,343,909 shares of common stock as if such conversion had occurred on September 30, 2023.

After giving further effect to our issuance and sale of 7,333,333 shares of our common stock in this offering at an assumed initial public offering price of \$15.00 per share (which is the midpoint of the price range set forth on the cover page of this prospectus) and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2023, would have been \$120.4 million, or \$2.53 per share of common stock. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$2.03 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of \$12.47 per share to new investors purchasing shares of common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock.

The following table illustrates this dilution:

Assumed initial public offering price per share of common stock	\$15.00
Historical net tangible book value (deficit) per share as of September 30, 2023	\$(147.26)
Increase per share attributable to the issuance of the 2022 Convertible Notes, the conversion of outstanding convertible preferred stock and settlement of the 2022 Convertible Notes	147.76
Pro forma net tangible book value per share as of September 30, 2023 before this offering	0.50
Increase in pro forma as adjusted net tangible book value per share attributable to investors in this offering	2.03
Pro forma as adjusted net tangible book value per share after this offering	2.53
Dilution per share to new common stock investors in this offering	\$12.47

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A \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately \$0.14, and dilution in pro forma as adjusted net tangible book value per share to new investors by approximately \$0.86, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase an additional 1,099,999 shares of our common stock in this offering in full, the pro forma as adjusted net tangible book value of our common stock would increase to \$2.79 per share, representing an immediate increase to existing stockholders of \$0.26 per share and an immediate dilution of \$12.21 per share to new investors participating in this offering, in each case assuming an initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, as of September 30, 2023, after giving effect to this offering, the number of shares of our common stock purchased from us, the total consideration paid, or to be paid, to us and the average price per share paid, or to be paid, by existing stockholders and by the new investors. The calculation below is based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range listed on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing stockholders ⁽¹⁾	40,219,283	85%	\$287,240,261	72%	\$ 7.14
New investors	7,333,333	15%	110,000,000	28%	\$ 15.00
Total	47,552,616	100%	397,240,261	100%	

(1) The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases that existing stockholders may make in this offering.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share would increase (decrease) the total consideration paid by new investors and the total consideration paid by all stockholders by \$6.8 million, assuming the number of shares offered by us remains the same and after deducting estimated underwriting discounts and commissions but before estimated offering expenses.

The above table assumes no exercise of the underwriters' option to purchase additional shares. If the underwriters' option to purchase additional shares were exercised in full, our existing stockholders would own 83% and our new investors would own 17% of the total number of shares of our common stock outstanding upon completion of this offering.

Except as otherwise indicated, the discussion and the tables above assume no exercise of the underwriters' option to purchase additional shares of our common stock and excludes:

- 9,217,769 shares of common stock issuable upon exercise of outstanding stock options granted under the 2011 Plan as of September 30, 2023, at a weighted average exercise price of \$4.95 per share;
- 40,829 shares of common stock issuable upon the vesting and settlement of outstanding RSUs granted under the 2011 Plan, as of September 30, 2023, at a weighted average grant date fair value of \$11.21 per share;
- 4,298,825 shares of common stock that will become available for future issuance under the 2024 Plan, which will become effective in connection with the completion of this offering (which

number includes (i) 1,517,600 shares of common stock issuable upon the exercise of stock options granted in connection with this offering under the 2024 Plan to certain of our executive officers, directors and employees, at an exercise price per share equal to the initial public offering price in this offering and (ii) 724,262 shares of common stock available for future issuance under the 2011 Plan), as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the 2024 Plan;

- 487,070 shares of common stock that will become available for future issuance under the ESPP, which will become effective in connection with the completion of this offering, and shares of our common stock that become available pursuant to provisions in the ESPP that automatically increase the share reserve under the ESPP;
- 216,827 shares of common stock issuable upon the exercise of outstanding warrants held by entities affiliated with SVB Financial Group as of September 30, 2023, at a weighted average exercise price of \$3.28 per share; and
- 1,673,276 shares of common stock issuable upon the exercise of outstanding warrants issued in July and September 2023, as of September 30, 2023, at an assumed exercise price of \$15.00.

To the extent that stock options or warrants are exercised, RSUs are vested and settled, new stock options are issued under our equity incentive plan or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the sections titled "Summary Consolidated Financial Data" and our consolidated financial statements and related notes and other information included elsewhere in this filing. In addition to historical data, this discussion contains forward-looking statements about our business, results of operations, cash flows, financial condition and prospects based on current expectations that involve risks, uncertainties and assumptions. Our actual results could differ materially from such forward-looking statements. Factors that could cause or contribute to those differences include, but are not limited to, those identified below and those discussed in the sections titled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" included elsewhere in this filing. Additionally, our historical results are not necessarily indicative of the results that may be expected for any period in the future. We use words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "predict," "project," "potential," "seek," "should," "will," "would," and similar expressions to identify forward-looking statements.

Business Overview

We are a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including type 2 diabetes and obesity. Despite advances in treatment over the last 50 years, type 2 diabetes, or T2D, and obesity continue to be a principal and rapidly growing driver of morbidity and mortality. According to the Centers for Disease Control and the International Diabetes Federation, approximately 100 million people in the United States have prediabetes and/or obesity, and an additional 25 million people have T2D on medical therapy. In 2022, there was \$65 billion in annual pharmaceutical spending on drugs aimed at controlling glucose and body weight, all attributable to medicines requiring chronic administration, none of which modifies underlying disease progression. Highly potent drugs in the GLP-1RA class are now available to lower blood sugar, lower weight, and prevent cardiovascular mortality. However, a retrospective study conducted by Polonsky *et al.* analyzing medical claims data between July 2012 and January 2019 demonstrated that a majority of patients on a weekly GLP-1RA (i.e., semaglutide, dulaglutide or exenatide extended release) discontinued therapy at 12 months. Discontinuation of these agents typically leads to an immediate loss of metabolic benefit and weight rebound, as seen in Eli Lilly's SURMOUNT-4 study with tirzepatide and Novo Nordisk's STEP-1 extension study with semaglutide. We believe the unmet need has now shifted from temporary glucose lowering and weight loss strategies to approaches that can enable durable maintenance of metabolic health without daily or weekly pharmacotherapy. Our goal is to develop durable disease-modifying therapies that are designed to provide long-term maintenance of metabolic health without requiring lifetime treatment by targeting the organ-level root causes of T2D and obesity. We believe there is significant clinical and economic opportunity for new approaches to achieve a major leap forward by enabling long-term control over T2D and obesity without the burden of chronic therapies.

Since our formation in 2010, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, acquiring or discovering product candidates and securing related intellectual property rights and conducting discovery, research and development activities for our product candidates. The Revita DMR System, or Revita, is approved in Europe under a Conformité Européenne, or CE, Mark and has received reimbursement authorization in Germany. In the first half of 2023, we initiated a limited commercial pilot in a single center in Dusseldorf, Germany. We do not have any products approved for sale in the United States. To date, we have financed our operations primarily through sales of our convertible preferred stock and debt financing.

We have incurred significant operating losses since our inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and commercialization of one or more of our current or future product candidates in the United States. For the years ended December 31, 2022 and 2021 and the nine months ended September 30, 2023, we incurred net losses of \$46.5 million, \$38.7 million and \$57.9 million, respectively. As of September 30, 2023, we had an accumulated

deficit of \$327.4 million. We expect to continue to incur significant losses for the foreseeable future and we expect these losses to increase substantially if and as we:

- advance the development of Revita and Rejuva through preclinical and clinical development, and, if approved by the FDA or other comparable foreign regulatory authorities, commercialization;
- incur manufacturing costs for our product candidates;
- increase our manufacturing capacity;
- seek regulatory approvals for any of our product candidates that successfully complete clinical studies;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- invest in measures to protect and expand our intellectual property;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize;
- expand our manufacturing and develop our commercialization efforts; and
- operate as a public company.

We do not anticipate generating revenue from product sales in the United States unless and until we successfully complete clinical development and obtain marketing approvals for one or more of our product candidates, if ever. We are currently establishing our commercial infrastructure to support the anticipated marketing and distribution of our product candidates. Subject to receiving marketing approval, we may need to enter into arrangements with third parties for the sale, marketing and distribution of our product candidates. Accordingly, if we obtain marketing approval for any of our product candidates, we will incur significant additional commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations with other companies and strategic alliances. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we would have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Components of our Consolidated Results of Operations

Revenue

We generate revenue from sales and leasing of Revita in Germany, which is approved in Europe under a CE Mark and has received reimbursement authorization in Germany. To date, we have generated insignificant revenue in Germany since the limited pilot commercial launch of Revita in the first quarter of 2023. In the United States, we have not generated any revenue, and do not expect to generate any revenue unless and until we successfully complete clinical development and obtain marketing approvals for one or more of our product candidates, if ever. If our development efforts for our product candidates are successful and result in regulatory

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approval or collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from collaboration or license agreements that we may enter into with third parties, or any combination thereof. We cannot predict if, when or to what extent we will generate revenue from our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates in the United States.

Cost of Goods Sold

We manage the final assembly and testing of Revita in the manufacturing space at our headquarter in Lexington, Massachusetts. We contract third-party manufacturers to produce certain key parts of our single-use devices and consoles. Cost of goods sold primarily consist of material costs, direct labor and manufacturing overhead costs.

Operating Expenses

Research and Development Expenses

Research and development expenses primarily consist of personnel-related expenses, including salaries, bonuses, fringe benefits and other compensation-related costs, including stock-based compensation expense, for employees engaged in research and development functions. Research and development expenses also include costs of conducting our ongoing clinical studies, such as expenses associated with our clinical research organization, or CRO, who provides project management and other services related to our Revitalize-1 study, outside service fees paid to third party consultants and contractors related to our product candidate engineering, quality assurance and regulatory approval, contract manufacturing of our product candidate used in clinical studies as well as research expenses related to our Rejuva gene therapy platform.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and other long-term assets, which are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

A significant portion of our research and development costs have been, and will continue to be, external costs. We track these external costs, such as fees paid to our CRO, preclinical study vendors and other third parties in connection with our product engineering, sub-assembly component manufacturing and manufacturing process development, clinical studies, preclinical studies and other research activities on a program-by-program basis. We also use a portion of our personnel and infrastructure resources for our research and development efforts, which are shared across multiple programs under development, and as such, are not tracked on a program-by-program basis. The following table reflects our research and development expense, including direct program-specific expense summarized by program, indirect expenses, and personnel-related expenses recognized during each period presented:

(in thousands)	Nine Months Ended		Year Ended	
	September 30,	2022	2022	2021
Direct program-specific expenses:				
Revita	\$ 9,130	\$ 9,567	\$ 12,527	\$ 11,036
Rejuva	1,795	1,928	2,685	1,489
Total direct program-specific expenses	10,925	11,495	15,212	12,525
Indirect expenses	2,935	2,251	3,049	2,436
Personnel-related expenses (including stock-based compensation)	14,012	11,991	16,093	11,474
Total research and development expenses	<u>\$ 27,872</u>	<u>\$ 25,737</u>	<u>\$ 34,354</u>	<u>\$ 26,435</u>

We expect our research and development expenses will increase significantly in the future as we:

- hire and retain additional personnel, including research, clinical, development, manufacturing, quality control, quality assurance, regulatory and scientific personnel;
- continue to conduct our ongoing Revitalize-1 pivotal study, including additional clinical studies under our Revita clinical program;
- continue to advance the research and development of our discovery and preclinical programs, such as Rejuva;
- seek regulatory approval for any product candidates that successfully complete clinical studies; and
- develop, establish and validate our commercial-scale current good manufacturing practices and manufacturing process.

Selling, General and Administrative Expenses

Selling, general and administrative expenses primarily consist of personnel-related costs, including salaries, bonuses, fringe benefits and other compensation-related costs, including stock-based compensation expense, for our personnel and external contractors involved in our executive, finance, legal and other administrative functions as well as our commercial function, who is involved in market access related activities. Selling, general and administrative expenses also include costs incurred for outside services associated with such functions, including costs associated with obtaining and maintaining our patent portfolio and professional fees for accounting, auditing, tax, legal services and other consulting expenses.

We anticipate that our selling, general and administrative expenses will increase significantly in the future as we:

- hire and retain additional selling, general and administrative personnel to support the expected growth in our research and development activities and the preclinical and clinical development of our product candidates;
- continue to expand our commercial and administrative function to support the growth of our Revita commercialization in Germany as well as potential future launches in other geographic locations;
- incur additional commercialization expenses prior to any regulatory approval of our product candidates;
- pursue payor coverage and reimbursement for our current and future product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- incur increased expenses associated with operating as a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services, director and officer insurance premiums, and investor and public relations costs.

Other Income (Expenses), Net

Interest Income (Expense), Net

Interest expense primarily consists of cash and non-cash interest related to our Term Loans drawn down in 2019. See “Loan and Security Agreements” section below for more details about our debt agreements. Interest income is primarily generated from cash interest earned on our cash, cash equivalent and restricted cash balances.

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Loss From Debt Extinguishment

Loss from extinguishment of debt represents loss from the early repayment of the Term Loans in January 2022.

Change in Fair Value of Notes Payable

In January 2022, we entered into a financing arrangement with certain lenders in which we issued convertible promissory notes, or the 2022 Convertible Notes. In July 2023, we repaid one of the promissory notes to one lender and issued amended and restated convertible promissory notes to the remaining lenders in replacement of, but not in payment of, the remainder of the 2022 Convertible Notes. In September 2023, we entered into a credit agreement with certain lenders that provides for term loans, or the 2023 Notes. See “Loan and Security Agreements” section below for more details about our debt financing agreements. We elected the fair value option to account for these notes payable, which are remeasured at the end of each reporting period with changes in fair value recognized as a component of other income (expense), net. We will continue to recognize changes in fair value of the notes payable until they are repaid in cash or converted into equity upon an equity financing event or a change of control event. In connection with this offering, the 2022 Convertible Notes will convert into common stock and we expect the liability will be reclassified to common stock and additional paid-in capital.

Change in Fair Value of Warrant Liabilities

In January 2014, we issued a fully vested warrant to purchase shares of our Series B convertible preferred stock in connection with a loan and security agreement entered into in January 2014. In July 2023, we issued fully vested warrants to purchase shares of our common stock in connection with the issuance of the amended and restated 2022 Convertible Notes. In September 2023, we issued fully vested warrants to purchase shares of our common stock or convertible preferred stock in connection with the 2023 Notes. These warrants were classified as liabilities on our consolidated balance sheet and were initially recorded at fair value on the grant date. They are subsequently remeasured to fair value at the end of each reporting period with changes in fair value recognized as a component of other income (expense), net. We will continue to recognize changes in fair value of the warrant liabilities until the warrants are exercised, expire or qualify for equity classification.

Critical Accounting Policies and Significant Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing elsewhere in this prospectus, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our audited consolidated financial condition and results of operations.

Stock-Based Compensation

We measure all stock options and other stock-based awards based on their fair value on the date of the grant. Those awards typically have a graded vesting schedule and compensation expense for awards with only service conditions are recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. Compensation costs recognized for performance-based awards reflect the number of awards that are expected to vest during the requisite service period and are adjusted to reflect those awards that ultimately vest upon final determination of the performance conditions achieved. Historical performance patterns, to the extent that they are indicative to the performance conditions to be achieved, are used in developing estimates for the probability of attaining these performance conditions.

We use the Black-Scholes option pricing model, which incorporates assumptions and estimates, to measure the fair value of its option awards on the date of grant of each stock option award.

We determined the assumptions for the Black-Scholes option-pricing model as discussed below. Each of these inputs is subjective and generally requires significant judgment to determine. Forfeitures are accounted for as they occur.

- *Fair Value of Our Common Stock.* Prior to this offering, our stock was not publicly traded, and therefore we estimated the fair value of our common stock, as discussed in “Determination of the Fair Value of Common Stock” below.
- *Expected Term.* The expected term represents the period that the stock-based awards are expected to be outstanding. As we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term, the expected term of stock options granted has been determined using the simplified method, which is the average of the midpoints between the vesting date and the contractual term for all vesting tranches.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on the rate of the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.
- *Expected Volatility.* Because we do not have a trading history of our common stock, the expected volatility was derived from the average historical stock volatilities of several public companies within our industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards.
- *Dividend Rate.* The expected dividend is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.

If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously.

Determination of the Fair Value of Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering independent third-party valuations of our common stock as well as our board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. These independent third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. We estimated the value of our equity using market approaches. In

conducting the valuations, our board of directors, with input from management, considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold convertible preferred stock and the superior rights and preferences of the convertible preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and current status of our ongoing clinical studies;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the therapeutics and medical device industry, and trends within the therapeutics and medical device industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or a sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the therapeutics and medical device industry.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment.

When estimating the value of our equity, we applied a hybrid approach by performing a scenario-based analysis, in which we estimated the probability-weighted value across multiple scenarios. In one scenario, the equity value was determined by back-solving overall equity value to the price paid by recent financing transactions. The fair value of our equity was then allocated to various securities within our capital structure by applying an option pricing method. The option pricing method estimates the fair value of each class of security based on the potential to profit from the upside of the business, while taking into account the unique characteristics of each class of security. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. We also considered an IPO scenario in which the shares of the convertible preferred stock are assumed to convert to common stock at the time of the IPO. The future value of the common stock is discounted back to the valuation date at an appropriate risk-adjusted discount rate to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

We performed common stock valuations at various dates, which resulted in fair value of our common stock of \$11.85, \$11.42, \$8.59, \$8.18 and \$11.21 per share as of the end of December 2021, March 2022, June 2022, December 2022, and June 2023, respectively. These common stock valuations were based on a probability weighted equity value considering both the estimated value at a potential future private liquidity event and the estimated value at a potential IPO. The principal factor contributing to the decrease in the valuation of our common stock from December 2021 to December 2022 was the adverse external market conditions which resulted in declining estimated equity value, reduced probability-weighting of the IPO scenario, increase in the estimated time to an IPO event and the corresponding increase in discount for lack of marketability. The increase in the valuation of our common stock from December 2022 to June 2023 was primarily attributable to the improved external market conditions during this period that led to our progress towards an IPO event, which resulted in an increase in the probability-weighting of the IPO scenario and a decrease in the estimated time to an IPO event along with the corresponding decrease in the discount for lack of marketability.

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There are significant judgments and estimates inherent in the valuations. These judgments and estimates include assumptions regarding our future operating performance, the stage of development of our product candidates, the timing and probability of a potential IPO or other liquidity event and the determination of the appropriate valuation methodology at each valuation date. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation expense could be materially different.

Once a public trading market for our common stock has been established in connection with the consummation of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for equity-based awards, as the fair value of our common stock will be determined based on the trading price of our common stock on the Nasdaq Global Market.

The following table summarizes by grant date and type of award, the number of equity-based awards granted between January 1, 2022 and the date of this prospectus, the per share exercise price, the fair value of common stock on each grant date and the per share estimated fair value of the awards:

<u>Grant Date</u>	<u>Type of Award</u>	<u>Number of Shares Subject to Awards Granted</u>	<u>Per Share Exercise Price</u>	<u>Fair Value of Common Stock on Grant Date</u>	<u>Per Share Estimated Fair Value of Awards on Grant Date</u>
March 8, 2022	Stock option	480,877	\$ 11.85	\$ 11.85	\$ 6.40
September 7, 2022	Stock option	1,142,072	\$ 8.59	\$ 8.59	\$ 5.56
November 2, 2022	Stock option	243,195	\$ 8.59	\$ 8.59	\$ 5.00
December 7, 2022	Stock option	140,718	\$ 8.59	\$ 8.59	\$ 4.91
March 16, 2023	Stock option	955,878	\$ 8.18	\$ 8.18	\$ 4.72
June 7, 2023	Stock option	172,406	\$ 8.18	\$ 8.18	\$ 4.81
August 21, 2023	Stock option	37,686	\$ 11.21	\$ 11.21	\$ 6.65
August 21, 2023	Restricted stock units	40,829	\$ —	\$ 11.21	\$ 11.21
September 13, 2023	Stock option	516,177	\$ 11.21	\$ 11.21	\$ 6.67
November 10, 2023	Stock option	151,427	\$ 11.21	\$ 11.21	\$ 6.76
November 10, 2023	Restricted stock units	563,680	\$ —	\$ 11.21	\$ 11.21

Determination of the Fair Value of Notes Payable

We elected the fair value option to account for our 2022 Convertible Notes and 2023 Notes, and remeasure the fair value at each reporting date.

The fair value of the 2022 Convertible Notes was estimated using a Monte Carlo simulation model, which incorporates significant assumptions and estimates. These assumptions and estimates include, but are not limited to, the timing and probability of the conversion events, expected volatility of the price of the underlying equity, risk-free interest rate, scenario weightings, and estimated equity values, which are impacted by external market conditions. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our fair value of the notes payable could be materially different.

The fair value of the 2023 Notes at the inception date of September 7, 2023 was estimated at the difference between the total proceeds from the 2023 Notes and the estimated fair value of the associated warrants issued. This assumption was based on the rationale that the fair value of the notes and warrants at issuance equated to the total proceeds of the 2023 Notes as the credit agreement of the 2023 Notes were entered into with

the lenders in an arm's-length transaction. The fair value of the 2023 Notes at September 30, 2023 was considered to approximate the fair value at the inception date with an increase equal to the accrued payment-in-kind interest during September 2023. The fair value of the 2023 Notes at subsequent reporting periods is expected to be determined using a Monte Carlo simulation model.

Determination of the Fair Value of Warrant Liabilities

We remeasure the fair value of our warrant liabilities at the end of each reporting period. The fair value was estimated using either a Black-Scholes option-pricing model or a Monte Carlo simulation model, depending on the nature of the warrants. The valuation model used incorporates significant assumptions and estimates, which include, but are not limited to, the fair value per share of the underlying shares, the remaining contractual term of the warrants, risk-free interest rate and expected volatility of the price of the underlying shares.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including central laboratories and research organizations, in connection with preclinical development activities and our research programs;
- CRO and investigative sites in connection with preclinical and clinical studies; and
- Clinical Manufacturing Organizations, or CMOs, in connection with devices and consumables used in the clinical studies.

We base our expenses related to preclinical and clinical studies on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and our CRO that conduct and manage preclinical and clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Results of Operations

Nine Months Ended September 30, 2023 and 2022

The following table summarizes our consolidated results of operations for the nine months ended September 30, 2023 and 2022:

(in thousands)	Nine Months Ended September 30,		Change	
	2023	2022	Amount	%
Revenue	\$ 113	\$ —	\$ 113	100.0%
Cost of goods sold	75	—	75	100.0%
Gross profit	38	—	38	100.0%
Operating expenses:				
Research and development	27,872	25,737	2,135	8.3%
Selling, general and administrative	10,021	12,235	(2,214)	(18.1%)
Total operating expenses	37,893	37,972	(79)	(0.2%)
Loss from operations	(37,855)	(37,972)	117	(0.3%)
Other income (expense), net	(20,056)	2,377	(22,433)	(943.8%)
Net loss and comprehensive loss	<u>\$(57,911)</u>	<u>\$(35,595)</u>	<u>\$(22,316)</u>	62.7%

Nine Months Ended September 30, 2023 Compared to Nine Months Ended September 30, 2022

Revenue and Cost of Goods Sold

We commenced commercial activities in Germany in the first quarter of 2023. Prior to 2023, we had no revenue or costs of goods sold.

Operating Expenses

Research and Development Expenses

Research and development expenses increased by \$2.1 million, or 8.3%, during the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022, primarily due to increased personnel related expenses as well as clinical and medical affairs expenditures. Personnel related expenses, including salaries, bonuses and certain fringe benefits, increased by \$1.2 million as a result of the expansion of our workforce and annual merit increase in salary. In addition, stock-based compensation increased by \$0.8 million related to new option grants issued to new hires and existing employees. Medical affairs expenses increased by \$1.0 million, primarily driven by activities in connection with collaborative medical research. Clinical study expenses increased by \$0.8 million due to the progress made in Revitalize-1 upon the approval of a new study protocol. These increases were partially offset by a decrease of \$1.7 million in engineering expenditures as a result of reduced product development effort.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by \$2.2 million, or 18.1%, during the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022, primarily due to the \$2.7 million write-off of previously capitalized IPO costs recorded in the second quarter of 2022 as we delayed our initial IPO plan due to adverse market conditions in 2022. Offering costs related to the IPO effort in 2023 of approximately \$1.4 million were capitalized and recorded as part of other long-term assets as of September 30, 2023.

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In addition, professional services spending related to public relations, recruiting and marketing activities also decreased by \$2.0 million. These decreases were partially offset by an increase of \$1.9 million in debt issuance costs and \$0.3 million in personnel related expenses, including salaries, bonuses and certain fringe benefits.

Other Income (Expense), Net

Other income (expense), net changed by \$22.4 million from net other income of \$2.4 million during the nine months ended September 30, 2022 to net other expense of \$20.0 million during the nine months ended September 30, 2023. The change was primarily attributable to change in fair value of notes payable and warrants, increased interest income and decreased loss from debt extinguishment.

We recognized a loss of \$19.4 million from the increase in fair value of the 2022 Convertible Notes during the nine months ended September 30, 2023 compared to a gain of \$2.2 million from the decrease in fair value of the 2022 Convertible Notes during the nine months ended September 30, 2022, resulting in a total fluctuation of \$21.9 million between the two nine-month periods. The loss from increase in fair value of the 2022 Convertible Notes during the nine months ended September 30, 2023 was primarily driven by reduced remaining estimated time to assumed conversion events and the new debt terms associated with the reissuance of the 2022 Convertible Notes along with the concurrent issuance of warrants to purchase common stock. The gain from decrease in fair value of the 2022 Convertible Notes during the nine months ended September 30, 2022 was primarily driven by adverse external market conditions which resulted in declining estimated equity value, reduced probability-weighting of the IPO scenario and an increase in the estimated time to an IPO event. In addition, we also recognized a loss of \$0.3 million from the increase in fair value of the 2023 Notes during the nine months ended September 30, 2023 related to interests accrued on the 2023 Notes.

We recognized a loss of \$1.2 million from the increase in fair value of warrant liabilities during the nine months ended September 30, 2023, mainly related to the warrants issued in connection with the reissuance of the 2022 Convertible Notes in July 2023. The increase was primarily driven by an increase in estimated underlying equity value due to reduced remaining estimated time to assumed conversion events.

The changes in fair value above were partially offset by a \$0.4 million increase in interest income earned from our cash deposits in the bank due to higher interest rates and \$0.3 million less loss from debt extinguishment, which was a one-time expense incurred in January 2022 related to the early repayment of the Term Loans in January 2022.

Years Ended December 31, 2022 and 2021

The following table summarizes our consolidated results of operations for the years ended December 31, 2022 and 2021:

(in thousands)	Year Ended December 31,		Change	
	2022	2021	Amount	%
Operating expenses:				
Research and development	\$ 34,354	\$ 26,435	\$ 7,919	30.0%
Selling, general and administrative	15,031	10,493	4,538	43.2%
Total operating expenses	49,385	36,928	12,457	33.7%
Loss from operations	(49,385)	(36,928)	(12,457)	33.7%
Other income (expense), net	2,932	(1,807)	4,739	(262.3%)
Net loss and comprehensive loss	<u>\$ (46,453)</u>	<u>\$ (38,735)</u>	<u>\$ (7,718)</u>	19.9%

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

Operating Expenses

Research and Development Expenses

Research and development expenses increased by \$7.9 million, or 30.0%, during the year ended December 31, 2022 as compared to the year ended December 31, 2021, primarily due to increased personnel related expenses, product development expenses and investments in our Rejuva gene therapy platform. Personnel related expenses, including salaries, bonuses and certain fringe benefits, increased by \$4.2 million as a result of the expansion of our workforce to support Revitalize-1 and the progress of our Rejuva program. In addition, stock-based compensation increased by \$0.2 million related to new option grants issued to new hires and existing employees. Product development expenses increased by \$2.5 million due to efforts to improve single use device design and develop next generation consoles. Expenditures related to our investment in our Rejuva gene therapy platform increased by \$1.2 million as a result of positive progress made with respect to the program. Manufacturing expenses increased by \$0.5 million as we increased production to prepare for the anticipated higher demand from Revitalize-1 enrollment. We also had a \$0.3 million increase in medical affairs related activities such as medical education and communication. These increases were partially offset by a \$1.6 million decrease in clinical expenditures primarily driven by our strategic decision to transition select clinical operations associated with Revitalize-1 in-house as well as decreased spending on a previous clinical study.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$4.5 million, or 43.2%, during the year ended December 31, 2022 as compared to the year ended December 31, 2021, primarily due to increased personnel related expenses and public offering costs. Personnel related expenses, including salaries, bonuses and certain fringe benefits, increased by \$1.1 million as a result of the expansion of our workforce to support our growth. Stock-based compensation also increased by \$0.6 million related to new option grants issued to new hires and existing employees. In addition, in the second quarter of 2022, we recorded a write off of \$2.7 million related to previously capitalized IPO costs as we delayed our initial IPO plan due to adverse market conditions in 2022.

Other Income (Expense), Net

Other income (expense), net changed by \$4.7 million from net other expenses of \$1.8 million during the year ended December 31, 2021 to net other income of \$2.9 million during the year ended December 31, 2022. The change was primarily attributable to increased interest income, decreased interest expense and change in fair value of convertible notes payable. Interest income increased by \$0.8 million due to higher interest rates in 2022. Interest expense decreased by \$1.4 million as we fully repaid our Term Loans in January 2022. We also recognized a \$2.3 million gain from the decrease in fair value of convertible notes payable associated with the 2022 Convertible Notes and a \$0.5 million gain from the decrease in fair value of convertible preferred stock warrant liability. Both of the decreases in fair value were primarily driven by adverse external market conditions which resulted in declining estimated equity value, reduced probability-weighting of the IPO scenario and an increase in the estimated time to an IPO event. These increases were partially offset by a \$0.3 million loss from debt extinguishment resulting from the early repayment of the Term Loans in January 2022.

Liquidity and Capital Resources

We believe that we maintain a level of liquidity sufficient to allow us to meet our cash needs in the short-term. Over the long-term, we manage our cash and capital structure to maximize shareholder return, maintain its financial condition and maintain flexibility for future strategic initiatives. We continuously assess our working capital needs, debt and leverage levels, debt maturity schedule, capital expenditure requirements and future investments.

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As of December 31, 2022 and September 30, 2023 (unaudited), we had approximately \$49.3 million and \$44.5 million, respectively, in cash and cash equivalents. Our cash and cash equivalents at September 30, 2023 is not sufficient to fund our current operating plan for at least 12 months from the issuance date of this prospectus.

Loan and Security Agreements

2019 Notes

In February 2019, we entered into a loan and security agreement with SVB, or the 2019 Note, that provided for borrowings of up to \$15 million in two Term Loan advances defined as “Term A Loan” and “Term B Loan”, collectively referred to as the Term Loans. On February 5, 2019, we drew down \$3 million under Term A Loan, and on May 31, 2019, we drew down an additional \$7 million under Term A Loan. On October 3, 2019, we drew down \$5 million under Term B Loan.

The outstanding balances under the Term Loans bear interest at a floating annual rate that equals the greater of 1.5% above the Wall Street Journal prime rate or 6.75%. The Term Loans initially required interest-only repayments through December 31, 2020. After the interest-only period, the Term Loans require 24 equal monthly principal repayments of the outstanding balances plus accrued interest through the maturity date on December 1, 2022.

On the date that the 2019 Note is paid in full or becomes due and payable, we are required to make a payment, or the Final Payment, in addition to the regular monthly payments of principal plus accrued interest, equal to 6% of the original principal amount of the Term Loans extended by the lender.

In February 2019, in connection with entering into the 2019 Note, we issued to SVB and an affiliated investor warrants to purchase up to an aggregate of 119,934 shares of our common stock, at an exercise price of \$3.3263 per share, or the 2019 warrants. Of the 119,934 shares, 79,965 shares were exercisable upon the issuance of the warrants and an additional 39,969 shares became exercisable upon the drawdown of the Term B Loan. The 2019 warrants have a contractual term of ten years from the date of issuance. As of September 30, 2023, the 2019 warrants have not been exercised.

On December 31, 2020 and February 26, 2021, we entered into two amendments to the 2019 Note, or the Amendments, whereby the Term Loans were amended to extend the interest-only period through December 31, 2021, upon achievement of certain clinical milestone as specified in the Amendments, with principal to be repaid equally over 12 consecutive calendar months starting January 1, 2022. In connection with entering into the first Amendment, we issued to SVB and an affiliated investor, warrants to purchase up to an aggregate of 41,682 shares of our common stock, at an exercise price of \$3.8842 per share, or the 2020 warrants. The 2020 warrants expire ten years from the date of issuance. As of September 30, 2023, the 2020 warrants have not been exercised.

As of December 31, 2021, we had outstanding balance of the Term Loans under the Loan and Security Agreement of \$15.7 million. On January 3, 2022, we repaid in full the Term Loans under the Loan and Security Agreement by making a lump-sum payment to SVB for a total amount of \$16.1 million, which consisted of the outstanding principal balance of the Term Loans of \$15.0 million, the Final Payment of \$0.9 million, the prepayment premium of \$0.1 million and accrued interest of \$0.1 million.

2022 Convertible Notes

On January 11, 2022, we entered into a financing arrangement with certain lenders in which we issued the 2022 Convertible Notes in exchange for an aggregate principal amount of \$20.1 million.

Effective upon the closing of an equity financing event, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes will automatically be converted into shares of the same class and series of capital stock of we issued to other investors in the financing event at a conversion price equal to (i) in the

event of an IPO, 80% of the price per share of the public company securities paid by other investors in the IPO; or (ii) in the event of a non-IPO, 80% of the opening price on the applicable stock exchange on the closing date; or (iii) in the event of a private financing round, 80% of the price per share of the financing securities paid by other investors in the financing round. In no event should the conversion price be (a) less than the amount equal to \$875.0 million divided by our fully diluted capitalization as of immediately prior to the closing of the financing event, or the Floor Valuation; or (b) more than an amount equal to \$1.1 billion divided by our fully diluted capitalization as of immediately prior to the closing of the financing event, or the Valuation Cap.

In the event of a Change of Control, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes will, at the option of the Lenders, (1) be repaid in cash as of the closing of such Change of Control; or (2) be converted into our common stock at a conversion price equal to 80% of the fair market value of our common stock as determined in good faith by our Board of Directors, provided that, if the successor company is a publicly traded issuer, the conversion price will be determined by a volume-weighted average price per share of the successor company's stock on the applicable stock exchange for the five trading days prior to the Change of Control; and provided further that, in the event stockholders are to receive any non-cash consideration pursuant to the Change of Control, the Lenders shall receive the same non-cash consideration, in the same proportion, and the value of such non-cash consideration received by the Lenders shall be determined in accordance with the agreement governing such Change of Control. In no event should the conversion price be less than the Floor Valuation or more than the Valuation Cap.

On July 11, 2023, we repaid \$0.1 million in cash to one of the original lenders and issued amended and restated convertible notes to certain of the lenders in replacement of, but not in payment of, the remainder of the 2022 Convertible Notes. As a part of these amendments, among other changes, such lenders agreed to extend the maturity date of the outstanding principal and accrued but unpaid interest on the 2022 Convertible Notes to December 31, 2024, or the Amended Maturity Date, and remove the Floor Valuation. Following these amendments, \$20.9 million in aggregate principal under the 2022 Convertible Notes will remain outstanding and accrue interest at the rate of 10% per year until they are paid or converted in full. In connection with entering into these amendments, we issued to such lenders warrants, or the July 2023 warrants, to purchase shares of our common stock immediately exercisable for a variable number of shares based on the principal amount of the 2022 Convertible Notes, as amended, of \$20.9 million and an exercise price, at the holders' choice, of (a) \$17.9927 per share, (b) the lowest original issue price of shares of Preferred Stock we issue in our next bona fide private preferred equity financing round, (c) in the event of any convertible note, or similar convertible security financing, the conversion price contemplated by such convertible security, or (d) in the event of an IPO, the per share offering price to the public in such IPO. The July 2023 warrants have a contractual term of ten years from issuance.

In the event the 2022 Convertible Notes are still outstanding on the Amended Maturity Date, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes would be converted, at the option of the holders, into shares of our Series F Preferred Stock.

As of September 30, 2023 and December 31, 2022, the balance of the 2022 Convertible Notes was carried at its fair value of \$27.2 million and \$17.8 million, respectively.

2023 Notes

On September 7, 2023, we entered into a credit agreement, as amended from time to time, with Symbiotic Capital Opportunities Holding, L.P. and Catalio Structured Opportunities AIV I LP, or the Lenders, that provides for term loans in an aggregate principal amount of \$45.0 million, or the 2023 Notes, payable in two tranches. The first tranche, with a principal amount of \$30.0 million, was extended on September 7, 2023, resulting in net proceeds of approximately \$28.4 million. The second tranche, with a principal amount of \$15.0 million, may be extended upon our achievement of certain operating and funding milestones as defined in the 2023 Notes, by July 31, 2024. The 2023 Notes also provide for a third tranche with an uncommitted principal amount of \$20.0 million that may be extended to us, subject to the Lenders' prior written consent in their sole discretion.

The credit agreement, as amended, contains the following financial covenants: (i) a minimum liquidity covenant requiring us to maintain a minimum \$10.0 million balance in cash and cash equivalents on deposit in accounts, subject to certain exceptions, and (ii) a financing milestone covenant requiring that (a) we have received proceeds from an equity financing or series of financings (including the net proceeds from this offering) of at least \$40.0 million during the period commencing on September 7, 2023, or the Closing Date, and ending on or prior to February 15, 2024, and (b) we have received equity financing or series of financings of at least \$100.0 million (inclusive of such equity financing or series of financings in the preceding clause (a)) during the period commencing as of the Closing Date and prior to June 30, 2024. If we do not raise at least \$100.0 million in net proceeds in connection with this offering, we will need to raise additional capital to satisfy the financing milestone covenant in our credit agreement.

The outstanding balances under the 2023 Notes bear interest at a floating annual rate equal to the greater of 5.5% above the Wall Street Journal prime rate or 13.25%. On and prior to September 30, 2024, 6.0% of the interest is payable in kind and added to the outstanding principal amount of the 2023 Notes. Beginning September 30, 2026, we are required to make principal payments in the amount of 1.5% of the aggregate principal amount outstanding, including accrued PIK interest, each month. The first principal payment date can be extended to September 30, 2027, at our election, if certain financing milestones as defined in the 2023 Notes are achieved on or prior to September 30, 2026. In addition, upon any principal payment, we are required to make an additional payment to the Lenders a 6.0% fee, or the Exit Fee, over the principal and accrued PIK interest paid. The aggregate Exit Fee of the 2023 Notes should equal to 6.0% of the total commitment of \$45.0 million plus all accrued PIK interest. All remaining outstanding principal balance, accrued interest and Exit Fee on the 2023 Notes shall be due and payable on the maturity date of September 7, 2028.

In connection with entering into the 2023 Notes, we issued to the Lenders warrants, or the September 2023 warrants, to purchase, at the holders' choice, shares of (i) our Series F Preferred Stock, (ii) the most senior series of our preferred stock that is then authorized, or (iii) our common stock. The September 2023 warrants are immediately exercisable for a variable number of shares based on a total fixed dollar value, of \$4.2 million, and an exercise price, at the holders' choice, of (a) \$17.9927 per share of common stock or \$8.3843 per share of Series F Preferred Stock, (b) the lowest original issue price of any series of preferred stock we issue after the issuance date of the September 2023 warrants, (c) the conversion or exercise price of any convertible debt security, option, or warrant we issue after the issuance date of the September 2023 warrants, or (d) the price at which our common equity was first sold to the public in a firm-commitment underwritten offering or otherwise. The September 2023 warrants have a contractual term of ten years from issuance.

As of September 30, 2023, the balance of the 2023 Notes was carried at its fair value of \$27.5 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance our product candidates. In the United States, we do not have any products approved for sale and have not generated any revenue from any sources, including product sales. Revita is approved in Europe under a CE Mark and has received reimbursement authorization in Germany. We initiated a pilot commercial launch of Revita in Germany in the first quarter of 2023 and has since generated insignificant revenue due to the limited scope of the launch. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

As of September 30, 2023, we had cash and cash equivalents of \$44.5 million. We believe that our existing cash and cash equivalents and the net proceeds from this offering, will enable us to fund our operating expenses, debt repayment obligations and capital expenditure requirements through 2025. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into collaborations with third parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of research and development for our current and future product candidates, including our current and planned Revita clinical studies, and ongoing preclinical development for our current and future product candidates;
- the scope, prioritization and number of our research and development programs;
- the scope, costs, timing and outcome of regulatory review of our product candidates;
- the costs of securing manufacturing materials for use in preclinical and clinical studies and, for any product candidates for which we receive regulatory approval, use as commercial supply;
- our ability to seek, establish and maintain a collaboration to develop our product candidate with a collaborator, including the financial terms and any cost-sharing arrangements of any such collaboration;
- the costs and timing of future commercialization activities for any of our product candidates for which we receive regulatory approval;
- the amount and timing of revenue, if any, received from commercial sales of any product candidates for which we receive regulatory approvals;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we may acquire or in-license other products, product candidates, technologies or intellectual property, as well as the terms of any such arrangements; and
- the costs of continuing to expand our operations and operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical studies is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales in the United States or elsewhere. Revita is approved in Europe under a CE Mark and has received reimbursement authorization in Germany. We initiated a pilot commercial launch of Revita in Germany in the first quarter of 2023 and has since generated insignificant revenue due to the limited scope of the launch. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Our expectation with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned.

Adequate additional funds may not be available to us on acceptable terms, or at all. Market volatility resulting from pandemics, monetary policy changes, or other factors could also adversely impact our ability to

access capital as and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Additional debt financing and convertible preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may have to significantly delay, reduce or eliminate some or all of our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

For additional information on risks associated with our substantial capital requirements, please see “Risk Factors—Risks Related to Financial Condition and Capital Requirements.”

Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and development programs or future commercialization efforts.

Cash Flows

Unaudited Nine Months Ended September 30, 2023 and 2022

The net change in cash, cash equivalents and restricted cash for the unaudited nine months ended September 30, 2023 and 2022 was as follows:

(in thousands)	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	<u>\$(32,224)</u>	<u>\$(33,709)</u>
Net cash used in investing activities	(223)	(56)
Net cash provided by financing activities	<u>27,993</u>	<u>4,352</u>
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (4,454)</u>	<u>\$ (29,413)</u>

Operating Activities

Cash used in operating activities for the nine months ended September 30, 2023 of \$32.2 million was primarily driven by personnel related expenses, including salaries, bonuses, and fringe benefits, and spending on our ongoing Revitalize-1 study, Rejuva-related research activities, as well as professional services related to our corporate and general administrative activities. Our net loss of \$57.9 million was partially offset by non-cash expenses of \$23.9 million, including \$19.5 million loss from change in fair value of notes payable, \$1.2 million loss from change in fair value of warrant liabilities, \$3.0 million of stock-based compensation, and \$0.2 million of depreciation expense. In addition, \$1.9 million of the net loss was related to debt issuance costs that were presented in cash used in financing activities. Cash used in operating activities was also impacted by changes in working capital and other assets and liabilities of \$(0.2) million.

Cash used in operating activities for the nine months ended September 30, 2022 of \$33.7 million was primarily driven by personnel related expenses, including salaries, bonuses, and fringe benefits, spending on our

ongoing clinical studies, product engineering, Rejuva-related research activities as well as professional services related to our corporate and general administrative activities. Cash used in operating activities was primarily a result of our net loss of \$35.6 million. Non-cash expenses for the nine months ended September 30, 2022 included \$2.2 million of stock-based compensation, \$0.4 million of depreciation expense, and \$0.3 million loss on debt extinguishment, which were offset by \$2.2 million gain from change in fair value of notes payable, and \$0.1 million gain from change in fair value of convertible preferred stock warrant liability. Cash used in operating activities was also impacted by changes in working capital and other assets and liabilities of \$1.3 million.

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2023 and 2022 were related to the purchase of property and equipment.

Financing Activities

Cash provided by financing activities of \$28.0 million for the nine months ended September 30, 2023 was primarily driven by the \$28.4 million capital raised from the issuance of the 2023 Notes, net of issuance costs, partially offset by an additional issuance costs of \$0.3 million paid to third party service providers such as legal fees, and a \$0.1 million partial repayment of the 2022 Convertible Notes.

Cash provided by financing activities of \$4.4 million for the nine months ended September 30, 2022 was primarily driven by \$20.1 million capital raised from the issuance of the 2022 Convertible Notes, net of issuance costs, offset by \$16.0 million repayment of the Term Loans. We also received proceeds of \$0.3 million from stock option exercises.

Years Ended December 31, 2022 and 2021

The net change in cash, cash equivalents and restricted cash for the years ended December 31, 2022 and 2021 was as follows:

(in thousands)	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	\$ (46,243)	\$ (33,462)
Net cash used in investing activities	(56)	(51)
Net cash provided by financing activities	4,350	99,879
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (41,949)</u>	<u>\$ 66,366</u>

Operating Activities

Cash used in operating activities for the year ended December 31, 2022 was primarily driven by personnel related expenses, including salaries, bonuses, and fringe benefits, spending on our ongoing clinical studies and product engineering as well as professional services related to our corporate and general administrative activities. Our net loss of \$46.5 million was partially offset by non-cash items totaling \$1.5 million, including \$0.5 million of depreciation expense, \$0.3 million loss on debt extinguishment, \$3.1 million of stock-based compensation, net by \$0.1 million gain from change in fair value of convertible preferred stock warrant liability, and \$2.3 million gain from change in fair value of convertible notes payable. Cash used in operating activities was also impacted by changes in working capital and other assets and liabilities of \$1.2 million.

Cash used in operating activities for the year ended December 31, 2021 was primarily driven by personnel related expenses, including salaries, bonuses, and fringe benefits, spending on our ongoing clinical studies as well

as professional services related to our corporate and general administrative activities. Our net loss of \$38.7 million was partially offset by non-cash items of \$3.6 million, including \$0.7 million of depreciation expense, \$2.1 million of stock-based compensation, \$0.4 million of non-cash interest expense related to the Term Loans, and \$0.4 million loss from change in fair value of convertible preferred stock warrant liability. Cash used in operating activities was also impacted by changes in working capital and other assets and liabilities of \$1.7 million.

Investing Activities

Cash used in investing activities for the years ended December 31, 2022 and 2021 were related to the purchase of property and equipment.

Financing Activities

Cash provided by financing activities of \$4.4 million for the year ended December 31, 2022 was primarily driven by \$20.1 million capital raised from the issuance of the 2022 Convertible Notes, offset by \$16.0 million repayment of the Term Loans. We also received proceeds of \$0.3 million from stock option exercises.

Cash provided by financing activities of \$99.9 million for the year ended December 31, 2021 was primarily driven by capital raised from the issuance of Series F Preferred Stock, net of issuance costs.

Going Concern

We have financed our operations to date primarily through sales of convertible preferred stock and debt financing. As of September 30, 2023, we had cash and cash equivalents totaling \$44.5 million and net working capital of \$38.4 million. We have a history of operating losses and had an accumulated deficit of \$327.4 million as of September 30, 2023.

Our future success is dependent on our ability to develop product candidates and ultimately upon our ability to attain profitable operations. We are subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital with favorable terms, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of our products. The successful discovery and development of product candidates requires substantial working capital which may not be available to us on favorable terms or not at all.

We have generated insignificant revenue from product sales since our limited pilot commercial launch in Germany in the first quarter of 2023. Management does not anticipate generating revenue from product sales in the United States unless and until we successfully complete clinical development and obtain marketing approvals from one or more of the product candidates. As a result, management expects continuing operating losses in the future. We do not believe that our available cash and cash equivalents of \$44.5 million as of September 30, 2023 is sufficient to fund our current operating plan for at least twelve months after the date the consolidated financial statements are issued. We expect to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions and, if necessary, we will be required to implement cost reduction strategies, which could curtail or delay our current clinical activities. As a result, substantial doubt exists about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our 2022 Convertible Notes issued in January 2022 and amended on July 11, 2023 accrue interest at a fixed annual rate of 10%, so they do not give rise to interest rate exposure associated with changes in interest rates. Our term loans drawn under the 2023 Notes require monthly payment of interest at a floating annual rate that equals the greater of 5.5% above the Wall Street Journal prime rate or 13.25%, 6% of which is payable in kind and added to the outstanding principal amount of the loans until September 30, 2024. We do not believe that an immediate 10% increase or decrease in the Wall Street Journal prime rate would have a material effect on our operating results.

Credit Risk

As of September 30, 2023, the majority of our cash and cash equivalents were maintained at various financial institutions in the United States, and our current deposits are in excess of insured limits. We believe the financial institutions that maintain our cash and cash equivalents possess sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us.

Foreign Currency Risk

Substantially all of our business is currently conducted in U.S. dollars. We do not believe that an immediate 10% increase or decrease in the relative value of the U.S. dollar to other currencies would have a material effect on our operating results.

Inflation Risk

Inflationary factors, such as increases in our operating expenses, may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, a high rate of inflation in the future may significantly increase our operating expenses.

Recent Accounting Pronouncements

See Note 2 to our audited Consolidated Financial Statements for the years ended December 31, 2022 and 2021 as well as Note 2 to our unaudited Consolidated Financial Statements for the nine months ended September 30, 2023 included elsewhere in this prospectus for more information.

JOBS Act Accounting Election

We are an “emerging growth company” within the meaning of the Jumpstart Our Business Act of 2012, or JOBS Act. Section 107(b) of the JOBS Act provides that an emerging growth company can leverage the extended transition period, provided in Section 102(b) of the JOBS Act, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. We have elected to use this extended transition period and, as a result, our financial statements may not be comparable to companies that comply with public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002.

We would cease to be an emerging growth company on the date that is the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more; (2) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt during the previous three years or (4) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

A Letter From Our Co-Founder

In the course of human history, metabolic diseases like type 2 diabetes and obesity have recently emerged as the principal constraint on human health, longevity and productivity. In the United States alone, approximately 100 million people have prediabetes and/or obesity and are at risk of disease progression. By 2030, we will be spending \$2 trillion a year worldwide combating type 2 diabetes alone (and still losing). If we want a healthier society, we need to unlock a better approach to treating metabolic diseases.

I have unfortunately seen firsthand how type 2 diabetes can have devastating physical and mental implications for those afflicted with the disease. I have observed the impact of diabetes not only as a cardiologist and researcher, but also as a son to a father struggling with the disease and its burdensome daily management. I have been constantly frustrated observing people living with diabetes, including my father, who continue to worsen as they battle this debilitating disease despite their best efforts using today's available treatments. Disease progression continues to worsen in our patients despite decades of investment and research and an ever-increasing number of disease management options. The current treatment paradigm is simply not working for most people living with type 2 diabetes.

Many people mistakenly assume that type 2 diabetes and obesity are simply the fault of people who make poor choices and then suffer the consequences of these choices. There is a lot of blaming and shaming of patients with type 2 diabetes and obesity in the United States, driven by a mindset that assumes behavioral weakness, human error, and lack of self-care. We believe this blame mindset is not only wrong, but dangerous. It's dangerous because we have allowed ourselves to consider these diseases as gluttonous problems of human choice rather than correctable problems of human physiology.

Our bodies are simply not designed for the abundant food environment of the modern world. We are built for an ancient world, a world in which food was scarce, not particularly tasty, and often not available when it was needed. Our ancestors, whose genes allowed them to survive through difficult times, passed those very same genes down to us – genes that now significantly increase the risk of type 2 diabetes in the modern world. This disease of excess blood sugar has arisen as an unintended, yet inevitable, consequence of this mismatch between our ancient genes and our modern dietary environment.

My co-founder, Jay Caplan, and I started Fractyl Health with the belief that a better understanding of the root causes of metabolic disease will create a pathway to new and better solutions that can address the significant residual unmet need in their treatment. We have assembled a mission-driven team full of innovators, united in a passion to develop therapies aiming to eradicate type 2 diabetes and obesity—the type of therapies we would want for our family members and loved ones with the disease.

Fractyl Health's purpose is to defend humanity from the metabolic diseases of modernity. Over the past several years, we have gained a deeper understanding of the changes that occur in the gut and pancreas in response to modern diets. We are singularly focused on developing therapies that are designed to target the root causes of metabolic diseases and delivering our therapies as broadly as possible to as many patients as possible as rapidly as possible.

We believe this approach is better for patients, better for physicians and better for society. Turning the tide on type 2 diabetes and obesity is achievable, but it requires intestinal fortitude. It takes guts.

A handwritten signature in blue ink that reads "Harith Rajagopala". The signature is written in a cursive, flowing style.

Co-Founder and Chief Executive Officer

BUSINESS

Overview

We are a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including type 2 diabetes and obesity. Despite advances in treatment over the last 50 years, type 2 diabetes, or T2D, and obesity continue to be principal and rapidly growing drivers of morbidity and mortality. According to the Centers for Disease Control and the International Diabetes Federation, approximately 100 million people in the United States have prediabetes and/or obesity, and an additional 25 million people have T2D on medical therapy. In 2022, there was an estimated \$65 billion in annual pharmaceutical spending on drugs aimed at controlling glucose and body weight, all attributable to medicines requiring chronic administration, none of which modifies underlying disease progression. Highly potent drugs in the GLP-1RA class are now available to lower blood sugar, lower weight, and prevent cardiovascular mortality. However, a retrospective study conducted by Polonsky *et al.* analyzing medical claims data between July 2012 and January 2019 demonstrated that a majority of patients on a weekly GLP-1RA (i.e., semaglutide, dulaglutide or exenatide extended release) discontinued therapy at 12 months. Discontinuation of these agents typically leads to an immediate loss of metabolic benefit and weight rebound, as seen in Eli Lilly's SURMOUNT-4 study with tirzepatide and Novo Nordisk's STEP-1 extension study with semaglutide. We believe the unmet need has now shifted from temporary glucose lowering and weight loss strategies to approaches that can enable durable maintenance of metabolic health without daily or weekly pharmacotherapy. Our goal is to develop durable disease-modifying therapies that are designed to provide long-term maintenance of metabolic health without requiring lifetime treatment by targeting the organ-level root causes of T2D and obesity. We believe there is significant clinical and economic opportunity for new approaches to achieve a major leap forward by enabling long-term control over T2D and obesity without the burden of chronic therapies.

Emerging consensus on the role of the gut in driving human metabolic disease led our founders to design novel, differentiated disease-modifying therapies aiming to advance patient care from management into prevention and remission of underlying disease. The Revita DMR System, or Revita, our lead product candidate, is an outpatient procedural therapy designed to durably modify duodenal dysfunction, a major pathologic consequence of a high fat and high sugar diet, which can initiate T2D and obesity in humans. The duodenum regulates the human metabolic response to food intake, and modern diets drive dysfunctional hyperplasia of the duodenal mucosa. This results in alterations to physiologic signaling that affect glucose control and satiety. The Revita system is designed to enable durable and repeatable metabolic improvement via hydrothermal ablation of the dysfunctional duodenal mucosa to address duodenal pathology and consequent metabolic disease progression directly. We have observed the Revita DMR Procedure to be generally well tolerated and to have demonstrated durable blood glucose lowering and weight maintenance for two years post-procedure in controlled studies of patients with T2D who are inadequately controlled despite already taking certain ADAs and receiving lifestyle counseling. We have initiated a broad clinical program designed to evaluate Revita in multiple clinical studies across a range of patient populations from prediabetes and obesity to advanced T2D patients on long-acting insulin. We have obtained Breakthrough Device designation from the U.S. Food and Drug Administration, or the FDA, for Revita to perform hydrothermal ablation of the duodenal mucosa, or the Revita DMR Procedure, to improve glycemic control and eliminate insulin needs in T2D patients who are inadequately controlled on long-acting insulin.

We are currently enrolling our pivotal Revitalize-1 study in patients with inadequately controlled T2D despite being on up to three anti-diabetic agents, or ADAs, and daily insulin. We anticipate completing enrollment in the first half of 2024 and expect to report topline data in the fourth quarter of 2024. We are also planning to evaluate Revita in a two-part, parallel cohort, randomized, open-label clinical study, which we refer to as the Remain-1 study, for weight maintenance in patients with obesity who have lost at least 10% total body weight on GLP-1RA therapy and wish to discontinue their GLP-1RA without weight regain. We expect to submit an IDE and comparable documents to the FDA and comparable foreign regulatory authorities or notified bodies in the first quarter of 2024 for a potentially pivotal Remain-1 study. If the IDE for Remain-1 is approved, we plan to initiate the study and begin reporting updates

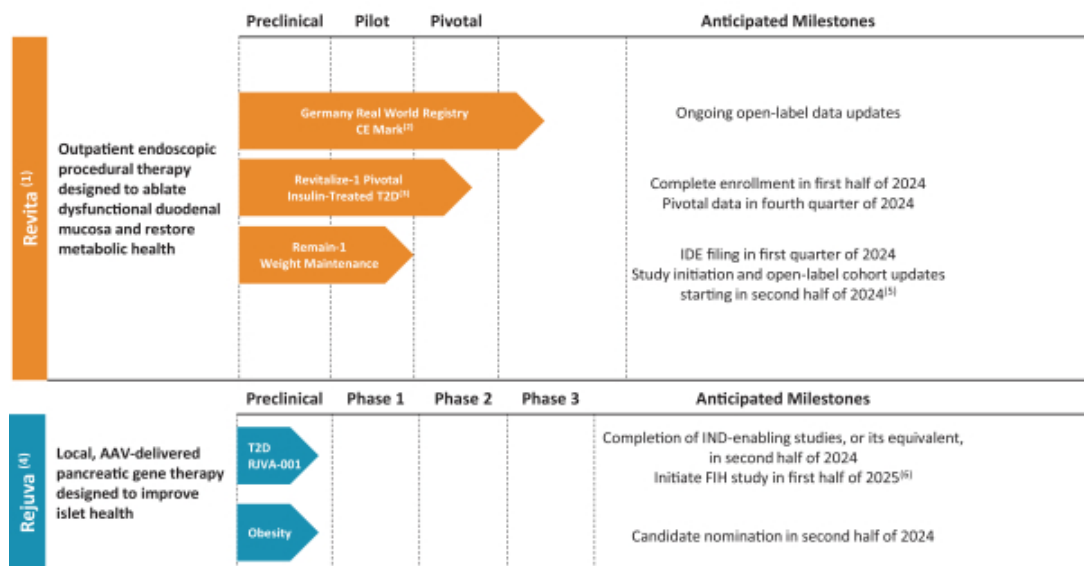
for the open-label cohort, which we refer to as the Reveal-1 cohort, in the second half of 2024. Revita is already approved for patients with inadequately controlled T2D in Europe. After securing reimbursement in Germany in the first half of 2023, we initiated our pilot commercial launch along with a Real World Registry study. We believe Revita has the potential to serve as a backbone therapy to prevent progression of T2D and for the prevention of weight gain, working in concert with behavioral therapies and standard of care pharmacology.

We are also developing Rejuva, a novel, locally administered, adeno-associated virus, or AAV, delivered pancreatic gene therapy, or PGTx, platform. Rejuva is designed to enable long-term remission of T2D and obesity by durably altering metabolic hormone function in the pancreatic islet cells of patients with T2D and obesity. In a preclinical head-to-head study, a glucagon-like peptide 1, or GLP-1, PGTx candidate demonstrated improvement in glycemic control, delayed T2D progression and reduction in weight compared to semaglutide (the active agent in Ozempic and Wegovy), an FDA-approved GLP-1RA. We believe these results highlight the potential benefits of metabolic treatment at the locus of disease in the pancreas. Our approach to pancreatic gene therapy is enabled by our expertise in developing proprietary delivery systems that target the gut locally and precisely. We plan to complete Investigational New Drug application, or IND, or IND-equivalent, enabling studies for RJVA-001, our first nominated GLP-1 PGTx candidate designed for the treatment of T2D, in the second half of 2024. If the IND, or IND-equivalent, for RJVA-001 is approved, we plan to initiate a first-in-human study in the first half of 2025.

We believe Revita and Rejuva, if approved, have the potential to revolutionize treatment across the spectrum of T2D and obesity, align the clinical and economic interests of key stakeholders around the long-term regression of metabolic disease, and, at their fullest potential, significantly reduce the burden of metabolic disease globally.

Our Development Pipeline

Our development pipeline for Revita and Rejuva PGTx candidates target large market indications in T2D and obesity and aim to transform treatment from chronic symptom management to disease-modifying therapies that target the organ-level root causes of metabolic disease. The following table summarizes our development pipeline and potential clinical opportunities across the spectrum of metabolic disease, from advanced T2D on insulin to obesity and prediabetes:



(1) Revita has been granted Breakthrough Device designation for the hydrothermal ablation of the duodenal mucosa to improve glycemic control and eliminate insulin needs in T2D patients inadequately controlled on long-acting insulin; and CE mark obtained from EU and UK in 2016 for Revita for the improvement of glycemic control in patients with inadequately controlled T2D despite oral and/or injectable glucose lowering medications and/or long-acting insulin.
 (2) The Germany Real World Registry study is a post-market, clinical follow-up study in real-world patients with inadequately controlled T2D on at least one ADA.
 (3) The Revitalize-1 study is a pivotal study in patients with inadequately controlled T2D despite being on up to three ADAs and daily insulin.
 (4) Product candidates under our Rejuva gene therapy platform will undergo Phase 1, Phase 2 and Phase 3 clinical trials.
 (5) If IDE is approved.
 (6) If IND is approved.
 * IND = Investigational New Drug Application with FDA or comparable regulatory body; IDE = Investigational Device Exemption with FDA or comparable regulatory body; FIH = first-in-human.

Our Team

We were founded by our Chief Executive Officer, Harith Rajagopalan, M.D., Ph.D., and our President and Chief Product Officer, Jay D. Caplan, with the goal of developing innovative procedures and novel therapeutics to improve the lives of patients with metabolic diseases, initially targeting T2D. Before starting Fractyl Health, Dr. Rajagopalan was a physician scientist and cardiovascular fellow at Brigham and Women’s Hospital. During his M.D./Ph.D. training at Johns Hopkins, Dr. Rajagopalan did award winning research on mechanisms of colorectal cancer formation with significant implications on cancer metabolism and published in leading scientific journals, including *Nature* and *Science*. Dr. Rajagopalan’s background in intestinal biology, cardiovascular medicine and stem cell research has contributed to the founding scientific insight behind Fractyl Health: intestinal stem cell biology fundamentally helps to explain one of the root causes of obesity and metabolic disease in humans, along with the attendant health consequences, including T2D, cardiovascular disease, or CVD, and colorectal cancer. Mr. Caplan is an electrical engineer by training and an experienced life sciences executive with an extensive track record of developing transformational medical products, including at ThermoCardio with the development of the HeartMate 2 Left Ventricular Assist Device. Our multi-disciplinary team consists of both seasoned biopharmaceutical and medical device professionals with deep industry experience. Our team brings together experts across multiple areas, including endocrinology (particularly in

metabolic diseases), gastroenterology, endoscopy, engineering and medical device development. Members of our team have worked with well-regarded biopharmaceutical and medical technology companies, such as Pfizer, AbbVie and Abbott, and we are supported by a leading group of life sciences investors.

What Sets Us Apart

Our vision is to develop transformative therapies that can prevent and eliminate metabolic disease. Our culture of scientific rigor and innovation is entrenched in all aspects of our organization and informs our goal of disrupting the current, inadequate chronic care model in T2D and obesity. We are focused on developing disease-modifying therapies to treat metabolic diseases by targeting the gut and pancreas, driving widespread adoption of our novel approach, delivering on the promise of improved experience for patients and health systems, and also potentially reducing costs for the healthcare system. We believe our vision is supported by the following strengths:

- ***Pioneering New Approaches Based on Deep Understanding of Metabolic Diseases.*** We are pioneering the development of disease-modifying therapies targeting the organ level root cause of metabolic disease. Our approach builds on over a decade of our research and the accumulation of independently published, supportive clinical evidence, all implicating the gut and pancreas as validated, untapped targets in T2D and obesity. We aim to restore and preserve the health of the key organs required for metabolic fitness and reduce the burden of metabolic disease for patients.
- ***Developing Disease-Modifying Therapies that Provide Long-Term Metabolic Benefits and the Potential to Shift the Treatment Paradigm in T2D and Obesity.*** Our Revita and Rejuva programs are designed to target dysfunction in the duodenum and pancreas, respectively, to provide long-term metabolic benefits from a single administration. For this reason, Revita and Rejuva offer the potential to target T2D and obesity in a manner that we believe is not addressed with currently available therapies, including the prevention and remission of the disease. Specifically, Revita has the potential to play a significant role in preventing T2D onset and weight gain, while Rejuva has the potential to drive remission of T2D and achieve durable weight loss. We believe Revita and Rejuva's unique features can provide significantly differentiated and compelling solutions to address the large unmet need in these metabolic diseases. If successful, we believe these programs can fundamentally disrupt the chronic care model for patients with or at risk for T2D and obesity, and could offer several key advantages, including sustained clinical benefit in glucose control and weight loss and reduced long-term disease management burden for patients.
- ***Rigorous Approach to Clinical Development.*** The Revita clinical program is designed to advance the development of Revita to potentially become a backbone procedural therapy across the spectrum of T2D and obesity. To date, we have evaluated Revita in over 300 patients across multiple clinical studies and we have observed over 500 patient-years of exposure data, favorable tolerability data, as well as favorable glycemic control and weight maintenance data. Our Rejuva platform with GLP-1 PGTx candidates has been evaluated in small and large animal models, as well as *ex vivo* murine and human islets. In a head-to-head preclinical study in a *db/db* mouse model, a GLP-1 PGTx candidate demonstrated improved glucose control, prevention of T2D progression and prevention of weight gain compared to semaglutide, an FDA-approved GLP-1 receptor agonist, or GLP-1RA. We plan to leverage our extensive clinical experience with Revita to inform our clinical plans with our Rejuva PGTx candidates.
- ***Aligning Interests of Key Stakeholders: Patients, Referring Physicians, Providers and Payors.*** We believe Revita and Rejuva, if approved, have the potential to offer clinical and economic benefits while reducing the burden of disease management compared to the current standard of care

in T2D and obesity. We believe both programs have the potential to broadly align interests across key stakeholders involved in the treatment of T2D and obesity, and may have the following benefits to these groups:

- *Patients.* Improving weight and glycemic control while reducing the number and burden of therapies required to adequately control T2D and obesity.
- *Referring Physicians.* Preventing weight gain and lowering HbA1c for specific patient populations with a procedural therapy that reduces the workload in disease management (i.e., rigorous patient medication, diet adherence) and improves quality metrics associated with the disease.
- *Providers.* Straightforward, easy to train outpatient procedures, which we believe could be safely deployed at scale across a large patient population. Intended to seamlessly integrate into existing endoscopist workflows and provide a new, potentially profitable service line for hospitals with a patient-friendly therapeutic option for a significant portion of their patients.
- *Payors.* Significant health economic benefits for payors who are currently struggling with the increasing expenses of T2D and obesity, driven primarily by unchecked disease progression and the lack of disease-modifying therapies.
- ***Purpose-Built Leadership Team with Shared Mission to Advance Patient Care in Metabolic Disease.*** Our diverse team, combining marketing, product development and therapeutic expertise, has over 150 years of collective experience in therapeutic development. We are mission-driven to develop novel disease-modifying therapies that can potentially reverse metabolic diseases for patients and for health systems. Our team aims to continuously advance and expand upon our body of knowledge in order to establish and maintain a scientific leadership position in our therapeutic areas of focus. We do so by collaborating with expert advisors who are leaders in metabolic disease, endocrine signaling and endoscopy. As part of these ongoing efforts, we have also convened the Erase T2D Task Force, a group of academic and scientific experts in the metabolic disease space, to serve as key advisors as we develop our understanding of the role of the gut in T2D. The Erase T2D Task Force is co-chaired by our CEO, Harith Rajagopalan, M.D., Ph.D., and Alan Cherrington, Ph.D., the former President of the American Diabetes Association and the winner of its Banting Medal for Scientific Achievement. Other members of the Erase Task Force include Geltrude Mingrone, M.D., Ph.D., David D'Alessio, M.D., and Randy Seeley, Ph.D.

Growth Strategies

Our mission is to develop transformative therapies that prevent and eliminate metabolic disease. In order to achieve this goal, we plan to employ the following strategies:

- ***Establish Practice-Changing Levels of Evidence for Revita Across the Spectrum of T2D and Obesity.*** Our stepwise approach to regulatory approvals will initially focus on patients with the highest unmet need in T2D, namely those treated with long-acting insulin, and obesity, and then progress to patients in earlier stages of T2D, and patients with high risk prediabetes. In March 2021, we initiated Revitalize-1, a pivotal clinical study of Revita in patients with inadequately controlled T2D despite being on multiple ADAs and insulin, and expect topline data in the fourth quarter of 2024. If successful, we intend to submit a Premarket Approval application, or PMA, to the FDA for Revita to improve glycemic control in T2D patients who are inadequately controlled on insulin. We are also planning to evaluate Revita in a two-part, parallel cohort, randomized, open-label clinical study for weight maintenance in patients with obesity who have lost at least 10% total body weight on GLP-1RA therapy and wish to discontinue their GLP-1RA without weight regain. We expect to submit an IDE in the first quarter of 2024 for a potentially pivotal Remain-1 study. We believe our Revita clinical program will provide comprehensive clinical evidence to support the potential of Revita as a disease-modifying procedural therapy for glycemic control in T2D, weight maintenance in obesity and the prevention of T2D.

- **Develop Rejuva Gene Therapy Platform to Enable Long-Term Remission of T2D and Obesity.** To further our core strategy to treat and significantly reduce the burden of T2D and obesity, we are developing the Rejuva gene therapy platform. Our Rejuva gene therapy platform utilizes our novel investigational pancreatic delivery device to administer gene therapy candidates to target the dysfunctional pancreatic beta cells that are a root cause of insulin insufficiency in T2D. We believe that the precise mechanical and molecular confinement of targeted, low dose gene therapy medicines, can address many of the challenges that limit the use of gene therapy in the pancreas and the use of systemic GLP-1RA drugs today. We plan to complete IND-enabling studies, or its equivalent, for RJVA-001 in the second half of 2024. If the IND, or IND-equivalent, for RJVA-001 is approved, we plan to initiate a first-in-human study in the first half of 2025.
- **Execute Targeted and Efficient Go-to-Market Strategy.** If Revita is approved in the United States, we plan to execute an efficient “hub-and spoke” commercialization strategy to capitalize on the aligned incentives of key stakeholders and drive rapid adoption. Leveraging key learnings and insights from the Revita clinical program and from the ongoing commercial pilot in Germany, we plan to assemble a targeted sales force initially focusing on centers of excellence with metabolically focused endocrinologists and advanced therapeutic endoscopists. We plan to initially target gastrointestinal, or GI, endoscopists with a dedicated interest in bariatric and metabolic endoscopy, as we believe their familiarity with our product candidate may make them early adopters. We also intend to roll out a robust procedural training and support program for GI endoscopists, which we believe will ensure seamless integration into their workflow. We also plan to work with Centers for Medicare & Medicaid Services and private insurers to seek to establish coverage and reimbursement for procedures using our product candidate, a key strategy to support the commercial viability of our product candidate with providers.
- **Broaden the Indication and Use of Revita.** If approved, we plan to leverage our platform, technology, core capabilities and the data gathered from our prior clinical studies and the Revita clinical program to expand the indication and use of Revita within other T2D patient segments and other serious diseases, including CVD and weight maintenance, among others. Because of our broadly accessible and disease-modifying approach, we intend to make Revita a backbone procedural therapy that can potentially significantly reduce the burden of T2D and obesity globally. We obtained a Conformité Européenne, or CE, Mark for Revita in Europe in 2016, reimbursement in Germany in 2022, and have built a direct sales force in Germany. We plan to expand a sales force in select major European markets upon successful completion of Revitalize-1. As we expand the adoption of Revita, we intend to evaluate potential partnerships and/or distributor relationships for its commercialization in other global geographies.
- **Expand Application of Rejuva Platform to Other Metabolic Targets Beyond GLP-1.** The Rejuva platform is modular and designed to enable local production of key metabolic hormones important for proper insulin production. Though our initial gene therapy candidate will include an AAV9 vector with a transgene that expresses GLP-1 hormone from the insulin promoter, our platform can enable production of a number of hormones, including, among others, gastric inhibitory polypeptide, or GIP, glucagon, peptide YY, or PYY, amylin. The versatility of the Rejuva platform has the potential to underpin a comprehensive, next-generation modality capable of targeting the root causes of various metabolic diseases.

Addressing Interlinked Metabolic Conditions: T2D and Obesity

Metabolic syndrome represents a spectrum of disorders that are primarily characterized by disturbances in the body’s ability to properly metabolize glucose, lipids, and other essential molecules. One of the most prevalent and ubiquitous manifestations of metabolic syndrome is obesity, a condition where excessive body fat accumulates to a degree that has the potential to adversely impact health. The presence of excess body fat in

obesity helps predispose at-risk individuals to other manifestations of metabolic disease, notably T2D, CVD, metabolic dysfunction-associated steatohepatitis, or MASH (formerly known as non-alcoholic steatohepatitis).

Whereas our ancestors lived in and adapted over centuries to ensure adequate energy supply in environments with limited nutrition, many people now live in a modern world with abundant access to calories and levels of nutrition for which we believe our bodies were never designed. The mismatch between our ancestral genetics and modern diets that are high in fat and sugar is a primary driver of metabolic diseases in the recent past. Emerging scientific consensus links these high fat and sugar diets to dysfunction in key metabolic organs that increase the risk of the development of obesity and T2D, including the gut and pancreas. There is a high degree of overlap between obesity and T2D. Obesity is a key factor in poor metabolic function in patients with T2D, and weight loss is seen as a critical therapeutic goal for T2D patients. According to the ADA Standards of Medical Care in Diabetes—2022, management of obesity is an important factor in the treatment of diabetes. According to the ADA, even a 5% weight loss can improve blood glucose levels and reduce need for medication. Therapeutic strategies that can both lower blood glucose and help with weight management could have longer-term benefits in prevention and remission of metabolic diseases.

Our Market Opportunity in Type 2 Diabetes

The International Diabetes Federation estimates that diabetes currently affects over 500 million adults worldwide, with nearly 1.3 billion people expected to be living with T2D globally by 2050. In the United States alone, 25 million people live with T2D on medical therapy and 5 million people live with advanced T2D on insulin therapy. Diabetes is expected to contribute more than \$2 trillion in global annual expenditure by 2030, according to an independent study by Bommer et al.

Diabetes mellitus affects how the body turns food into energy and disrupts the ability of the body to regulate appropriate levels of glucose in the blood, leading to chronically elevated blood glucose levels and life-threatening complications. There are two types of diabetes mellitus: Type 1 diabetes, or T1D, is a consequence of immune destruction of beta cells in the pancreas, while T2D is a component of the metabolic disease spectrum.

T2D is a disorder of rising blood glucose that is caused by a multitude of factors, which lead to two parallel, progressive disease processes within the body: insulin resistance and insulin insufficiency:

- **Insulin resistance** is the body's inability to appropriately utilize an insulin signal from the pancreas to remove glucose from the bloodstream. The resistance to insulin causes excessive glucose production in the liver and a chronic strain on the insulin producing beta cells of the pancreas, which ultimately leads to insulin insufficiency. The systemic metabolic dysfunction associated with insulin resistance is not limited to the pancreas. Insulin resistance is also associated with systemic chronic inflammation and other negative consequences throughout the body independent of blood glucose that can lead to disease, including in the liver, cardiovascular system, and brain.
- **Insulin insufficiency** in T2D is the gradual failure of the beta cells to produce sufficient insulin to meet the body's needs. Early on, an individual's genetic makeup and the gradual impact of diets high in fat and sugar lead to insulin resistance, requiring the pancreas initially to chronically overproduce insulin in order to maintain control of blood glucose within a normal range. Over time, both the stress of insulin resistance and the exhaustion of excessive insulin production can cause the progressive failure of beta cells and a decline in insulin production. This combination of insulin resistance and consequent progressive pancreatic failure results in high blood glucose levels.

Metabolic dysfunction and its associated insulin resistance occurs relatively early in life. At first, metabolic dysfunction is not immediately associated with elevated blood glucose, but it does contribute to

systemic chronic inflammation and the risk of weight gain, CVD, and stroke. Over time, insulin resistance causes a strain on the health of pancreatic beta cells, leading to decreased insulin production and insulin secretion, which leads to increases in blood glucose levels. When worsening pancreatic function leads to rising blood glucose above certain defined cutoff values for the population, the diagnosis of diabetes is made. A HbA1c test measures average blood glucose over a period of the past two to three months. Prediabetes is often diagnosed at HbA1c levels between 5.7% and 6.4% and diabetes is diagnosed when HbA1c reaches 6.5% or higher. Most society guidelines focus on controlling blood glucose to levels less than or equal to 7%, below which risk of diabetes related complications is low.

High cumulative life-long exposure to blood glucose in diabetes drives the development of diseases associated with small blood vessels (e.g., microvascular diseases in the eye, kidney, and peripheral nerves) and large blood vessels (e.g., macrovascular diseases in the heart and brain), potentially leading to life-threatening complications throughout the body, including early mortality. In addition, T2D is a major risk factor for cardiovascular events, such as heart attack and stroke. Ultimately, the mortality risk for patients with T2D is a nearly two-fold higher than in people without the disease, mainly due to cardiovascular complications of the disease. Large scale epidemiologic studies have shown that a 1% lowering of HbA1c lowers the overall risk of microvascular complications by approximately 35%. This demonstrates that the challenge is not only to substantially reduce HbA1c but also to sustain such a reduction throughout a patient's lifetime.

The Current Treatment Paradigm in T2D

The current standard of care for T2D is defined by life-long symptomatic management, focused on blood glucose control instead of disease modification. Despite the fact that T2D affects a significant fraction of the global population, there has not been a novel modality introduced to treat T2D in over a decade. While therapeutic advances in T1D have led to the approval of Tzield (teplizumab-mzwv) for the prevention of progression of T1D in 2022, and novel cell-based approaches to replacing beta cells in T1D, there has been an absence of therapeutic strategies tackling the root cause pathology of T2D. This lack of innovation is evidenced by the stubborn persistence of inadequate T2D control in patients. There are no approved disease-modifying therapies that target the organ-level root causes of T2D today.

The standard initial therapy in T2D is preventative care: dietary and lifestyle interventions aimed at altering the risk factors that contribute to progression of disease. While alterations to lifestyle are important, even intensive diets have not demonstrated sufficiently durable effectiveness to favorably impact long-term health in most patients due to lack of persistence and adherence. The Look AHEAD trial, conducted by the National Institute of Diabetes and Digestive and Kidney Diseases, was a randomized controlled trial comparing an intensive lifestyle program to standard diabetes education in overweight and obese T2D patients to track the development of CVD over time. The trial was stopped for futility after a median follow-up of 9.6 years. Eventually, even with diet and lifestyle interventions, blood glucose often worsens as ongoing insulin resistance causes progressive failure of pancreatic beta cells. At this point, symptomatic therapy to manage hyperglycemia is needed and most patients advance to medications and the chronic-care therapeutic model we see today.

Several classes of oral and injectable drugs exist for the management of hyperglycemia, and the sequential addition of medications on top of one another is directed by patient preference and payor pressure to minimize costs. Most patients with T2D will remain on an expanding list of medications to lower their blood glucose throughout the remainder of their lives. The sodium-glucose cotransporter-2 inhibitor, or SGLT2i (e.g., empagliflozin), and GLP-1RA (e.g., semaglutide), classes emerged over ten years ago as important new therapies in T2D with benefits beyond glucose lowering alone, including broader metabolic benefits on CVD and kidney disease risk. Guidelines call for patients to typically try SGLT2i and GLP-1RA if affordable before progressing to insulin therapy, helping to make the SGLT2i class an estimated \$12 billion market and the GLP-1RA class an estimated \$20 billion market in 2022. The significant market uptake of these drugs has come despite important shortcomings. SGLT2i and GLP-1RA medicines have a black box warning associated with significant safety risks, as well as tolerability challenges affecting medication adherence. For example, GLP-1RAs impact several

physiological processes and result in a variety of side effects, including nausea, vomiting and diarrhea. Since the introduction of these two classes over 10 years ago, there have been no significant new targets or approaches in the T2D disease category.

The advent of the GLP-1RA class of medicines for T2D has led to an explosion in prescriptions of these drugs due to their impressive potency, cardiovascular benefits, and favorable weight loss profile. According to a report by Trilliant Health, physicians signed more than nine million GLP-1RA prescriptions in the United States for Ozempic, Mounjaro and Saxenda in the last three months of 2022 alone. However, a retrospective study conducted by Polonsky *et al.* analyzing medical claims data between July 2012 and January 2019 demonstrated that a majority of patients on a weekly GLP-1RA (i.e., semaglutide, dulaglutide or exenatide extended release) discontinued therapy at 12 months. Discontinuation of these agents typically leads to an immediate loss of metabolic benefit and weight rebound, as seen in Eli Lilly's SURMOUNT-4 study with tirzepatide and Novo Nordisk's STEP-1 extension study with semaglutide. This lack of persistence to therapy and subsequent loss of benefit in both blood glucose and weight suggests that these agents do not offer durable disease modification in the disease and help explain the increasing burden of T2D in society, even with the availability of these potent drugs.

Eventually, even when adherence is maintained, medications lose durable effectiveness in the face of ongoing diabetes progression, and most patients typically progress to insulin therapy if they do not achieve suitable control on two or three ADAs. Most patients start with long-acting insulin, a daily injectable therapy, which lowers blood glucose by suppressing liver glucose production and helping cells absorb glucose from the bloodstream.

Insulin is an effective drug at lowering blood glucose in controlled clinical trials but presents significant limitations as a sustainable therapy, as evidenced by unfavorable real-world outcomes with this class of medicines. Despite its potency, fewer than 40% of patients achieve good glycemic control even after long-acting insulin is added to their regimen because of a failure on the part of patients and physicians to titrate insulin dose appropriately and a lack of adherence or persistence on therapy in many patients.

Failure to achieve blood glucose control with ADAs and even long-acting insulin leads to the need for more intensive insulin therapy with multiple daily injections, including long-acting and short-acting insulin formulations, or even to insulin pump therapy. This rigorous routine is a massive burden on patients, leading to decreased adherence, and ultimately, resistance towards therapy.

We believe the current symptom-driven approach to T2D management is misdirected and unreasonable. It asks patients for dietary and lifestyle changes in the face of an altered physiologic set-point in the body, rigorous and lifelong patient adherence and persistence to medicines, and unquestioning willingness to accede to increasingly complex therapies. This burdensome approach to care is often unmanageable and may leave many patients at risk, potentially resulting in chronic elevations in blood glucose that increase the likelihood of microvascular and macrovascular complications of T2D, and even death. There are no therapies that are approved today in T2D that offer disease modification, which we define as ongoing and durable preservation of pancreatic insulin production capacity even after therapy is discontinued.

We believe the same attention toward disease modification should be applied to T2D as is now already evident in T1D therapeutic development with goals of 1) diabetes prevention, defined as whether the treatment delays progression of diabetes, and 2) diabetes remission, defined as achieving a blood glucose level below the diabetic range for at least one year in the absence of active pharmacotherapy or ongoing procedures.

Our Market Opportunity in Obesity

Obesity is a disorder of altered metabolic setpoint and nutritional excess characterized by progressive weight gain and metabolic dysfunction that sits at the apex of a diverse range of negative health conditions, including T2D, CVD, and certain types of cancer. The International Diabetes Federation estimates that there are over 800 million people globally living with obesity today, with nearly 100 million suffering from obesity and

pre-diabetes in the US alone. With new innovations achieving greater degrees of potency than earlier agents, the obesity market is poised for immense growth, with industry expectations of approximately \$50 billion in drug sales by the end of the decade.

The human body has complex mechanisms to regulate weight, often compared to a thermostat that sets a “weight setpoint.” This setpoint is determined by a variety of factors, including genetics, environment, and behavior, and is regulated by a multitude of neural and hormonal signals originating in the intestine, pancreas, and adipose tissue, converging in the hypothalamus and other regions of the brain.

In individuals with obesity, the weight setpoint might be set or defended at a higher level, which is a key challenge in the management of this disease. When an individual with obesity loses weight (either by behavior changes or with medications), the body perceives the weight loss as a state of calorie deficit and risk of starvation. For this reason, the brain triggers a set of compensatory mechanisms, including increased hunger and decreased energy expenditure to try to restore the previous, but higher weight setpoint. The potential correction of the body’s altered metabolic setpoint can enable lasting benefits and translate to superior real-world outcomes.

The Current Treatment Paradigm in Obesity

Guidelines today focus on addressing excess weight in obesity, rather than developing strategies to lower or reset the body’s altered weight setpoint. Initial interventions focus on dietary changes and lifestyle modifications. The American College of Cardiology, or the ACC, and American Association of Clinical Endocrinologists, or the AACE, recommend patients with obesity should initially be prescribed aerobic exercise and resistance training, a reduced calorie diet, and behavioral intervention. The ACC and AACE guidelines recommend that behavioral interventions be escalated for patients who do not achieve 2.5% weight loss within 1 month of beginning lifestyle modifications. If lifestyle modifications are not successful, treatment may move into therapeutic involvement and surgery. The AACE guidelines recommend that pharmacotherapy combined with lifestyle modifications be considered in individuals with a BMI of at least 27 kg/m².

The GLP-1RA class of medicines have proven clinical efficacy in obesity. Wegovy (semaglutide) and Saxenda (liraglutide) are GLP-1RAs currently FDA-approved for obesity, with additional candidates in various development stages. In August 2023, Novo Nordisk’s SELECT trial demonstrated that treatment with semaglutide as an adjunct to the standard of care reduced the risk of heart attack, stroke, or heart disease-related death by 20% in overweight or obese individuals with cardiovascular disease and no prior history of T2D. Current prescription trends suggest widespread off-label usage of GLP-1RAs in obesity, such as Ozempic (semaglutide) and Mounjaro (tirzepatide), demonstrating extensive patient interest in access to this class of drugs.

Similar to what we have seen in T2D, critical unmet need remains in obesity despite the potency of GLP-1RAs. As with glucose control, GLP-1RAs have a “rebound effect” in obesity, in which weight loss is not maintained in the long term once medication is stopped. A 2022 third-party study exploring weight regain and cardiometabolic effects after withdrawal of 2.4 mg of once-weekly semaglutide found that participants regained two-thirds of their prior weight loss one year after treatment discontinuation, with similar changes in cardiometabolic variables. In July 2023, results from Eli Lilly’s SURMOUNT trials for tirzepatide demonstrated a slowing of the rebound effect, but only with significant lifestyle modifications. We believe there remains a critical unmet need in obesity for a therapeutic option that provides long-term benefit even after treatment discontinuation.

In an era of potent but non-durable weight loss therapies, we believe goals for anti-obesity medications should be 1) weight maintenance, defined as the prevention of weight regain over the course of at least one year, and 2) obesity remission, defined as achieving durable weight loss without the need for ongoing obesity-specific pharmacologic or surgical treatments. Therapeutic strategies that can achieve weight maintenance and obesity remission have the potential to provide a step change in outcomes for patients with obesity.

Our Approach

We design and develop novel, differentiated, disease-modifying therapies that precisely target and alter the function of the diseased organs responsible for T2D and obesity. Despite the development of highly potent medicines that can improve glucose control and weight, significant unmet needs remain in these diseases due to high rates of drug discontinuation over time, the loss of metabolic benefit upon drug discontinuation, and the inability of medicines to arrest the progressive nature of these conditions. Our vision is to develop transformative therapies that have the potential to prevent and eliminate metabolic diseases.

Our product candidates have the potential to offer a major advance in healthcare because they are designed as disease-modifying treatments that provide long-term metabolic benefits from a single administration, and are therefore potentially positioned to target the *prevention* and *remission* of disease, critically important categories in T2D and obesity treatment that cannot be addressed with current pharmacology. In order to be maximally impactful, these therapies must also be delivered at a scale that can match the incidence and prevalence of metabolic disease around the world. We believe our product candidates are not only unique in their potential for disease modification, but also in their design for broad accessibility for large populations. Accordingly, we believe our candidates have the capacity to revolutionize treatment of T2D and obesity and, at their fullest potential, significantly reduce the burden of metabolic disease globally.

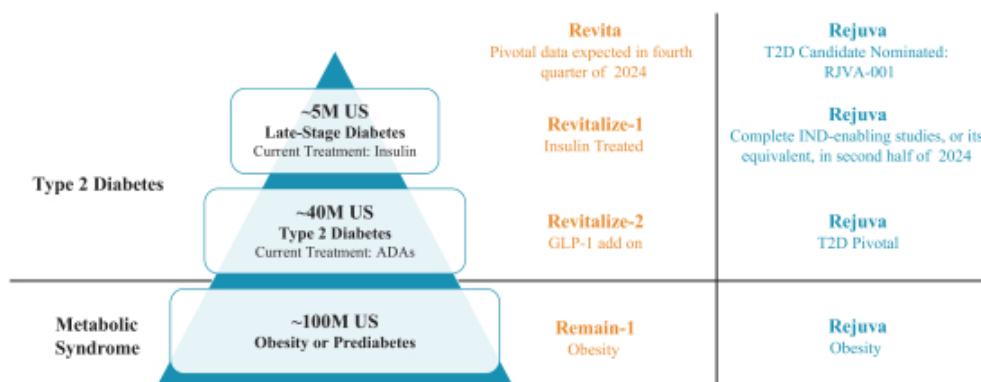
ADA Mission Statement: "To prevent and cure diabetes..."



Our Solutions

We believe there is a significant market opportunity for disease-modifying treatments that provide long-term metabolic benefits across the spectrum of T2D and obesity and we are developing a suite of product candidates that will target all phases of these diseases. Our Revita clinical development program is designed to evaluate Revita in multiple concurrent clinical studies across a range of patient populations from advanced T2D on insulin to obesity and prediabetes. We are also developing Rejuva to enable long-term remission of T2D and obesity by potentially restoring pancreatic metabolic function in patients with these diseases.

Significant Market Opportunity for One-Time Treatments Targeting Root Causes of Obesity and Type 2 Diabetes



Overview of Revita

Revita is an outpatient procedural therapy designed to durably modify duodenal dysfunction, a major pathologic consequence of a high fat high sugar diet, which can initiate T2D and obesity in humans. The duodenum is the first segment of the small intestine and the first site of nutrient absorption within the body. The duodenal mucosa regulates the human metabolic response to food intake, and chronic exposure to modern diets high in fat and sugar drive a functional maladaptation of stem cells in the duodenum and lead to dysfunctional hyperplasia of the duodenal mucosa. These diet-induced changes to the structure and function of the duodenal mucosa disrupt physiologic nutrient sensing and signaling mechanisms from the gut to the brain, with resulting alterations to systemic metabolic activity that affect glucose control and satiety through multiple downstream organ systems. Emerging scientific consensus has identified this dysfunction in the gut as a root cause of obesity and metabolic dysfunction and therefore propose targeting gut dysfunction to address downstream metabolic diseases. There are no therapies approved today that target the duodenal mucosa for regeneration and renewal.

The Revita system is designed to enable durable and repeatable metabolic improvement by targeting duodenal dysfunction with an outpatient, endoscopic procedural therapy. Revita uses heat energy to ablate the dysfunctional duodenal mucosa, including the duodenal stem cells residing at the base of the mucosa, to enable regeneration and renewal of the duodenum and restore normal metabolic signaling from the gut. The Revita procedure provides thermal protection to the duodenum before ablating the superficial mucosa by (1) isolating the mucosa from the deeper muscle layer of the duodenum and then (2) hydrothermally ablating the superficial layer of the duodenal lining with a proprietary balloon catheter and control console. The procedure takes less than 45 minutes and can be conducted in an outpatient setting in a manner that allows immediate return to daily life for patients. In the days following the ablation procedure, the duodenal mucosa regenerates, which we believe leaves the duodenal lining revitalized and better able to properly coordinate the gut’s metabolic signaling mechanisms.

Revita is designed to treat patients ranging from those who have advanced T2D who have exhausted medical therapies and require insulin therapy to those with prediabetes and obesity. For people with T2D treated with medicines and insulin, Revita is intended to improve glucose control and prevent or delay further progression of their disease. For individuals with prediabetes and obesity, Revita is designed to address upstream metabolic dysfunction that puts them at risk for the progression of T2D and obesity.

Potential Benefits of Revita

We believe that Revita's unique individual features combine to provide a significantly differentiated solution to T2D and obesity, offering the following potential benefits:

- **Durable and Repeatable Benefit.** Revita is designed to improve metabolic health, blood glucose levels, and weight in patients with inadequately controlled T2D. Based on a long-term follow-up study of the per protocol, or PP, population in our Revita-1 study, we observed that Revita, in combination with at least one ongoing oral anti-diabetic agent, or OAD, and lifestyle counseling, had a statistically significant mean HbA1c reduction of 1.0% (n=27) and a statistically significant raw change in weight of -3.1 kg (n=25) compared to sham patients at 24 months. A pooled analysis of data collected on secondary endpoints assessing weight in all of our controlled clinical studies across the United States and Europe demonstrated a 3.4% (n=100) mean reduction in total body weight loss at four weeks in patients with T2D on multiple ADAs after undergoing a single Revita DMR Procedure and showed a sustained mean body weight loss of 4.0% (n=94) at 48 weeks. We believe this is an important and differentiated therapeutic profile in obesity management. In addition, we believe our Revita system has the potential to enable repeat Revita procedures over time.
- **Tolerability.** In clinical studies to date, Revita has been observed to be generally well tolerated, with most patients resuming normal daily activities one day after the procedure and none requiring prescription pain medications. Our proprietary Revita technology is designed to provide thermal protection before ablation, enabling isolation of the mucosa from deeper tissue structures and sparing pain fibers in the muscle while reducing risk of tissue injury.
- **Broad Implementation.** Revita is a modular system that can potentially be incorporated into the endoscopist workflow by leveraging familiar skillsets of advanced endoscopists. Revita is intended to fit into most endoscopy suites and typically requires fewer than four cases for the endoscopist to acquire proficiency. It is designed to be an outpatient procedure that can be performed by a trained therapeutic endoscopist in less than an hour. Today, over 20,000,000 endoscopies are performed each year in the United States, including over 600,000 advanced endoscopic procedures, by nearly 10,000 gastroenterologists. The Revita DMR Procedure is designed to be a simple add-on procedure to the 4.7 million endoscopies already performed on T2D patients annually.
- **Real World Outcomes.** Because it is a procedural therapy, Revita does not rely on perfect patient adherence or persistence to chronic therapy for its anticipated clinical effects. Unlike diet and lifestyle interventions or pharmacologic management, the benefits of Revita are intended to be conferred at the time of the procedure and not reliant upon ongoing therapeutic maintenance. This allows a shift in patient focus from escalating chronic disease management burden to ongoing health maintenance after the procedure.
- **Patient Friendly.** Revita is designed to offer a straight-forward, outpatient experience requiring less than a half-day visit, and allowing patients to typically return to their normal daily lives the very next day. Furthermore, the Revita DMR Procedure has thus far been observed to be compatible with other current interventions for T2D and obesity in broad use, including diet and lifestyle, as well as existing and emerging pharmacologic therapies.

Overview of Rejuva

Rejuva is a novel, locally administered, AAV-delivered PGTx platform designed to enable long-term remission of T2D and obesity by durably altering metabolic hormone function in the pancreatic islet cells of patients with T2D and obesity. Pancreatic islets are tiny clusters of cells distributed throughout the pancreas that

play a crucial role in endocrine function and glucose metabolism. There are several cell types within the pancreatic islet, including alpha cells responsible for glucagon production and beta cells responsible for insulin production. Metabolic dysfunction in obesity and prediabetes can lead to progressive beta cell dysfunction and eventual failure, loss of insulin production and secretion, and the development of T2D. There are no therapies approved today that target the pancreatic islet in T2D for repair or replacement.

Our Rejuva gene therapy platform utilizes our novel investigational pancreatic delivery device to administer gene therapy candidates to target the dysfunctional pancreatic beta cells that are a root cause of insulin insufficiency in T2D. Rejuva is a modular, physiologic gene therapy platform with three key elements designed to enable successful pancreatic gene therapy: (1) a proprietary delivery catheter designed to enable local, low dose therapeutic delivery directly to the pancreas via endoscopic access, (2) vectors with tropism for the pancreatic islet to enable successful transduction and gene delivery with limited biodistribution via this route of administration, and (3) transgenes with tissue-restricted promoters and metabolically active peptides that can durably impact glucose and weight control. Rejuva is designed to directly administer a gene therapy into the body and tail of the pancreas via mechanical confinement of virus with local administration and molecular confinement of transgene expression with tissue-specific promoters. These hormones are intended to rejuvenate beta cell health and restore the body's natural ability to produce insulin. The first gene therapy candidate for Rejuva will be a locally administered AAV9 viral vector that expresses a full-length GLP-1 hormone from the insulin promoter.

Potential Benefits of Rejuva

We believe that Rejuva's individual features combine to provide a significantly differentiated solution to T2D and obesity, offering the following potential benefits:

- ***Novel Approach to a Highly Validated Target.*** Our Rejuva platform candidates are being developed as an investigational pancreatic delivery device and local, AAV-delivered PGTx to durably improve islet health in the pancreas. Our first Rejuva PGTx candidate is intended to augment intra-islet GLP-1 receptor activation, leveraging well established biology on GLP-1 signaling and potentially leading to improved beta cell health and glucose control in patients with T2D and obesity.
- ***Precise Local Delivery.*** Our Rejuva gene therapy platform is designed to provide precise local delivery of gene therapy to the pancreas in a single endoscopic procedure. Our Rejuva platform leverages standard-of-care techniques for pancreatic tissue access and possesses key proprietary device elements and procedure steps, thereby reducing procedural risk. We believe our Rejuva gene therapy candidates will benefit from localized administration, potentially avoiding the risk of high dose systemic administration that has been observed with other gene therapy candidates or GLP-1 receptor analogs.
- ***Preclinical Pharmacology and Toxicology Profile.*** In preclinical studies, we observed that a single administration of a GLP-1 PGTx candidate achieved durable and statistically significant improvements in blood glucose control and weight loss in *db/db* mice. In a preclinical proof-of-concept head-to-head study in a *db/db* model, after a single administration of a GLP-1 PGTx candidate, we observed (compared to chronic semaglutide at 10 nmol/kg daily):
 - statistically significant average reduction of fasting plasma glucose, or FPG, levels of 50.9% ($p < 0.0001$) at eight weeks;
 - non-statistically significant decrease in fasting insulin of 48.6% ($p=0.374$) during a glucose tolerance test at eight weeks; and
 - statistically significant decrease in total body weight of 19.6% ($p<0.0001$) at four weeks.

Additionally, no adverse events related to the pancreas, liver or other tissues were observed in our rodent or large animal studies.

- ***Building Upon Clinical and Real-World Experience with Revita.*** The gene therapy candidates from our Rejuva platform benefit from the extensive clinical and real-world experience that we have accumulated through our Revita program. Rejuva PGTx candidates can be delivered by the same treating physicians and in the same setting as the DMR procedure, utilizing the same Revita console and leveraging the same distribution network. Moreover, we believe the metabolic benefits of Rejuva PGTx candidates have the potential to be complementary to, and perhaps synergistic with, the Revita DMR Procedure.
- ***Rigorous Development Plan.*** We anticipate completing IND-enabling studies, or its equivalent, for RJVA-001 in the second half of 2024. If the IND, or IND-equivalent, for RJVA-001 is approved, we plan to initiate a first-in-human study in the first half of 2025.
- ***Interchangeable Platform for Metabolic Therapy.*** The Rejuva platform enables selection of multiple metabolically active peptide hormones (GLP-1, GIP, PYY, amylin, glucagon, etc.), either individually or combinatorially, with the same local delivery and plasmid construct for differential therapeutic profiles over time.

By employing Revita and Rejuva to target the prevention and remission of T2D and obesity, we believe it is possible to provide a step change in outcomes for patients above and beyond the current chronic management strategies that exist today. If we are able to obtain approval for these product candidates in the United States, we believe these therapies will enable us to chart a course towards significantly reducing the burden of T2D and obesity globally.

Our Targets: the Gut and Pancreas

“All disease begins in the gut.”

- Hippocrates

The Role of the Gut in the Central Regulation of Metabolism

In recent years, there has been an increase in research tying gut health to diseases throughout the body – ranging from obesity to T2D to dementia. One aspect of this research is the emerging consensus that an important root cause of metabolic disease is the impact of modern diets on the gut, one of our body’s critical metabolic control systems. Advances in our understanding of integrative organ physiology has begun to reveal the complex role that the gut plays in interfacing with the food we eat and coordinating the body’s response to that food. The gut possesses the largest nervous system outside the brain, the largest hormone producing endocrine system, a huge and complex microbiome, and the largest immune system in the body. Different segments of the intestine have different endocrine producing cells and different neurohormonal effects on the brain’s response to the meal. These mechanisms work together to provide a defensive barrier and an early warning detection system to help the body prepare for and deal with the food we ingest.

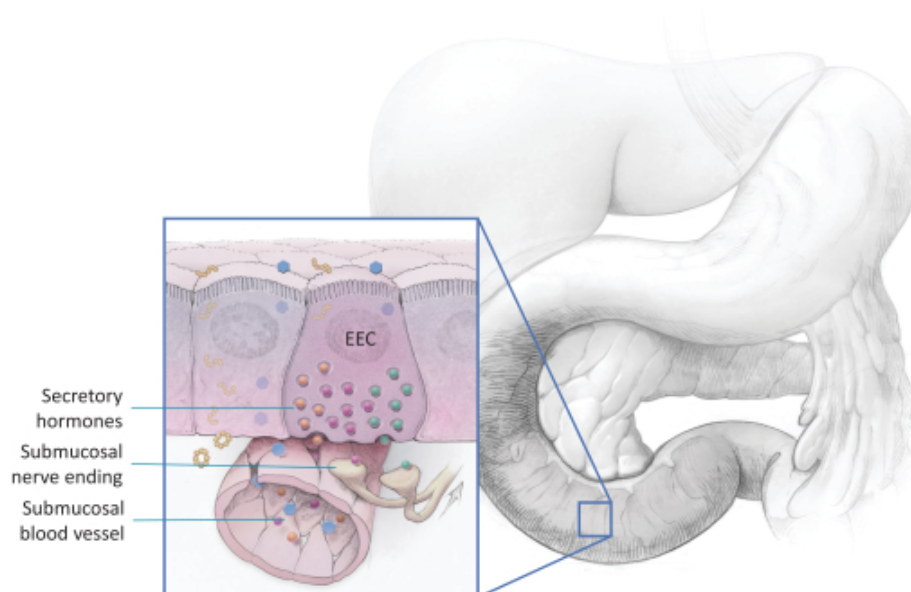
Diets have changed a great deal over the past several decades, with a shift away from relatively calorie poor, fiber rich, natural foods, to the inexpensive and abundant supply of ultra-processed foods that are very high in simple fats and sugars. Our founders, along with several scientific groups around the world, have begun to detail the specific changes that these modern diets cause on the gut and the impact these changes exert on the body and brain. While the gut has long been recognized as an acute nutrient sensor with signaling mechanisms to the other metabolic organs of the body, its role in regulating the body’s metabolic status over longer periods of time has been underappreciated. Recent advances have demonstrated that the chronic exposure of the intestine to

high levels of fats and sugars lead to structural and functional changes of the lining of the proximal gut that may signal a metabolic shift to the brain and body. These insights provide a window into the adaptive role of the intestinal mucosa in helping to define metabolic parameters within the body—informing the metabolic regulation of insulin resistance versus sensitivity, hunger versus satiety, energy utilization versus energy storage, and protection from hypoglycemia versus protection from hyperglycemia. Moreover, these diet-induced changes are geographically confined to the upper small intestine, particularly the duodenum, an area of the body that is directly accessible via routine upper endoscopy via the mouth. This new research provides, for the first time, an accessible potential target of pathology within the gut that sits at the apex of the complex metabolic changes throughout the body underlying metabolic diseases, including T2D and obesity.

Structural and functional changes in the duodenal lining occur in response to high fat, high sugar diets, and can lead to T2D and obesity

After food passes through the stomach, it moves to the duodenum, which is approximately the first 25 cm to 30 cm of the small intestine, where nutrient absorption first begins in the body. The lining of the duodenum, known as the mucosa, is composed of several cell types, including absorptive cells called enterocytes and hormone-producing enteroendocrine cells, or EECs (comprising approximately 1% of the cells of the mucosa). EECs sense the presence or absence of nutrients in the duodenum and send chemical signals via the bloodstream and direct connections to nerve cells in the gut to the brain and body to help mediate glucose control, as depicted below.

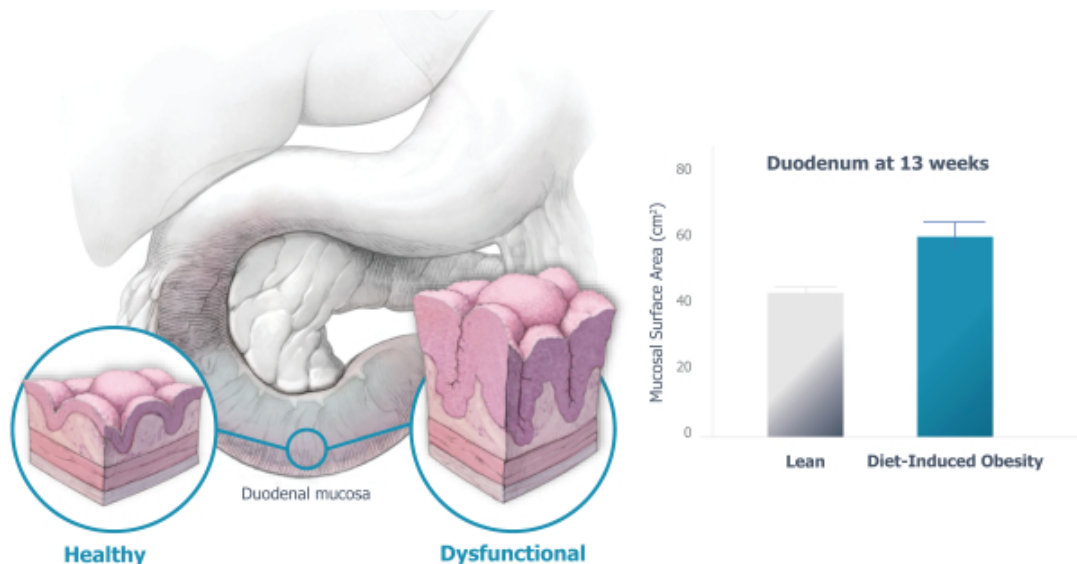
EECs in Duodenal Lining Send Neurohormonal Signals to Brain and Body



Studies analyzing the small intestine in diabetic patients and animal models have identified functional maladaptation of the intestinal mucosa after chronic dietary exposure to high concentrations of fat and sugar similar to the composition of modern diets. Geltrude Mingrone (a consultant to Fractyl and a member of our Erase Task Force), et al. showed in 2010 that a high fat diet in rats can cause overgrowth of the duodenal mucosa. Working with colleagues at King's College London, we extended these observations to show that mucosal overgrowth may occur in the duodenum and proximal jejunum but does not extend to further segments of the intestine, such as the ileum. Further, Aliluev et al. observed that high fat, high sugar diets alter intestinal

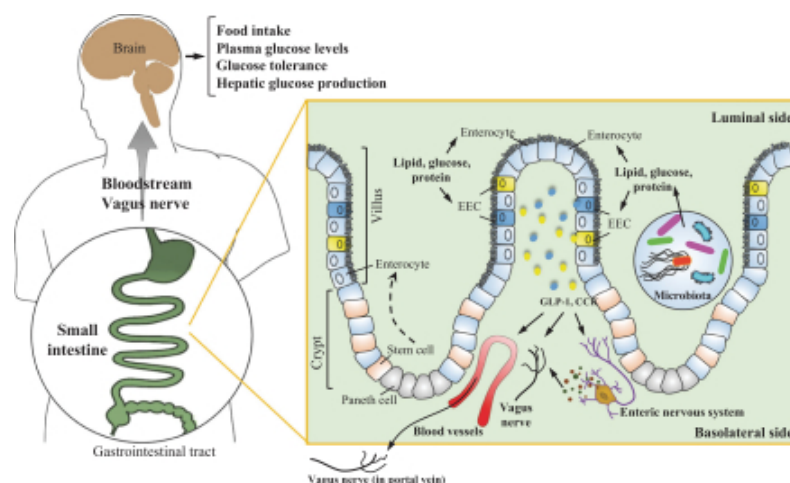
stem cell homeostasis leading to an overgrowth (i.e., hyperplasia) of the duodenal mucosa. The figure on the left demonstrates that chronic exposure to these diets may lead to the development of a dysfunctional duodenal lining. The image below on the right depicts the effect of a high fat diet on the growth of the mucosa in a rodent chronically fed a high fat diet, which led to a 50% increase in mucosal surface area over time, relative to a normal diet-fed rodent.

High Fat and Sugar Diets May Cause Overgrowth and Dysfunction of Duodenal Mucosa



This finding of a nutrient-induced stem cell division process that causes structural and functional changes of the duodenal mucosa has now been replicated by multiple independent groups in the United States and Europe, and across organism species and disease models. Michael Theodorakis et al. have demonstrated similar observations in diabetic humans, showing through duodenal biopsies that the mucosa in the duodenum of patients with T2D becomes thickened and exhibits changes to the hormone-producing cell populations in the duodenum.

Hyperplasia and dysfunction of the duodenum is associated with more mucosal cells, a greater surface area for nutrient absorption, and in turn more EECs for neurohormonal signaling, altering the body's response to the metabolic signal from this region of the gut. The greater surface area of the duodenal lining accelerates nutrient absorption and nutrient sensing and signaling from EECs in the proximal intestine. Multiple downstream mechanisms have been implicated in the role of this gut dysfunction in causing metabolic dysfunction. According to Duca et al., EECs in the duodenum respond to ingested nutrients by secreting hormones, including GLP-1 and cholecystokinin, which enter the circulation and trigger local nervous system activation on the basolateral surface of those cells. In this way, the brain can receive neurohormonal signals from the gut and uses this integrated information to regulate blood glucose levels and weight by impacting glucose metabolism and energy metabolism throughout the body. In a healthy state, intraduodenal lipids triggers satiety and suppression of blood glucose levels through these mechanisms, but chronic high fat diets impair this gut-brain feedback in lipid sensing and signaling, leading to metabolic dysfunction (as depicted in the image below).



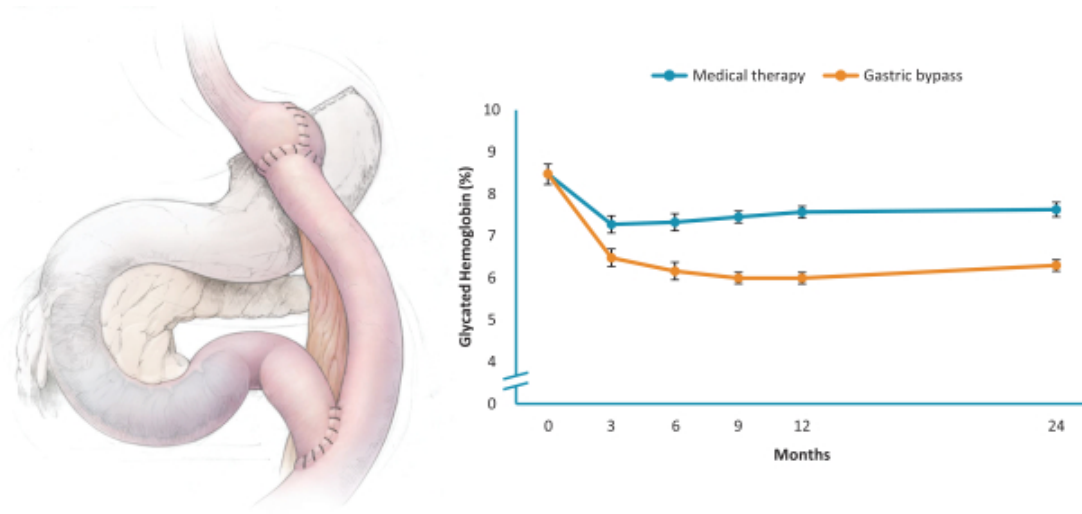
Source: Duca et al., *Nat Commun.* 2021; 12: 903; <http://creativecommons.org/licenses/by/4.0/>

We believe that, taken together, this recent preclinical and clinical evidence demonstrates that abnormal neurohormonal signaling from the duodenum to the rest of the body is an important contributor to metabolic dysfunction, which can increase the risk of T2D and obesity. This insight extends the conventional wisdom that excess weight and physical inactivity are the sole drivers of T2D by highlighting the important role of the duodenum in metabolic control.

Avoiding Nutrient Contact with the Duodenum can Reduce Insulin Resistance in T2D

Not only is there evidence that changes in the duodenum and duodenal nutrient sensing may directly and/or indirectly cause insulin resistance, but independent studies in animals and humans show that preventing or disrupting nutrient contact with the duodenal mucosa can ameliorate insulin resistance and its downstream clinical consequences. Metabolic surgeries that bypass the stomach and duodenum, originally intended for weight loss, have emerged as a treatment approach in T2D with superior metabolic benefits compared to the current standard of care. There is abundant and compelling surgical experience (performed in hundreds of thousands of patients with millions of patient-years of follow-up) showing significant and durable metabolic improvements that come from bypassing the duodenum in people with T2D and obesity (as depicted in the image below). These surgeries have now firmly positioned the duodenum as a validated novel target for T2D and an organ whose function can be safely and effectively altered for metabolic improvement.

Gastric Bypass Surgery Leads to Significant and Sustained Improvement in Blood Glucose

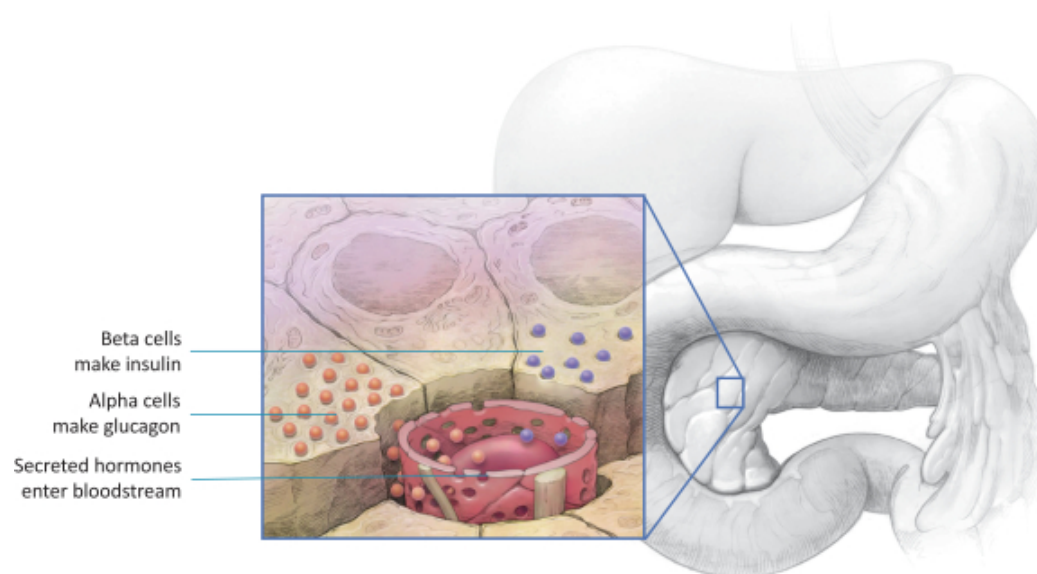


Source: Mingrone et al., *N Engl J Med* 2012; 366:1577-1585

The Role of the Pancreas in Metabolic Control

The pancreas is a hormone producing organ in the retroperitoneum surrounded by the duodenum, immediately below the stomach. It has functions related to the secretion of digestive enzymes into the duodenum to help process food for absorption (exocrine pancreas) and functions related to the secretion of hormones into the bloodstream to help maintain glucose control (including insulin and glucagon) from pancreatic islets distributed throughout the pancreas. The figure below shows cells within a pancreatic islet: alpha cells secrete glucagon into the bloodstream and beta cells secrete insulin. Glucagon and insulin are counter-regulatory hormones that act in opposite directions to raise or lower blood glucose levels, respectively.

Pancreatic Islet Cells Produce Glucagon and Insulin



Most people can compensate for their bodies' metabolic dysfunction by increasing the amount of insulin they produce in the beta cells of their pancreas to keep blood glucose levels within normal ranges. Patients who go on to develop T2D eventually experience a gradual loss of beta cell function, leading to reduced insulin production and insulin secretion over time. There are two principal causes for the loss of beta cell function in most people with T2D: (1) exhaustion of beta cell function in the face of longstanding metabolic dysfunction and chronically elevated blood glucose levels, and (2) damage to beta cells from the toxicity of circulating lipids (i.e., lipotoxicity) that are directly tied to metabolic dysfunction. By the time the diagnosis of diabetes is made, people have lost over 80% of their beta cell function, which we believe makes it essential that the physician intervene aggressively with therapies known to prevent or correct known pathophysiological disturbances in beta cell function.

Increasing GLP-1 Levels in the Pancreas can Improve Islet Metabolic Function

GLP-1 is a potent hormone that is produced in the distal intestine and secreted into the circulation in response to nutrient intake and also produced in the pancreatic islets by alpha cells, acting within the islet to regulate metabolic control. The role of GLP-1 hormone within the pancreatic islet in beta cell function and insulin production is one of the best understood hormonal mechanisms in all of medicine. The GLP-1 receptor is expressed in beta cells of the pancreas, where receptor activation has multiple acute and chronic actions on beta cell function: acutely, GLP-1 immediately stimulates insulin secretion in response to elevations in blood glucose; chronically, GLP-1 stimulates insulin gene transcription and islet cell survival. The GLP-1 receptor is also expressed in alpha cells of the pancreas, where receptor activation regulates glucagon expression to help control blood glucose levels. Studies have shown that there is impaired GLP-1 signaling in the pancreatic islet in T2D, and increased GLP-1 signaling can compensate for impaired insulin secretion, preserve beta cell function and survival, and therefore improve glucose homeostasis in T2D. The beneficial effects of GLP-1 on pancreatic islet function have been further shown by the effects of the GLP-1RA class of medicines, which have demonstrated meaningful improvements in insulin production and pancreatic responsiveness to blood glucose.

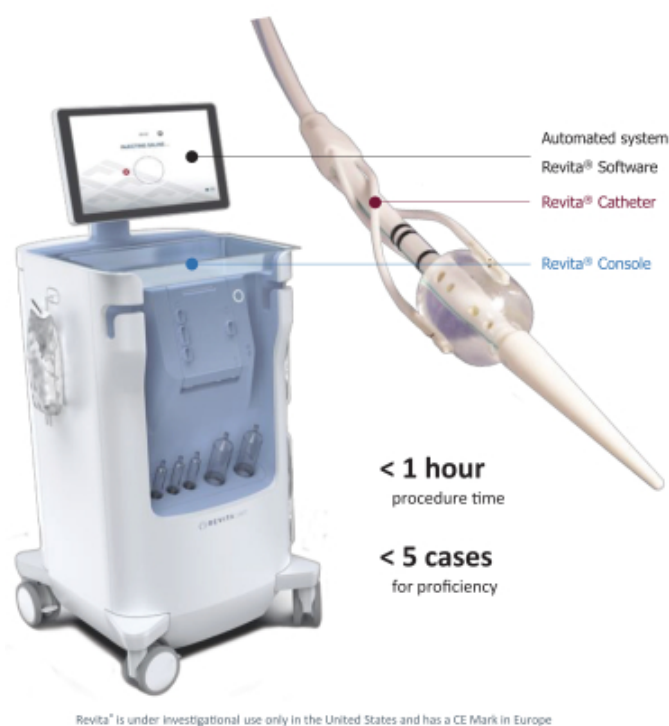
Revita and Rejuva are designed to treat T2D and obesity by directly targeting the gut and pancreas, respectively, to address root cause pathologies in these organs that drive metabolic disease. By leveraging our expertise in developing novel, differentiated, disease-modifying therapies, and our insights into the biology of the gut and pancreas, we believe our therapeutic approaches, if approved, have the ability to alter the paradigm for treating T2D and obesity by remediating the most fundamental causes of the disease.

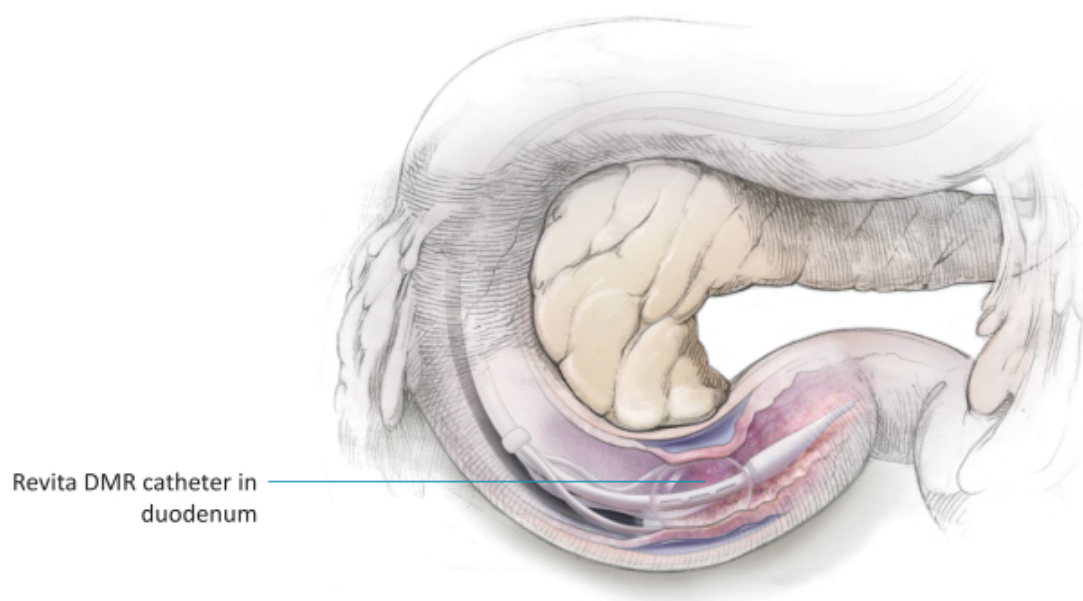
Revita Product Description

Device Overview

Revita is comprised of (i) the Revita console that houses our proprietary technology and software, and (ii) a single-use Revita DMR catheter. The console's touchscreen-based graphical user interface is designed to provide ease-of-use and clear guidance on the performance and progress of the procedure for the physician. The console is designed to control the temperature of the ablative and cooling fluid, vacuum suction, facilitate the delivery of saline for the submucosal lift and the pressure and flow rate of water during the ablation cycle. In addition, the console houses sensors that are designed to monitor temperature, pressure and procedure status. We believe the console enables a targeted ablation process by enabling a proprietary safety mechanism that reduces penetration of heat to deeper tissues during the hydrothermal ablation procedure, and potentially reduces the risk of physician error by automating certain steps of the treatment process by guiding the physician step-by-step through the procedure. The image below depicts a prototype rendering of the modular Revita console with the proprietary Revita catheter. The catheter and graphical user interface are currently being used in our Revitalize-1 clinical study but the Revita console hardware below is not. We plan to seek approval from the FDA of a supplemental PMA for this console design modification. The Revita DMR catheter is comprised of three outward-facing ports on the exterior of our novel ablation balloon with a control handle on the proximal end. Each port on the catheter has an opening whose size and shape is designed to enable suction to selectively pull mucosal and submucosal tissue into the port, while preventing the deeper muscularis tissue from being pulled in. In addition, the catheter is thin, flexible and narrow, and is designed to be deliverable and trackable across the stomach into the small intestine over a standard endoscopic guidewire.

Modular Revita Console Powered by an Intuitive Touchscreen User Interface





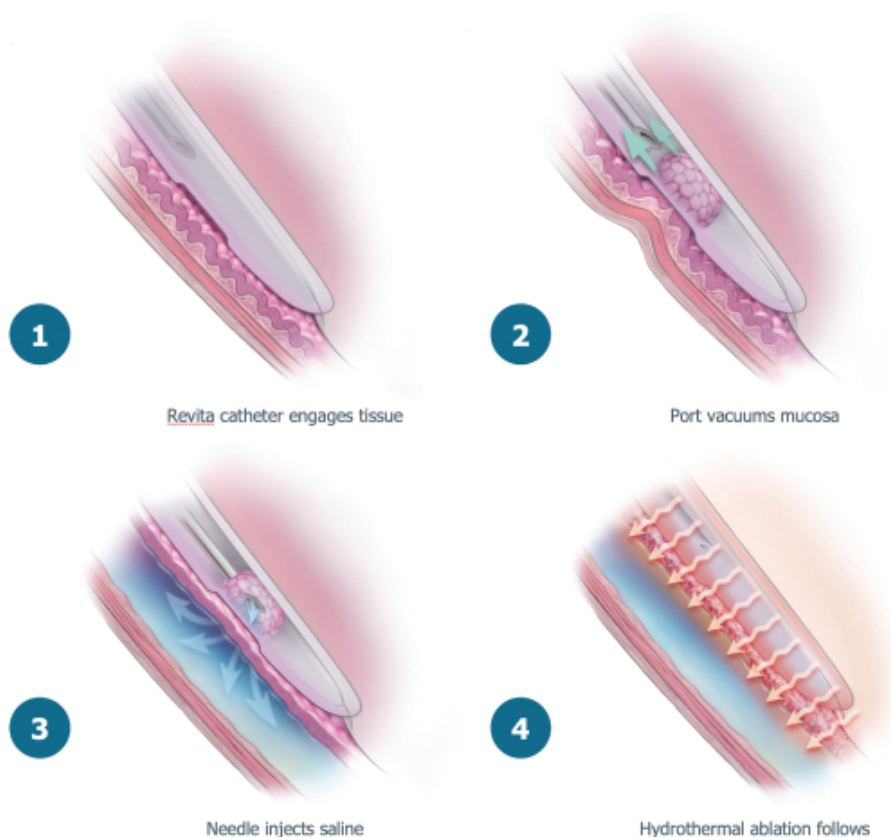
Procedure Overview

The Revita DMR Procedure is designed to be a minimally invasive, outpatient, endoscopic procedural therapy using a proprietary balloon catheter that is uniquely designed for the duodenal mucosa in a procedure that typically lasts less than an hour. Revita is designed to target the mucosal surface for ablation and induce intestinal stem cell-mediated regeneration. The procedure is performed by a trained endoscopist while the patient is under conscious sedation or general anesthesia. With the help of the Revita console, certain steps of the procedure are designed to be highly automated, which we believe minimizes the risk of physician error.

The procedure involves inserting the distal end of the single-use Revita catheter through the mouth over a guidewire past the stomach and into the duodenum, using fluoroscopy to assist placement. The catheter is then positioned distal to the ampulla of Vater (i.e., the hepatopancreatic duct where bile salts and pancreatic enzymes enter the GI tract) under direct endoscopic visualization. The procedure then involves a repeated sequence of thermal safety and hydrothermal ablation steps.

Thermal Safety. Our proprietary thermal safety procedural step involves an automated, circumferential instillation of saline into the submucosal space of the duodenum. This step is initiated through the user interface of the console and enables the lifting of the mucosa away from the underlying muscle layer. The catheter balloon is expanded with fluid to allow the catheter to engage with the mucosa and a vacuum connected to the console draws the mucosa into each of three injection ports on the catheter. The user interface of the console is then used to initiate saline delivery to the submucosal space via needles within the vacuum ports. This procedure step is designed to create a thermal barrier between the mucosa and the underlying muscular layer in order to reduce the risk of discomfort or unintended thermal injury, and to enable repeated procedures by ensuring that the mucosa can be safely lifted before performing thermal ablation.

Designed to Create a Protective Thermal Barrier for a Well Tolerated Procedure



Hydrothermal Ablation. After the thermal safety step is completed in a region of the duodenum, hydrothermal ablation is initiated through the console user interface. The ablation cycle involves the introduction and recirculation of water within the balloon. We believe this sequence of steps provides a controlled, uniform, “thin layer” ablation of the mucosa and superficial submucosa and potentially further reduces the risk of injuring deeper tissues. The first step fills the balloon with cold water to cool the duodenal tissue below body temperature prior to ablation. The second step is intended to deliver a precise dose of hydrothermal energy to the tissue to create a controlled coagulative ablation. The third step is intended to remove any residual heat from the tissue and to prevent unintended conduction of heat within the tissue.

The thermal safety and hydrothermal ablation steps are continued sequentially along the length of the duodenum, extending from just beyond the ampulla of Vater and proceeding distally until the full length of the duodenum is treated. The sequential thermal safety and hydrothermal ablation steps are designed to ensure the spatial and temporal alignment of the ablation within the previously lifted region before the thermal protective saline barrier dissipates. We have designed Revita’s hydrothermal ablation to be coagulating, where the proteins in the tissue are denatured but the tissue remains in place. In addition, our ablation procedure is designed to prevent bleeding and to allow overlapping ablations without excessive depth of ablation.

Upon completion of the procedure, the guidewire, catheter and endoscope are removed, leaving no long-term implant in the GI tract. The patient is typically discharged on the same day and is prescribed a

graduated post-procedure diet, starting with liquids and progressing to pureed foods and soft foods. Similar to other routine upper-GI endoscopic procedures, if Revita is approved, we anticipate that patients will resume normal activities the day after their procedure, which is supported by our observations to date.

Clinical Data Overview: Revita

We have evaluated the Revita DMR Procedure in over 300 patients in multiple clinical studies across numerous sites in South America, Europe and the United States. To date, we have observed the Revita DMR Procedure, when added to certain ADAs and lifestyle counseling, to be generally well tolerated and demonstrated durable blood glucose lowering and weight stabilization in patients for two years post-procedure. We are also currently evaluating the Revita DMR Procedure in our Revitalize-1 pivotal clinical study in patients with inadequately controlled T2D despite being on up to three ADAs and 20 to 100 units of insulin daily. Based on the data observed in our previously conducted clinical studies, we believe that the Revita DMR Procedure has the potential to procedurally treat the organ-level root cause of metabolic diseases, such as T2D and obesity.

The table below summarizes our ongoing, planned and completed clinical studies for the Revita DMR Procedure.

Study and Status	Study Design	Primary Objectives	Milestones
<p>Germany Real-World Registry. Study in patients with inadequately controlled T2D on at least one ADA Commenced in April 2023</p>	<ul style="list-style-type: none"> Prospective, post-market, clinical five-year follow-up of patients who have received the Revita DMR Procedure in a real-world setting 	<ul style="list-style-type: none"> To assess the safety and clinical effectiveness, quality of life and patient reported outcomes, and healthcare utilization expenditure of the Revita DMR Procedure 	<ul style="list-style-type: none"> Enroll patients and report data on an ongoing basis
<p>Revitalize-1. Pivotal clinical study in patients with inadequately controlled T2D despite being on up to three ADAs and 20 to 100 units of insulin daily Commenced in March 2021</p>	<ul style="list-style-type: none"> Stage 1: open-label, single-arm training stage Stage 2: Randomized, double-blind, crossover, sham-controlled, multi-center ~10-14 cm DMR Two arms: DMR and sham Stage 1: up to 140 patients Stage 2: up to 320 patients 	<ul style="list-style-type: none"> To demonstrate superiority of the Revita DMR Procedure to sham in improving glycemic control at 24 weeks 	<ul style="list-style-type: none"> Anticipate completing enrollment in the first half of 2024 Topline data expected in the fourth quarter of 2024
<p>Remain-1. Clinical study in patients who have lost at least 10% total body weight on GLP-1RA therapy and wish to discontinue their GLP-1RA without weight regain</p>	<ul style="list-style-type: none"> Two-part, multi-center, parallel cohort, randomized (2:1), open-label Reveal-1/open-label: up to 100 patients Randomized: 300 patients (DMR and sham) 	<ul style="list-style-type: none"> To demonstrate superiority of the Revita DMR Procedure to sham in weight maintenance after discontinuation of tirzepatide or semaglutide at 24 weeks 	<ul style="list-style-type: none"> We expect to submit an IDE and comparable documents to the FDA and comparable foreign regulatory authorities or notified bodies in the first quarter of 2024 for a potentially pivotal Remain-1 study We expect to initiate Remain-1 and begin reporting Reveal-1 cohort updates in the second half of 2024, subject to IDE approval
<p>Revitalize-2. Pivotal clinical study in patients with T2D who are inadequately controlled on two or three ADAs for whom insulin would be the next step in therapy Planned</p>	<ul style="list-style-type: none"> Stage 1: open-label, single-arm training stage Stage 2: Randomized, double-blind, sham-controlled, multi-center Two arms: DMR and sham Stage 1: up to 110 patients Stage 2: up to 400 patients 	<ul style="list-style-type: none"> To demonstrate superiority of the Revita DMR Procedure to sham in reducing hyperglycemia at 24 weeks 	<ul style="list-style-type: none"> Expect to initiate study after completion of the Remain-1 study

Study and Status	Study Design	Primary Objectives	Milestones
U.S. Pilot. Pilot study in patients with sub-optimally controlled T2D despite being on metformin in combination with one to two additional OADs Completed (prematurely ended)	<ul style="list-style-type: none"> Randomized (2:1), double-blind, crossover, sham-controlled, multi-center Two arms: DMR and sham 9 patients ~10 cm DMR No formal statistical powering 	<ul style="list-style-type: none"> Evaluate the safety and efficacy of the Revita DMR Procedure on certain glycemic endpoints 	<ul style="list-style-type: none"> The Revita DMR Procedure was generally well tolerated As agreed with the FDA, the study was prematurely ended due to the COVID-19 pandemic and subsequent authorization to proceed with the Revitalize-1 study
Revita-2. Clinical study in patients with sub-optimally controlled T2D despite being on an OAD and/or metformin Completed	<ul style="list-style-type: none"> Randomized, double-blind, crossover, sham-controlled, multi-center ~10 cm DMR Two arms: DMR and sham 108 patients 	<ul style="list-style-type: none"> Evaluate the safety and efficacy of the Revita DMR Procedure on certain T2D-related endpoints 	<ul style="list-style-type: none"> Baseline reduction of HbA1c, MRI-PDFF, HOMA-IR and weight when compared to the sham arm ($p^* < 0.05$) The Revita DMR Procedure was generally well tolerated
INSPIRE. Investigator-initiated pilot study in T2D patients on long-acting insulin Completed	<ul style="list-style-type: none"> Open-label, single-center ~15 cm DMR Single arm 16 patients 	<ul style="list-style-type: none"> Evaluate the feasibility of eliminating insulin therapy in T2D patients by combining the Revita DMR Procedure with a GLP-1 and lifestyle counseling 	<ul style="list-style-type: none"> 69%, 56% and 53% of patients at 24 weeks, 48 weeks and 72 weeks, respectively, were off insulin therapy with an HbA1c of 7.5% or less
Revita-1. Feasibility study in patients with poorly controlled T2D despite at least one OAD Completed	<ul style="list-style-type: none"> Open-label, multi-center ~9 cm DMR Single arm 46 patients 	<ul style="list-style-type: none"> Evaluate the safety and effectiveness of the Revita DMR Procedure on certain glycemic endpoints 	<ul style="list-style-type: none"> Baseline mean HbA1c reduction of 0.9% at 24 weeks ($p^* < 0.001$) Baseline mean reduction in total body weight of 3.1% sustained through two years ($p = 0.01$) The Revita DMR Procedure was generally well tolerated
Revita First-in-Human. Clinical study in patients with poorly controlled T2D despite at least one OAD Completed	<ul style="list-style-type: none"> Open-label, single-center Single arm: LS-DMR (~9 cm) and SS-DMR (~3 cm) 57 patients 	<ul style="list-style-type: none"> Evaluate the safety and feasibility of the Revita DMR Procedure over variable lengths of the duodenum 	<ul style="list-style-type: none"> Baseline mean HbA1c reduced by 2.5% at 12 weeks (LS-DMR) ($p^* < 0.05$) Baseline mean HbA1c reduced by 1.2% at 12 weeks (SS-DMR) ($p^* < 0.05$) The Revita DMR Procedure was generally well tolerated; duodenal stenosis observed in three patients with good resolution post-balloon dilation

* p-value represents the chance that the observed results occurred by chance alone. A p-value of less than 0.05 is considered statistically significant.

Key Metrics

The outcomes of our clinical studies are evaluated by a number of well-known validated glycemic metrics, including:

Glycosylated Hemoglobin (HbA1c %). HbA1c reflects average levels of blood glucose over the previous two to three months and is the most widely used clinical test to estimate mean blood glucose and monitor glycemic control.

Fasting Plasma Glucose (mg/dL or mmol/L). FPG measures the serum glucose concentration after an overnight fast of at least eight hours providing an instantaneous measure of glucose homeostasis.

Oral Glucose Tolerance Test. A oral glucose tolerance test, or OGTT, evaluates beta cell function after a patient ingests a fixed glucose solution. To perform the test, blood glucose is measured immediately prior to consumption and typically every 30 minutes two hours after consumption. Area under the curve, or AUC, OGTT is the calculation of the total excess of blood glucose measured during the course of the OGTT.

Revita Clinical Program Insights

Our Revita clinical program design has been informed by our prior clinical studies and expertise in the field of metabolic diseases, including T2D. We have evaluated the Revita DMR Procedure in over 15 clinical centers and it has been performed by more than 20 different endoscopists. We have followed most patients beyond 12 months

post-procedure to observe the long-term safety of the Revita DMR Procedure, including its effects on glucose homeostasis and weight, and, in all, we have observed over 500 patient-years of DMR procedure exposure data using Revita. Based on these experiences, we believe the Revita DMR Procedure has the potential to:

- improve glycemic control in T2D patients on insulin;
- improve glycemic control in T2D patients on one or more ADAs who are not yet on insulin;
- enable weight maintenance in patients with obesity; and
- reduce the risk of developing diabetes in patients with high-risk prediabetes

We are initially focused on developing Revita to improve glycemic control in T2D patients on insulin and plan to expand to pursue earlier indications in T2D, prediabetes, and obesity.

Ongoing Germany Real-World Registry

In April 2023, we initiated the Germany Real-World Registry, a prospective, post-market, clinical follow-up study to evaluate the Revita DMR Procedure in patients with inadequately controlled T2D. Our inclusion criteria includes patients ages 18 and over, with a baseline HbA1c between 7.0% and 10.0%, a BMI of less than or equal to 45 and on at least one ADA. The study will assess change in HbA1c, change in number of ADAs, safety and tolerability, quality of life and patient reported outcomes, and healthcare utilization expenditure over five years in patients with T2D after receiving the Revita DMR Procedure in a real-world setting.

As of January 16, 2024, we have enrolled 21 patients in the registry study and have received interim follow-up data from 14 patients. At three months post-procedure, we observed a median change in baseline HbA1c of -1.9% (9.2% to 7.3%) and a median change in baseline weight of -17.6 pounds (244.7 pounds to 227.1 pounds). Of these 14 patients, two patients discontinued all their previously prescribed ADAs. We believe these results suggest a significant overall improvement in metabolic health.

We plan to continue to enroll more patients in the Germany Real-World Registry across several centers and will continue to report on clinical, health economic, and patient-relevant outcomes from this study on an ongoing basis.

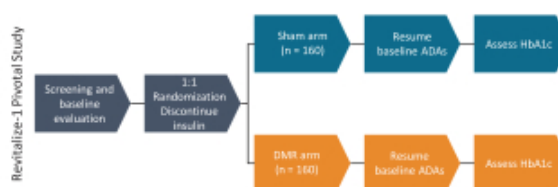
Ongoing Revitalize-1 Pivotal Clinical Study

In March 2021, we commenced Revitalize-1 (formerly known as REVITA-T2Di), a randomized, double-blind, crossover, sham-controlled, multi-center pivotal clinical study in patients with inadequately controlled T2D despite being on up to three ADAs and 20 to 100 units of insulin daily. The study is to take place across approximately 35 sites in the United States and the European Union. This pivotal clinical study is designed as a two-stage study. We plan to enroll up to 140 patients in the first stage and up to 320 patients in the second stage, with a primary endpoint at 24 weeks and a 48 week follow-up. The first stage is an open-label, single-arm study for each site to gain experience with the study protocol and the DMR procedure in two to four patients before moving into the pivotal study (i.e., stage 2) with the other patients. The clinical evaluation committee, or the CEC, will provide oversight on adequate training by the endoscopist and site readiness. Once confirmed by the CEC, the site will be opened to enrollment for the pivotal study.

The first ten patients enrolled in stage 1 of this study (consistent with an older version of our protocol) underwent a drug washout period that subsequently enrolled patients will not undergo. We plan to continue long-term follow-up of these patients in parallel with the other patients from this study. The table below depicts the Revitalize-1 clinical study design.

Revitalize-1 Pivotal Clinical Study Design (n = 320 patients)

Treatment	<ul style="list-style-type: none"> DMR or sham Outpatient, same day procedure
Population	<ul style="list-style-type: none"> Up to three ADAs Insulin (20 to 100 units/day) HbA1c: 7.5% to 10.0% BMI: >24 to <40kg/m² Age: 21 to 70 years old
Primary Endpoint	<ul style="list-style-type: none"> Change from baseline in HbA1c at 24 weeks, DMR vs. Sham
Key Secondary Endpoints	<ul style="list-style-type: none"> Percentage of patients who achieve a HbA1c of <7% at 24 weeks, DMR vs. sham Change from baseline in FPG at 24 weeks, DMR vs. sham Percentage of total body weight loss from baseline at 24 weeks, DMR vs. sham Percentage change from baseline in total daily insulin dose at 24 weeks, DMR vs. sham Percentage of patients without the need for insulin at 24 weeks, DMR vs. sham



The primary endpoint of Revitalize-1 will be the change from baseline in HbA1c (DMR vs. sham) at 24 weeks. The sham patients have the opportunity to crossover to the DMR arm at 48 weeks. A trained evaluator plans to assess all patients in the clinic post-procedure at various specified time intervals, including at four weeks, 12 weeks, 24 weeks and 48 weeks.

We expect to complete enrollment in the first half of 2024 and report topline data from the randomized phase of the study in the fourth quarter of 2024. In addition, enrolled patients and clinical investigators will remain blinded through 48 weeks, allowing an additional 24 weeks of follow-up data beyond the primary endpoint.

If Revitalize-1 is successful, we plan to file a PMA in the first half of 2025. As part of our PMA, we intend to submit the 24-week primary endpoint data and the follow-up data through 48 weeks. We have discussed this study design with the FDA, and we believe, based on correspondence with the FDA, this data may support a PMA for Revita to improve glycemic control in T2D patients who are inadequately controlled on insulin. Our decision to establish a 24-week primary endpoint to support a finding of effectiveness is based on FDA regulatory precedent for T2D drug products, including our correspondence with the FDA. In addition, we believe longer term data, including 48-week follow-up, may support claims of durable effectiveness.

If Revita is approved, longer term follow-up studies beyond 48 weeks will likely be performed as part of a PAS, including potentially studying the safety and effectiveness of repeat procedures, should they be necessary. Based on regulatory precedent, we believe a PAS may be conducted in parallel with the commercial launch of Revita.

Interim Data—Stage 1 Drug Washout (REVITA-T2Di) Cohort

The first ten patients enrolled in stage 1 of the REVITA-T2Di study (an older version of the Revitalize-1 protocol) underwent a drug washout period and a screening endoscopy. The inclusion criteria included an HbA1c of 7.5% to 9.5%, FPG of greater than or equal to 180 mg/dL to 270 mg/dL and being on metformin, long-acting insulin (20 to 60 units/day) and up to two additional ADAs. Patients were started on 10 mg of empagliflozin on day one post-procedure and increased to 25 mg (or the max tolerated dose) by day 15. One patient was found to have an intercurrent condition and was excluded at the time of endoscopy and was not treated. Nine subjects were therefore treated with Revita. All nine procedures were successfully completed across four treating centers

by five different endoscopists, including three endoscopists new to Revita as part of this study. Of the nine patients, two were not able to complete the 48-week follow-up due to discontinuations unrelated to the Revita DMR Procedure at four weeks and 23 weeks, respectively.

In the seven remaining patients, we observed a median HbA1c reduction of 1.6%, median FPG reduction of 77 mg/dL, median insulin dose reduction of 44% and median weight reduction of 9.3% at 48 weeks. Six of the seven patients reduced their insulin dose while one patient discontinued insulin completely.

In the nine treated patients, two device- or procedure-related adverse events, or DPRAEs, and three non-device or procedure-related treatment-emergent serious adverse events, or TESAEs, were reported. Of the two DPRAEs, one patient reported abdominal pain and another reported diarrhea, which are events that may also occur with routine endoscopies. The three non-device or procedure-related TESAEs reported were COVID-19, hypertension and euglycemic ketoacidosis (related to empagliflozin). The patient that was reported to have euglycemic ketoacidosis was one of the patients that discontinued the study. No device or procedure-related TESAEs or unanticipated adverse device effects, or UADEs, were reported.

Planned Remain-1 Clinical Study

We plan to initiate Remain-1, a two-part, multi-center, parallel cohort, randomized, open-label clinical study to assess weight maintenance in patients with obesity who have lost at least 10% total body weight on GLP-1RA therapy and wish to discontinue their GLP-1RA without weight regain. Part one will consist of the open-label cohort, or the Reveal-1 cohort, and part two will consist of the randomized, double-blind, sham-controlled cohort. We plan to conduct the Remain-1 study in the United States and Europe and expect to enroll up to 100 patients in the Reveal-1 cohort and 300 patients in the randomized cohort. Of the 300 patients expected in the randomized cohort, 200 will be in the DMR arm and 100 will be in the sham arm.

The primary objective of this study will be to evaluate the effectiveness of the Revita DMR Procedure on weight maintenance at 24 weeks after discontinuation of tirzepatide or semaglutide. Secondary objectives will include evaluating the effectiveness of the Revita DMR Procedure on the change in blood glucose levels, CVD risk factors and body composition. All patients enrolled in the study will receive diet and lifestyle counseling.

We expect to submit an IDE and comparable documents to the FDA and comparable foreign regulatory authorities or notified bodies in the first quarter of 2024 for a potentially pivotal Remain-1 study. If the IDE is approved, we plan to initiate the study and begin reporting updates on the Reveal-1 cohort in the second half of 2024.

Planned Revitalize-2 Pivotal Clinical Study

We plan to initiate Revitalize-2, a randomized, double-blind, sham-controlled, multi-center pivotal clinical study in patients with T2D who are inadequately controlled on two or three ADAs but not yet on insulin. The study is to take place across approximately 35 sites in the United States and 20 sites outside of the United States (with more than 50% of patients in the United States). This study is designed as a two-stage study and we plan to enroll up to 110 patients in the first stage, and up to 400 patients in the second stage, for a total of up to 510 patients.

The first stage is an open-label, single-arm study for each site to gain experience with the study protocol and the DMR procedure in patients before moving into the pivotal study (i.e., stage 2) with the other patients. Sites with previous experience performing the DMR procedure will be required to enroll one patient in stage 1, while sites that are naïve to performing the DMR procedure will be required to enroll two patients in this stage. Prior to entering stage 2, the CEC will review performance of the DMR procedure at each site and may recommend enrollment of additional patients in stage 1 at certain individual sites (maximum of two additional

patients) if needed to ensure proficiency of the DMR procedure. The table below depicts the Revitalize-2 pivotal clinical study design.

Revitalize-2 Pivotal Clinical Study Design (n = 400 patients)

Treatment	<ul style="list-style-type: none">DMR or shamOutpatient, same day procedure
Population	<ul style="list-style-type: none">Two or three ADAs, except insulin, meglitinides or sulfonylureasOngoing or discontinued GLP-1⁽¹⁾HbA1c: 8% to 10%BMI: ≥ 24 and ≤ 40kg/m²Age: 18 to 70 years old
Primary Endpoint	<ul style="list-style-type: none">Change from baseline in HbA1c at 24 weeks, DMR vs. sham
Key Secondary Endpoint	<ul style="list-style-type: none">Percentage of patients who achieve a HbA1c of $\leq 7\%$ without insulin rescue therapy at 24 weeks, DMR vs. sham



The primary endpoint will be to evaluate the efficacy of the Revita DMR Procedure on the change from baseline of HbA1c at 24 weeks. In addition, the patients and the clinical investigators will remain blinded through 48 weeks, allowing an additional 24 weeks of follow-up data beyond the primary endpoint.

The key secondary endpoint will be to evaluate the percentage of patients who achieve a HbA1c of less than or equal to 7% without insulin rescue therapy at 24 weeks.

Like the Revitalize-1 study and FDA regulatory precedent for T2D drug products, we have established a 24-week primary endpoint for the Revitalize-2 study. Further, we plan to keep patients blinded through 48 weeks to allow blinded and controlled safety and effectiveness assessments at 48 weeks. Based on feedback we obtained from the FDA regarding the primary endpoint of the Revitalize-2 study, we believe the FDA may seek an assessment of effectiveness at 48 weeks to better understand the durability of the Revita DMR Procedure as part of a PMA. We intend to discuss durability assessments at 48 weeks further with the FDA. If the Revitalize-2 study is completed subsequent to a potential Revita PMA approval pursuant to the Revitalize-1 study, we plan to use the data from Revitalize-2 to file for an expanded label as part of a PMA supplement.

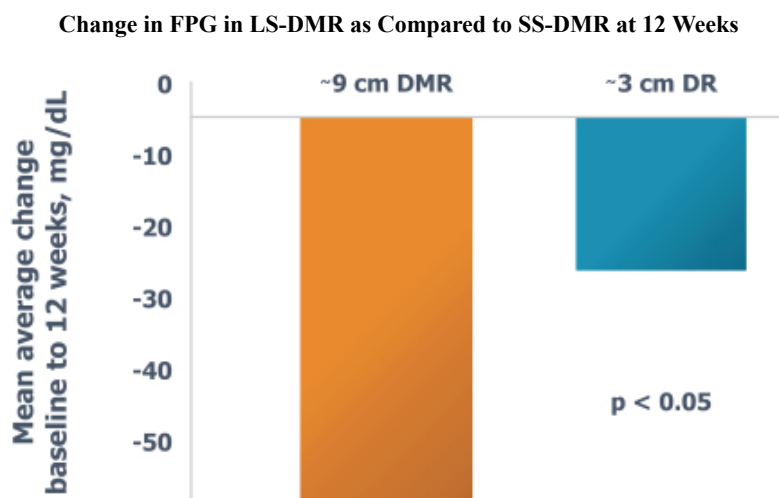
We plan to initiate the Revitalize-2 study after the Remain-1 study is complete.

Revita First-in-Human Clinical Study

In 2013, we initiated the Revita FIH clinical study in 39 T2D patients. Our inclusion criteria included patients ages 28 to 75, with a baseline HbA1c between 7.5% and 12%, a BMI between 24 and 40, documentation of preserved pancreatic function (as defined by a fasting C-peptide value of greater than or equal to 1 ng/mL), on at least one stable OAD for a minimum of three months and a T2D diagnosis within the past ten years. Patients either received long-segmented ablation (mean length ablated: 9.3 cm), or LS-DMR, or short-segmented ablation (mean length ablated: 3.4 cm), or SS-DMR. The open-label feasibility study took place in Santiago, Chile and was conducted to evaluate the safety and feasibility of the Revita DMR Procedure over variable lengths of the duodenum. All patients were assessed in the clinic by a trained evaluator post-procedure at various specified time intervals, including at four weeks, 12 weeks and 24 weeks.

This study was designed as a single-arm, open-label feasibility study. The Revita DMR Procedure was observed to be feasible and generally well tolerated, with ablations performed in escalating lengths of the duodenum ranging from 3 cm to 9 cm in length. Exploratory endpoints evaluated included, among others, the baseline mean change of HbA1c and baseline mean change of FPG. We observed that the patients who received LS-DMR had a statistically significant 2.5% reduction in baseline mean HbA1c at 12 weeks post-procedure as

compared to 1.2% for the patients who received SS-DMR ($p < 0.05$). At 24 weeks post-procedure, similar baseline mean HbA1c reduction of 1.4% and 0.7% were observed in the LS-DMR and SS-DMR cohorts, respectively, with a statistically significant overall baseline mean HbA1c reduction of 1.2% at 24 weeks in the full cohort (LS-DMR and SS-DMR) ($p < 0.001$). Early and sustained improvement in FPG was also observed among the full cohort, as depicted in the graph below.



The Revita DMR Procedure was observed to be generally well tolerated, with mostly mild and transient GI symptoms. Three patients experienced duodenal stenosis that required an endoscopic balloon dilation with good resolution. We observed no GI bleeds, infection, pancreatitis, or evidence of malabsorption or significant hypoglycemia.

Revita-1 Feasibility Study

In 2015, we initiated an open-label, multi-center feasibility study in 46 patients. Our inclusion criteria included patients ages 28 to 75, with a baseline HbA1c between 7.5% and 11%, a BMI between 24 and 40 kg/m², on at least one stable OAD for a minimum of three months and had a T2D diagnosis within the past ten years. The study took place across multiple sites in Europe and South America, and was conducted to evaluate the safety and effectiveness of the Revita DMR Procedure on certain glycemic endpoints. Patients either underwent a dual-catheter DMR or single-catheter DMR procedure of nine to ten centimeters and were stratified into the safety population (n=46) or PP population (n=34). All patients were assessed in the clinic by a trained evaluator post-procedure at various specified time intervals, including at four weeks, 12 weeks, 18 weeks and 24 weeks. In addition, we conducted a long-term follow-up study of the PP population through 24 months.

The primary endpoint of the study was to evaluate the baseline mean reduction of HbA1c at 24 weeks. We observed a statistically significant absolute baseline mean HbA1c reduction of 0.9% in the PP population at 24 weeks ($p \leq 0.001$). In addition, we observed a statistically significant baseline mean HbA1c mean reduction of 0.8% and 1.0% in the dual-catheter patients and the single-catheter patients, respectively, in the PP population ($p \leq 0.001$ for both). We also observed a statistically significant absolute baseline mean HbA1c reduction of 1.0% in the PP population at 48 weeks ($p \leq 0.001$).

Secondary endpoints included, among others, baseline mean reduction of FPG, insulin resistance and weight. We also conducted post-hoc analyses of the baseline mean reduction of ALT and AST at 24 weeks. To quantify the reduction in insulin resistance, we used the Homeostatic Model Assessment of Insulin Resistance, or

HOMA-IR. This model is able to quantify insulin resistance by evaluating a patients FPG and insulin levels. The table below depicts our observations of these secondary endpoints, including the ALT and AST post-hoc evaluations, at 24 and 48 weeks.

Measurement	Baseline	24 Weeks	24 Week Difference	P-Value*	48 Weeks	48 Week Difference	P-Value*
FPG (mmol/L)	10.7 ± 0.4	9.0 ± 0.4	-1.7 ± 0.5	≤ 0.001	8.9 ± 0.4	-1.8 ± 0.5	≤ 0.001
HOMA-IR	8.2 ± 1.0	5.2 ± 0.8	-2.9 ± 1.1	0.007	4.9 ± 0.6	-3.3 ± 0.9	≤ 0.001
Weight (kg)	90 ± 2	88 ± 2	-2 ± 1	≤ 0.001	88 ± 2	-2 ± 1	≤ 0.001
ALT (IU/L)	40 ± 2	31 ± 1	-8 ± 3	0.016	30 ± 1	-9 ± 3	≤ 0.001
AST (IU/L)	28 ± 2	23 ± 1	-5 ± 2	0.002	22 ± 1	-6 ± 1	≤ 0.001

* P-values resulting from ANOVA repeated measurement analysis with Bonferroni correction

In the long-term follow-up study of the PP population, we observed statistically significant mean changes of HbA1c, FPG and weight. Out of the 34 patients in the PP population, seven patients discontinued follow-up in the HbA1c analysis and six patients discontinued follow-up in the FPG and weight loss analysis prior to the 24-month check-in. The table below depicts our observations in the long-term follow-up study of the PP population at 24 months.

Measurement	Baseline	24 Months	P-Value*
HbA1c	8.5 ± 0.7	7.5 ± 1.1(n=27)	0.034
FPG (mg/dL)	198.4 ± 41.2	165.9 ± 0.9(n=28)	< 0.001
Weight** (kg)	88.9 ± 11.8	-3.1 ± 6.0(n=25)	0.010

* P-values resulting from ANOVA repeated measurement analysis with Bonferroni correction
 ** Raw change

No UADEs or device-related SAEs were reported. Three device-related events occurred in one subject, including two reports of abdominal pain and one report of nausea on the first day after the procedure. Each device-related event was resolved with medication. There were a total of ten SAEs reported in seven patients, one of which was considered procedure-related. The single procedure-related SAE occurred in a single-catheter patient where the patient experienced a mildly elevated body temperature and an increase in C-reactive protein. The investigator elected to keep the patient in the hospital overnight for observation, which made the event an SAE. This event was determined to be not device-related.

The other SAEs reported were patient specific and determined to not be device-related. For example, one patient experienced SAEs from a new diagnosis of lung cancer and died approximately 11 months post-procedure. Overall, the Revita DMR Procedure was observed to be generally well tolerated in the full cohort.

Revita-2 Clinical Study

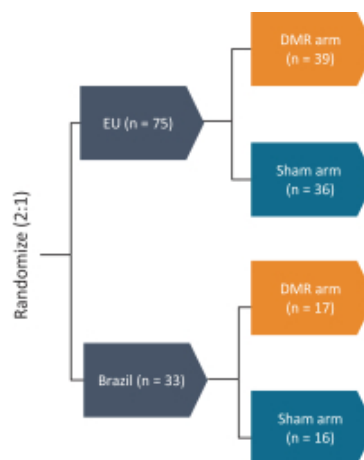
In March 2017, we initiated a randomized, double-blind, crossover, sham-controlled clinical study in 108 patients with sub-optimally controlled T2D despite being on OADs and/or metformin across multiple sites in Europe and Brazil. The study was conducted to evaluate the safety and efficacy of the Revita DMR Procedure, as measured by certain T2D-related endpoints. The primary endpoints of the study were to evaluate the baseline change of HbA1c at 24 weeks and the absolute baseline change of proton density fat fraction (a validated biomarker used to quantify liver fat) through magnetic resonance imaging, or MRI-PDFF, at 12 weeks (mITT). Secondary endpoints included, among others, (i) the absolute baseline change of MRI-PDFF in patients with a baseline MRI-PDFF of greater than 5%, indicating NAFLD or NASH, (ii) the absolute change of MRI-PDFF in patients with a baseline FPG of 180 mg/dL or greater, (iii) reduction in insulin resistance and (iv) weight loss.

All patients initially went through a 4-week run-in period to confirm lack of blood glucose control in conjunction with medication compliance and nutritional counseling. Patients then either underwent the DMR procedure or the sham procedure. The dosage of each patient’s OADs was held constant from the start of the run-in period through week 24. All patients were assessed in the clinic by a trained evaluator post-procedure at various specified time intervals, including at four weeks, 12 weeks, 18 weeks and 24 weeks. The table below depicts the Revita-2 clinical study design.

Revita-2 Clinical Study Design (n = 108 patients)

Treatment	<ul style="list-style-type: none"> DMR or sham Outpatient, same day procedure
Population	<ul style="list-style-type: none"> OADs and/or metformin⁽¹⁾ HbA1c: 7.5% to 10% Fasting insulin > 7.0 µU BMI: >24 to ≤40kg/m² Age: 28 to 75 years old
Primary Endpoint	<ul style="list-style-type: none"> Baseline change of HbA1c at 24 weeks, DMR vs. sham Absolute baseline change of MRI-PDFF at 12 weeks, DMR vs. sham (mITT)
Key Secondary Endpoints	<ul style="list-style-type: none"> Baseline change of MRI-PDFF at 12 weeks, DMR vs. sham Reduction of HOMA-IE at 24 weeks, DMR vs. sham Weight loss at 24 weeks, DMR vs. sham

(1) No changes in medications in 12 weeks prior to study entry



In the overall study, we observed an HbA1c reduction of 1.0% in DMR group as compared to 0.7% in sham group, and an MRI-PDFF reduction of 5.4% in DMR group as compared to 2.9% in sham group. A pre- specified test of heterogeneity in the statistical analysis plan led to the separation of the analyses of the Brazilian and European modified intention-to-treat, or mITT, and PP populations. This separation was due to (i) the lack of homogeneity between the populations identified by our statistical analysis plan, (ii) key clinical observations demonstrating the Brazilian population had implausible large improvements in glucose control and weight, including patients in the sham arm, which was inconsistent with results observed in the European sham patients, (iii) independent on-site audits in Brazil showed key differences compared to Europe in the documentation of use of medications (changes in medications) and more intensive glucose monitoring and nutritional guidance, and (iv) other post-hoc statistical analyses confirming key differences in the two populations.

Both HbA1c and MRI-PDFF primary endpoints were met in the European population and demonstrated statistically significant superiority of DMR as compared to sham.

European Population Results

We observed a 0.60% baseline mean reduction of HbA1c at 24 weeks in the mITT European DMR arm (n=38), which was statistically significantly greater than the 0.30% reduction observed in the mITT European sham arm (n=33; p=0.033). In the PP European DMR arm (n=32), we observed a 0.8% baseline mean reduction of HbA1c at 24 weeks, which was statistically significantly greater than the 0.3% reduction observed in the PP European sham arm (n=32; p=0.004). We observed a 5.4% absolute baseline median reduction of MRI-PDFF in the mITT European DMR arm (n=30) and the PP European DMR arm (n=28) at 12 weeks for these patients, which was statistically significantly greater than the 2.2% reduction observed in the mITT European sham arm (n=30; p=0.035) and the 2.2% reduction observed in the PP European sham arm (n=28; p=0.011).

Secondary endpoints included, among others, (i) the baseline change of MRI-PDFF in patients with a baseline MRI-PDFF of greater than 5%, indicating NAFLD or NASH, at 12 weeks, (ii) reduction in insulin

resistance (HOMA-IR) at 24 weeks and (iii) weight loss at 24 weeks. At 12 weeks post-procedure, we observed a 32.1% median reduction of MRI-PDFF in the European DMR arm, which was statistically significantly greater than the 17.9% reduction observed in the European sham arm (p=0.020). We observed a 1.3 median reduction of HOMA-IR in the mITT European DMR arm (n=33) and the PP European DMR arm (n=31) at 24 weeks, which was significantly greater than the 0.4 reduction observed in the mITT European sham arm (n=25; p=0.060) and the 0.4 reduction observed in the PP European sham arm (n=25; p=0.047). In addition, we observed a statistically significant median weight loss of 2.4 kg in the mITT European DMR arm (n=38) as compared to a median weight loss of 1.4 kg in the mITT European sham arm (n=34; p=0.012) at 24 weeks. In the PP European DMR arm (n=35), we observed a statistically significant median weight loss of 2.5 kg as compared to a median weight loss of 1.4 kg in the PP European sham arm (n=34; p=0.005).

Brazilian Population Results

The results we observed in the Brazilian population were similar to those seen in the European population, except for the MRI-PDFF endpoint. We observed a greater reduction of HbA1c, HOMA-IR and weight in the Brazilian DMR arm as compared to the Brazilian sham arm at 24 weeks. These results were not statistically significant due to the small sample size of the Brazilian population and the separation of these populations as discussed above. Because of the small sample size of the Brazilian population and the findings of the audit, these results should be interpreted with caution.

Adverse Events

No UADEs or device-related SAEs were reported. Adverse event of special interest, or AESI, rates were comparable between the DMR and sham arms. In the Brazilian population, 11.8% of the randomized DMR patients experienced SAEs, all of which were considered to be related to the study procedure and not Revita. In addition, there were no clinical or laboratory signs of adverse events related to malabsorption, anemia, pancreatitis, biliary complications, or infection reported. The table below depicts the AEs observed in the study, separated by European and Brazilian sites, as part of the analyses described above.

	Europe						Brazil					
	DMR n=39			Sham n=37			DMR n=17			Sham n=16		
	# of events	n (%)	95% CI	# of events	n (%)	95% CI	# of events	n (%)	95% CI	# of events	n (%)	95% CI
<i>Summary (through 24 weeks post treatment)</i>												
SAE	0	0	(0.0 to 9.0)	0	0	(0.0 to 9.5)	3	2 (11.8)	(1.5 to 36.4)	0	0	(0.0 to 20.6)
UADE	0	0	(0.0 to 9.0)	0	0	(0.0 to 9.5)	0	0	(0.0 to 19.5)	0	0	(0.0 to 20.6)
AESI	19	13 (33.3)	(19.1 to 50.2)	16	10 (27.0) (13.8 to 44.1)	74	12 (70.6)	(44.0 to 89.7)	76	10 (62.5)	(35.4 to 84.8)	
<i>Most common (>5%) AESI by preferred term (<30 days post treatment)</i>												
Abdominal pain	9	7 (17.9)	(7.5 to 33.5)	2	2 (5.4)	(0.7 to 18.2)	6	5 (29.4)	(10.3 to 56.0)	2	2 (12.5)	(1.6 to 38.4)
Diarrhea	1	1 (2.6)	(0.1 to 13.5)	2	2 (5.4)	(0.7 to 18.2)	1	1 (5.9)	(0.2 to 28.7)	1	1 (6.3)	(0.2 to 30.2)
Nausea	1	1 (2.6)	(0.1 to 13.5)	0	0	(0.0 to 9.5)	2	2 (11.8)	(1.5 to 36.4)	0	0	(0.0 to 20.6)
Vomiting	1	1 (2.6)	(0.1 to 13.5)	0	0	(0.0 to 9.5)	1	1 (15.9)	(0.2 to 28.7)	0	0	(0.0 to 20.6)
Hypoglycemia	3	3 (7.7)	(1.62 to 20.9)	3	2 (5.4)	(0.7 to 18.2)	11	6 (35.3)	(14.2 to 61.7)	21	7 (43.8)	(19.8 to 70.1)
<i>Most common (>5%) AESI by preferred term (>30 days post treatment)</i>												
Abdominal pain	1	1 (2.6)	(0.1 to 13.5)	2	2 (5.4)	(0.7 to 18.2)	0	0	(0.0 to 19.5)	0	0	(0.0 to 20.6)
Hypoglycemia	1	1 (2.6)	(0.1 to 13.5)	4	2 (5.4)	(0.7 to 18.2)	53	5 (28.4)	(10.3 to 56.0)	52	8 (50.0)	(24.7 to 75.4)

INSPIRE Pilot Study

In 2017, van Baar et al. initiated an open-label, single-center pilot study in 16 patients with T2D on guideline-directed long-acting insulin. The study took place in the Netherlands and was conducted to evaluate the feasibility of eliminating insulin therapy in T2D patients by combining the Revita DMR Procedure with a GLP-1 and lifestyle counseling, including a tailored diet. All patients were assessed in the clinic by a trained evaluator post-procedure at various specified time intervals, including at 6 months, 12 months and 18 months, and the results of this study were published in *Gastrointestinal Endoscopy*. The table below depicts the INSPIRE pilot study design.

Treatment	<ul style="list-style-type: none">• DMR• Outpatient, same day procedure• Add GLP-1⁽¹⁾
Population	<ul style="list-style-type: none">• Long-acting insulin⁽²⁾• HbA1c: ≤ 8%• C-reactive peptide: ≥ 0.5 ng/mL• BMI: ≥ 28 and ≤ 40 kg/m²• Age: 25 to 75 years old
Primary Endpoint	<ul style="list-style-type: none">• Percentage of patients free of insulin therapy through 6 months with HbA1c ≤ 7.5% at 6 months
Key Secondary Endpoints	<ul style="list-style-type: none">• Baseline reduction of HbA1c, HOMA-IR and weight at 6 months

(1) Insulin therapy discontinued immediately after DMR procedure

(2) Liraglutide, an FDA-approved GLP-1RA, was introduced two weeks post-procedure with a stepwise dose increase to 1.8 mg/day or the max tolerated dose

The primary endpoint of the pilot study was the percentage of patients free of insulin therapy through 6 months with an HbA1c less than or equal to 7.5% at 6 months. Investigators observed 69% of patients were free of insulin therapy with an HbA1c less than or equal to 7.5% at 6 months. This result was not statistically significant.

Secondary endpoints were the changes in multiple glycemic and metabolic parameters and the percentage of patients free of insulin with an HbA1c less than or equal to 7.5% at 12 and 18 months, respectively. Out of the 16 patients enrolled, one discontinued follow-up prior to the 18-month check-in. The table below depicts the secondary endpoint observations.

Measurement	Baseline	12 Months	P-Value	18 Months	P-Value
<i>Glycemic parameters</i>					
Patients off insulin	0 (0)	9 (56)		8 (53)*	0.0008
HbA1c	7.5 (7.1-7.9)	7.3 (6.6-8.2)	0.690	7.1 (6.6-7.5)	0.208
HOMA-IR	8.4 (4.3-12.0)	3.8 (2.4-7.9)	0.015	3.9 (2.0-6.0)	0.006
FPG (mmol/L)	10.1 (8.9-12.0)	7.1 (6.6-9.5)	0.006	7.3 (6.7-8.4)	0.011
Fasting insulin (pmol/L)	104 (49-178)	71 (45-121)	0.116	63 (34-110)	0.036
Fasting C-peptide (nmol/L)	0.63 (0.55-0.91)	0.58 (0.39-0.70)	0.224	0.46 (0.39-0.59)	0.245
<i>Metabolic parameters</i>					
Weight (kg)	87.8 (80.2-99.7)	80.8 (73.2-95.8)	0.001	80.7 (73.8-96.8)	0.001
BMI (kg/m ²)	28.8 (26.5-31.7)	27.7 (23.4-30.1)	0.001	26.4 (23.5-30.2)	0.001
MRI-PDFF**	8.1 (4.0-13.5)	5.6 (2.8-10.9)	0.035		

* One patient did not agree to continue follow-up to 18 months

** MRI-PDFF was known in 15 of 16 patients

We believe this study demonstrated that a single Revita DMR Procedure in combination with GLP-1 and lifestyle counseling, may eliminate the need for insulin therapy in T2D patients while improving glycemic control and overall metabolic health.

U.S. Pilot Study

In March 2019, we initiated a randomized, double-blind, crossover, sham-controlled pilot study. Our inclusion criteria included patients ages 28 to 65, with a baseline HbA1c between 7.5% and 9.5%, a BMI between 28 and 40 kg/m² and were on metformin in combination with one to two additional OADs across multiple sites in the United States. The doses of two of the OADs must have been at least half the maximum labeled dose (or highest tolerated) with no changes in medication in the 12 weeks prior to screening. The plan was to randomize 18 patients in a 2:1 ratio in favor of DMR. However, as discussed and agreed with FDA, the study was prematurely ended in July 2020 due to the COVID-19 pandemic and subsequent approval of the Revitalize-1 trial.

In total, nine patients were enrolled in this study and one patient randomized to the DMR arm received the sham procedure, which was considered a major protocol violation. The primary objective of the study was to evaluate the feasibility and safety of the Revita DMR Procedure. As a pilot evaluation, no statistical or powering assumptions were developed and implemented regarding the efficacy evaluation. Unblinding occurred at week 24 and sham treatment arm subjects who accepted the offer to crossover received DMR treatment and were followed for an additional 24 weeks.

All patients initially went through a 4-week run-in period to assess the stability of glycemic control in conjunction with medication compliance and diet and exercise counseling. Patients then either underwent the

DMR procedure or the sham procedure. The dosage of each patients OADs was held constant from the start of the run-in period through week 24. All patients were assessed in the clinic by a trained evaluator post-procedure at various specified time intervals, including at four weeks, 12 weeks, 18 weeks, and 24 weeks.

The primary endpoint of the study was to evaluate the change in baseline HbA1c at 24 weeks as compared to sham using descriptive statistics. Baseline was defined as the last observation recorded prior to the DMR or sham procedure. We observed endpoint data in only three patients because of the onset of the COVID-19 pandemic. In those three patients, a 0.33% baseline mean reduction of HbA1c at 24 weeks in the DMR arm was observed as compared to a 0.70% baseline mean reduction of HbA1c at 24 weeks in the sham arm. In addition, we observed a 0.80% baseline mean reduction of HbA1c at 18 weeks in the three crossover patients.

Due to the small sample size of this study, we were not able to draw any firm conclusions from the data presented above.

No SAEs, UADEs or TEAEs were reported. Incidents of AESIs, such as hypoglycemia and GI-related complications, were similar between the DMR and sham arms. Device-related TEAEs were reported at a lower incidence in the DMR arm, including the crossover patient, as compared to the sham arm. Each of the device-related TEAEs in the DMR arm, including diarrhea, oropharyngeal pain, abdominal distension, nausea and pyrexia, were also reported in the sham arm, except for nausea and fever.

Preclinical Studies Overview: Revita

We have evaluated the duodenum's role in glucose homeostasis in multiple preclinical studies, including a proof-of-concept study and large animal, human-excised tissue and human cadaveric studies. Taken together, we believe these studies provided support for the feasibility and safety of the Revita DMR Procedure before proceeding to human clinical studies.

Preclinical Studies: Proof-of-Concept

We conducted a preclinical study in a Goto-Kakizaki, or GK, rat model of T2D to evaluate whether selective removal of the duodenal mucosa may improve glucose homeostasis. The GK rat model was selected because it has been validated in bariatric surgical procedures to replicate human post-surgical improvement in glucose parameters. Due to the limitations of rat anatomy, the study was performed using abrasion rather than ablation. With a new catheter abrasion tool, rats were sedated, instrumented and had the first ten centimeters of their intestinal mucosa abraded. We observed that the abrasion of the intestinal mucosa resulted in a 34% improvement in AUC-OGTT blood glucose control (n=9) compared to sham-operated rats (n=5).

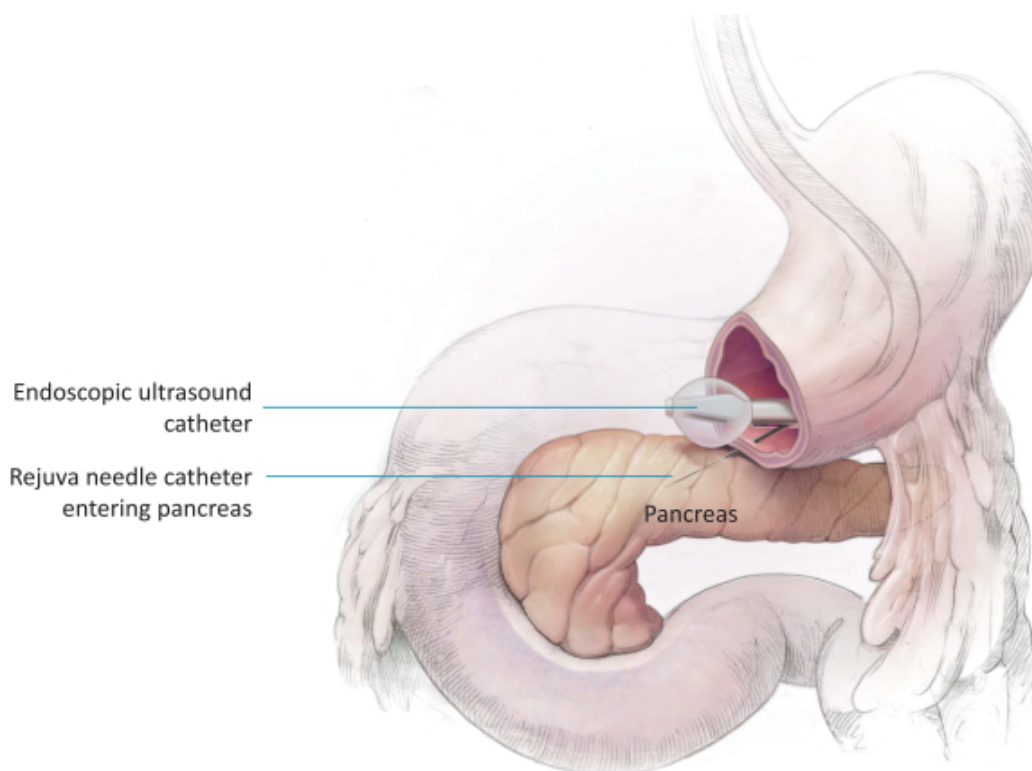
Preclinical Studies: Feasibility and Safety

We conducted preclinical studies in large animals, human-excised duodenal tissue and human cadavers to evaluate whether the Revita DMR Procedure may be feasible and tolerated in humans. Large animal studies were performed in Yorkshire pigs to assess the tolerability, feasibility and timeline of tissue healing following the DMR procedure. Human-excised duodenal tissue studies were performed to assess the feasibility of the Revita DMR Procedure in patients, which requires independent verification because of the anatomical differences in the duodenum between humans and animals. Lastly, human cadaveric studies were performed to interrogate catheter delivery and procedure development.

Rejuva Platform Description

Rejuva is a modular, physiologic gene therapy platform with three key elements designed to enable successful pancreatic gene therapy: (1) a proprietary delivery catheter designed to enable local, low dose therapeutic delivery directly to the pancreas via endoscopic access, (2) vectors with tropism for the pancreatic islet to enable successful transduction and gene delivery with limited biodistribution via this route of

administration, and (3) transgenes with tissue-restricted promoters and metabolically active peptides that can durably impact glucose and weight control. Rejuva is designed to directly administer a gene therapy into the pancreas with both mechanical and molecular confinement of the therapeutic candidate with local administration and tissue-specific promoters. The first gene therapy candidate for Rejuva will be a locally administered AAV9 viral vector with a GLP-1 receptor agonist transgene that expresses a GLP-1 hormone from the insulin promoter.



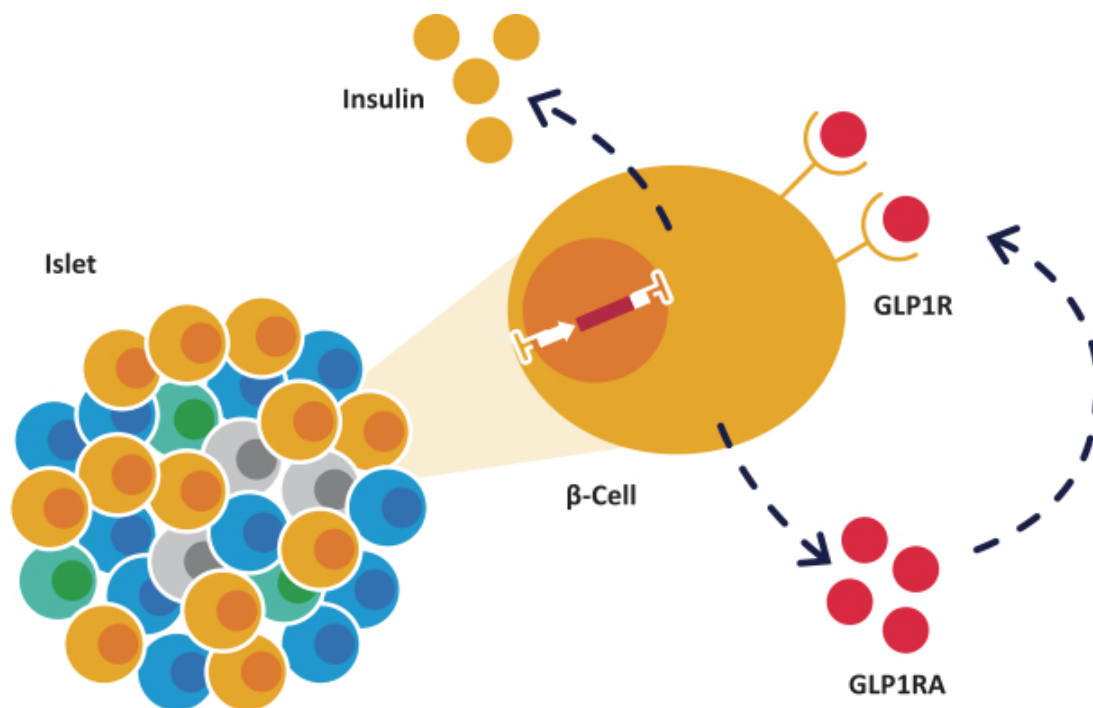
Rejuva Device Overview

The Rejuva catheter leverages (i) the Revita console that houses our proprietary technology and software, and (ii) a single-use Rejuva PGTx catheter. The console's touchscreen-based graphical user interface is designed to provide ease-of-use and clear guidance on the performance and progress of the procedure to the physician. The console houses sensors that are designed to monitor volume, pressure and flow rate of the delivery of the gene therapy candidates. We believe the console enables a targeted delivery process by enabling a proprietary safety mechanism that controls the parameters of delivery that are required to ensure minimal disruption to the pancreatic tissue, and potentially reduces the risk of physician error by automating certain steps of the treatment process by guiding the physician step-by-step through the procedure. The Rejuva catheter is composed of a narrow-gauge needle catheter that can be delivered through the working channel of a standard endoscopic ultrasound in which needle size, bevel shape, and aperture are designed to minimize risk of injury to the pancreas upon needle insertion.

Rejuva Drug Overview

The Rejuva drug platform is designed to be a modular, interchangeable platform composed of delivery vectors with high tissue tropism for the pancreatic islet and tissue-restricted promoters confining metabolically active transgene expression to islet cells. The first gene therapy candidate for Rejuva will be a locally administered, non-replicating

AAV9 viral vector with GLP-1 transgene under the control of a beta-cell specific promoter, an optimized human insulin promoter sequence. Our GLP-1 PGTx candidates are designed to express GLP-1 specifically in beta cells in a manner that will allow beta cells to produce, package, and secrete GLP-1 hormone in a similar method to insulin. In this way, the GLP-1 transgene product can act within the pancreatic islet on adjacent alpha and beta cells to augment local GLP-1 receptor activation and signaling. Because of this local expression, our GLP-1 PGTx candidates are designed to improve beta-cell health and function and thereby provide glycemic control while minimizing the side effects of systemic exposure to GLP-1RA. We believe our GLP-1 PGTx candidates will be a single administration with the potential to provide long-term metabolic benefits, even after therapy is discontinued, because the turnover rate of human beta cells is thought to be very low in adults. As such, AAV has already demonstrated durable persistence in the pancreas of rodents beyond a year with no observed decline in transgene signal.



Delivery Overview

Our Rejuva PGTx candidates are locally administered using a proprietary needle catheter that is uniquely designed for pancreas delivery in an outpatient, endoscopic procedure that may last less than thirty minutes. The procedure is performed by a trained endoscopist while the patient is under conscious sedation or general anesthesia. With the help of the Revita console, certain steps of the procedure are designed to be highly automated, which we believe minimizes the risk of physician error.

The procedure involves inserting the distal end of the single-use Rejuva catheter through the working channel of an endoscopic ultrasound imaging device and into the stomach. Ultrasound will be used to direct needle placement to the body and tail of the pancreas after identifying the pancreatic duct and other key anatomical structures. The needle is then advanced into the distal pancreas. The physician will confirm needle placement before enabling a precise dose of the drug candidate to be delivered into the pancreas by an automated syringe pump system in the console. During the administration, the console will measure the pressure and flow rate of the delivered fluid to prevent injury to the tissue and monitor the volume of delivery to control the precise dose of administration. A favorable benefit-risk profile of the device delivery can be enabled by directing the

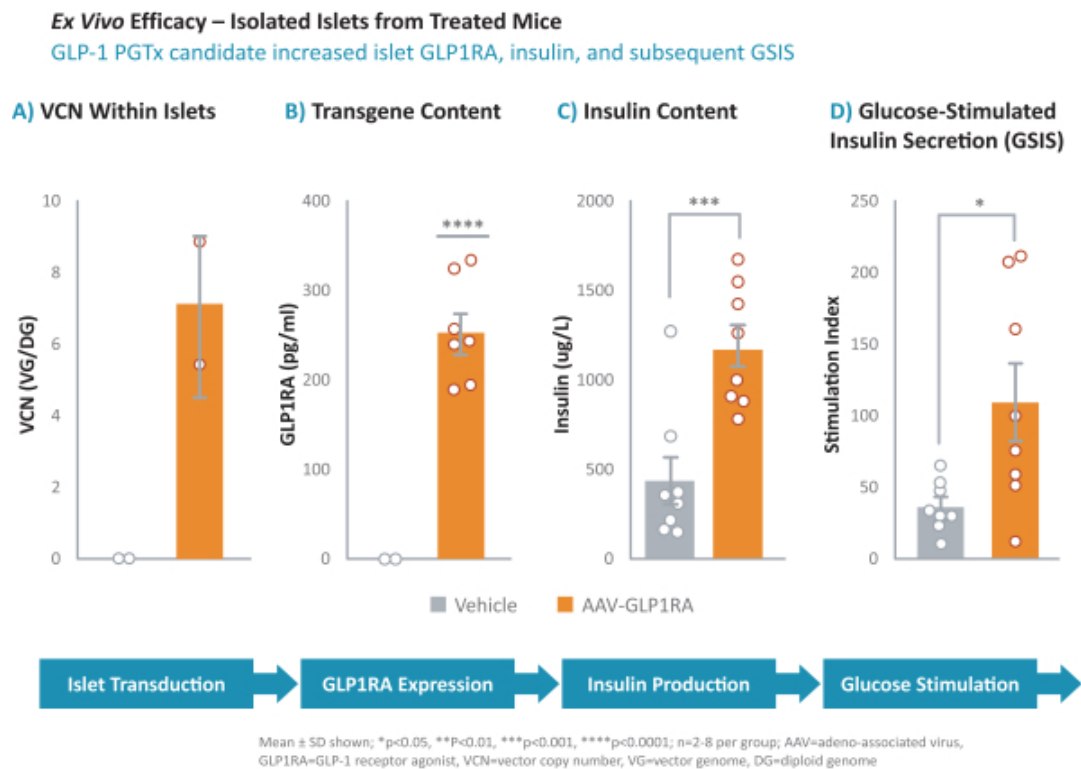
needle toward the body and tail of the pancreas, where a majority of pancreatic islets reside, and by avoiding the pancreatic duct in the head of the pancreas, where the risk of procedural pancreatitis would be higher.

Preclinical Data Overview: Rejuva Gene Therapy Platform

We have evaluated potential GLP-1 PGTx candidates in large and small animal studies. In survival studies in over 50 large animals, we have observed 100% technical success with our Rejuva device using our proposed clinical route of administration with no device-related adverse events observed thus far. In small animal pharmacology studies, we observed that our potential GLP-1 PGTx candidates were generally well tolerated, improved glycemic control, delayed T2D progression and reduced weight compared to vehicle or control and semaglutide. Given the data observed in our preclinical studies thus far, we believe that our Rejuva gene therapy candidates have the ability to provide clinical benefit in T2D and obese patients who currently have limited treatment options that provide long-term benefit even after treatment discontinuation.

Preclinical Studies: Proof-of-Concept

We have conducted multiple proof-of-concept studies with GLP-1 PGTx candidates consisting of AAV-delivered transgenes carrying an insulin promoter driving GLP-1RA sequences in *in vitro*, *ex vivo* human islets, *ex vivo* mouse islets, and *in vivo* survival studies in a *db/db* mouse model of T2D and obesity. In *db/db* mice 10 weeks after a single administration of a GLP-1 PGTx candidate, we observed dose-dependent expression of the GLP-1RA protein in whole pancreas explants and in isolated islets from animals sacrificed at that time point. Isolated pancreatic islets from treated mice grown *ex vivo* demonstrated increased insulin content and improved glucose-stimulated insulin secretion (as depicted in the image below), or GSIS, a hallmark of improved beta cell function.

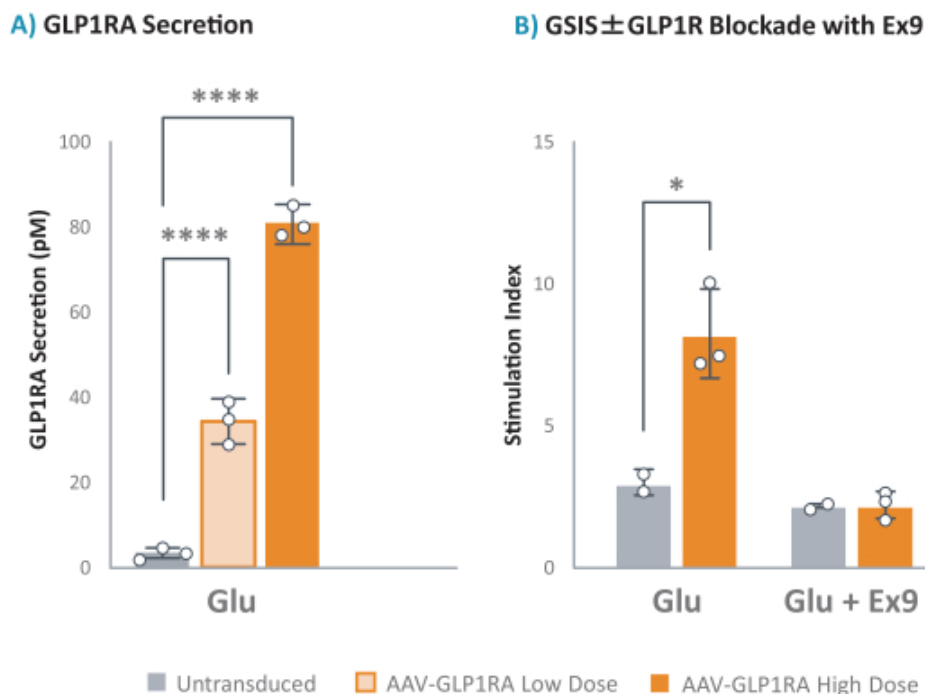


In the human EndoC-BH5 beta cell line, a GLP-1 PGTx candidate demonstrated dose-dependent increases in GLP-1RA secretion into the cell supernatant and improved GSIS. The improvement in GSIS was

blocked by the administration of a GLP-1 receptor antagonist (exendin-9), demonstrating that improvements to beta cell function by the GLP-1 PGTx candidate were achieved through GLP-1 receptor binding and activation (as depicted in the image below).

In Vitro Efficacy Proof-of-Concept in Human β -cell Line

GLP-1 PGTx candidate demonstrated GLP1RA protein secretion and improved β -cell function



Mean \pm SEM shown; * p <0.05, **** p <0.0001; n =2-3 per group. AAV=adeno-associated virus, Ex9=Exendin-9, GLP1RA=GLP-1 receptor agonist, Glu=glucose

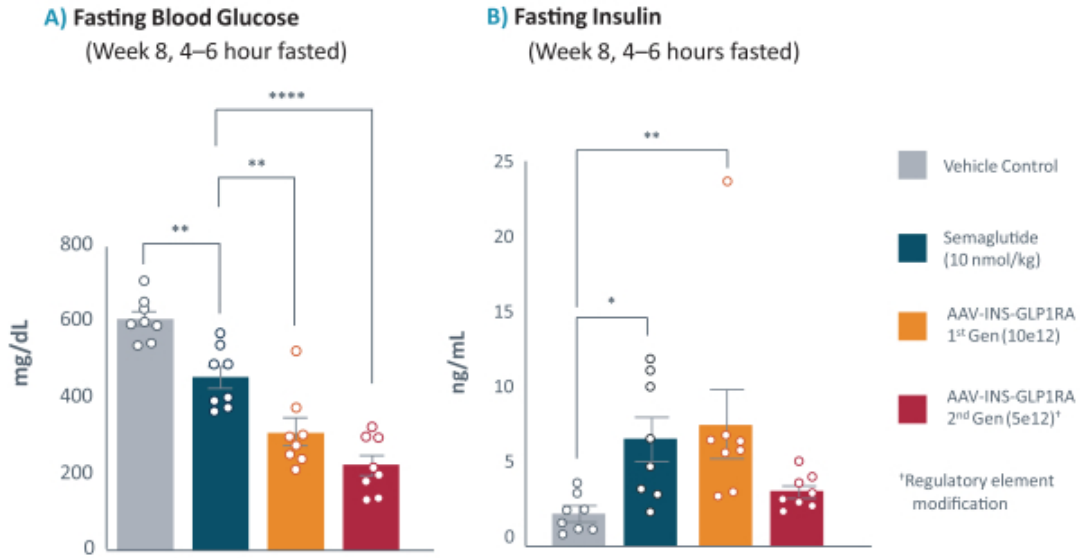
In *ex vivo* human islets, a GLP-1 PGTx candidate demonstrated dose-dependent transduction of up to 25% of beta cells within islets along with a doubling of GSIS. Taken together, we believe the results from EndoC-BH5 and healthy (non-diseased) human islets indicate that GLP-1 PGTx candidates have the potential to successfully transduce human beta cells and improve beta cell function even in healthy, non-diseased islets.

In proof-of concept preclinical *in vivo* studies in a *db/db* mouse model, we evaluated escalating doses of GLP-1 PGTx candidates in glucose lowering potency compared to vehicle. We observed dose-dependent improvements in FPG that were sustained for 64 days after a single administration of a GLP-1 PGTx candidate compared to vehicle control, along with sustained increases in fasting insulin at the same time point. We believe these results indicate that GLP-1 PGTx candidates have the potential to improve glucose control and beta cell insulin production and secretion in a durable manner.

In a head-to-head preclinical *in vivo* study in a *db/db* mouse model, we evaluated two GLP-1 PGTx candidates compared to semaglutide. We observed a statistically significant average reduction of FPG of 50.9% (p <0.0001) at eight weeks, a non-statistically significant decrease in fasting insulin of 48.6% (p =0.374) during a glucose tolerance test at eight weeks and a statistically significant decrease in total body weight of 19.6% (p <0.0001) at four weeks after a single administration of a GLP-1 PGTx candidate compared to semaglutide

10 nmol/kg administered daily. Based on this data, we believe this study suggests that a single administration of a GLP-1 PGTx candidate can achieve greater improvements in blood glucose control and weight loss and delayed T2D progression in *db/db* mice compared to semaglutide (as depicted in the images below).

Head-to-Head Study: Glucose Lowering in *db/db* Mouse
 GLP-1 PGTx candidate improved fasting glucose vs. daily semaglutide

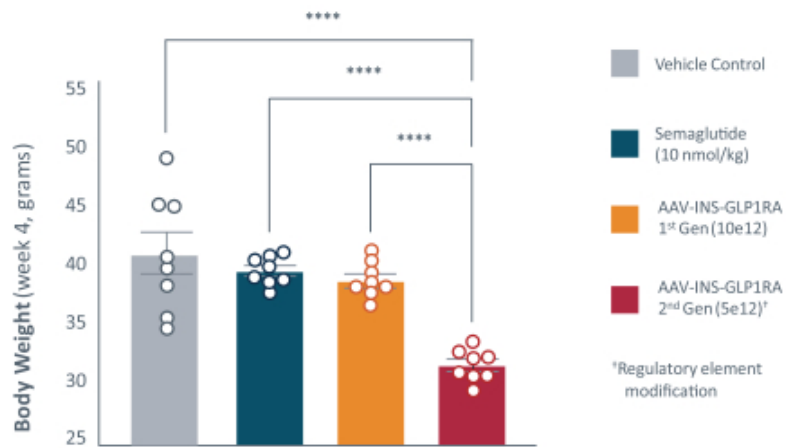


Mean ± SEM shown; *p<0.05, **p<0.01, ***p<0.0001; n=8 per group; AAV=adeno-associated virus, Gen=generation, GLP1=glucagon-like peptide 1, GLP1RA=GLP1 receptor agonist, INS=insulin promoter, PGTx=pancreatic gene therapy; semaglutide was commercially purchased

Head-to-Head Study: Body Weight Change
 GLP-1 PGTx candidate lowered total body weight vs. daily semaglutide

23% lower total body weight with GLP-1 PGTx candidate compared to vehicle

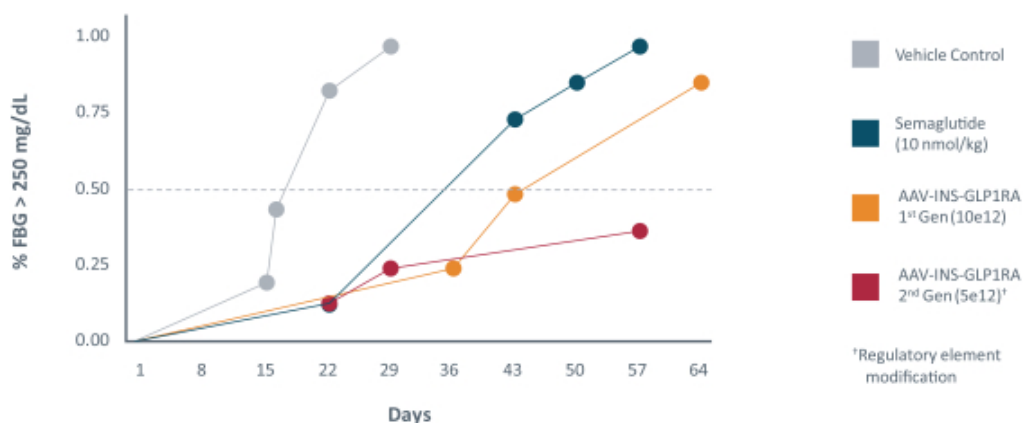
20% lower total body weight with GLP-1 PGTx candidate compared to semaglutide



Mean ± SEM shown; ****p<0.0001; n=8 per group; AAV=adeno-associated virus, Gen=generation, GLP1=glucagon-like peptide 1, GLP1RA=GLP1 receptor agonist, INS=insulin promoter, PGTx=pancreatic gene therapy; semaglutide was commercially purchased

Head-to-Head Study: Disease Progression and Durability

GLP-1 PGTx candidate shifted progression of disease vs. daily semaglutide

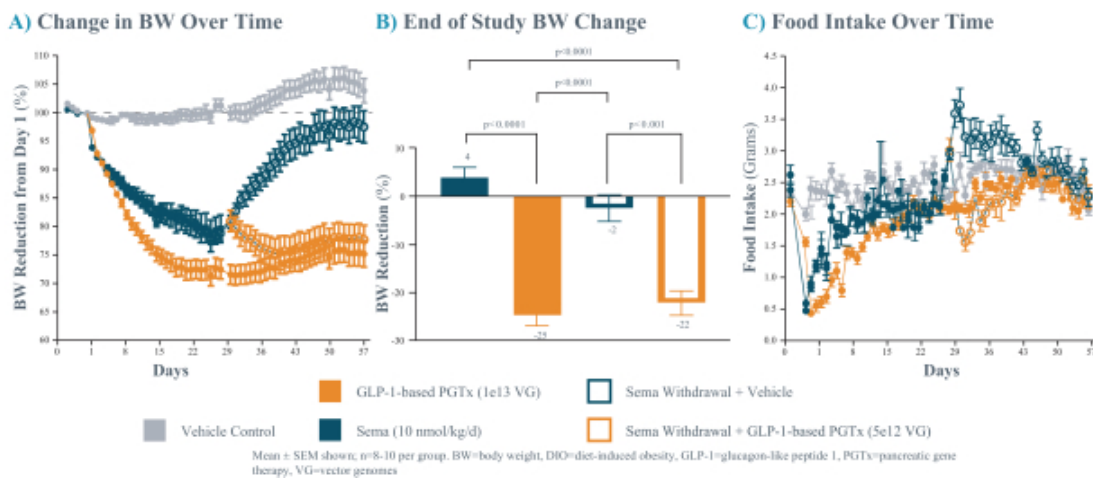


AAV=adeno-associated virus, FBG=fasting blood glucose, Gen=generation, GLP1=glucagon-like peptide 1, GLP1RA=GLP1 receptor agonist, INS=insulin promoter, PGTx=pancreatic gene therapy; semaglutide was commercially purchased

In a head-to-head preclinical *in vivo* study in a diet-induced obesity mouse model, we evaluated weight loss after a single administration of GLP-1 PGTx candidate compared to semaglutide 10 nmol/kg daily. At 28 days after administration, we observed a statistically significant reduction of total body weight of 27% for the GLP-1 PGTx candidate compared to 21% for semaglutide ($p < 0.05$ for the difference between GLP-1 PGTx candidate and semaglutide). Semaglutide-treated animals were then randomized on day 29 to withdrawal of semaglutide or a single administration of the GLP-1 PGTx candidate, and both groups were followed for an additional 4 weeks. On day 57, we observed weight loss of 25% in the obese rodents initially treated with the GLP-1 PGTx candidate, compared to weight gain of 4% in vehicles. Animals withdrawn from semaglutide regained weight to a net 2% body weight loss on day 57, while animals who crossed over from semaglutide to a single dose of the GLP-1 PGTx candidate maintained body weight loss on day 57 with 22% weight loss from baseline. Based on this data, we believe that a single administration of a GLP-1 PGTx candidate can achieve greater improvements in weight loss than semaglutide at the tested dose, durable improvements in weight loss

compared to vehicle control, and can offer a potential weight maintenance therapeutic solution to prevent weight regain after semaglutide discontinuation (as depicted in the image below).

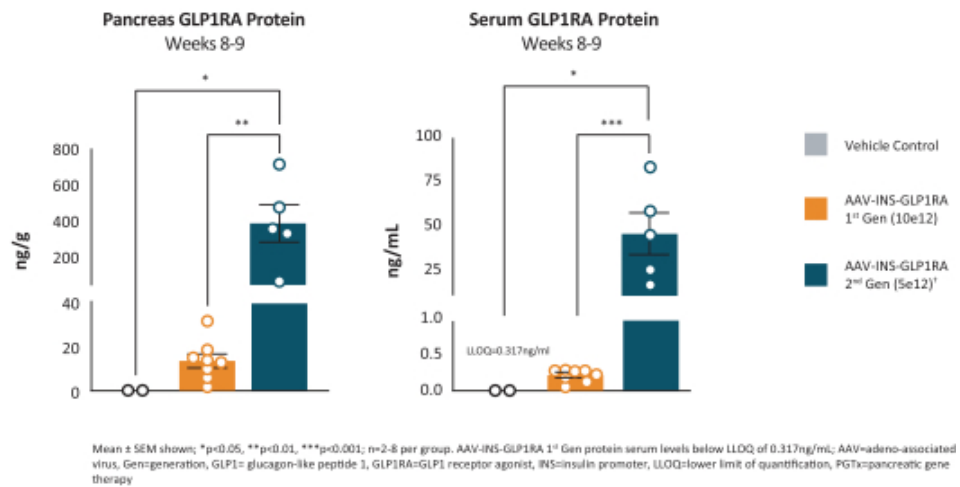
GLP-1 PGTx candidate sustained weight loss after semaglutide withdrawal



In vivo studies of GLP-1 PGTx candidates in *db/db* mice have demonstrated high specificity of transgene expression for the pancreatic islets with no detectable transgene expression in off-target tissues (e.g., the exocrine pancreas). We observed that promoter and regulatory element optimization in GLP-1 PGTx candidates demonstrated the potential for a broad dynamic range of transgene protein production at eight to nine weeks after a single administration of a GLP-1 PGTx candidate (as depicted in the image below). We believe these results indicate that GLP-1 PGTx candidates have the potential to provide durable metabolic benefits after a single administration with limited systemic exposure. No abnormal findings were observed in animal behavior or clinical chemistries. Histopathologic analysis showed no evidence of pancreatitis or pancreatic cancer.

GLP-1 PGTx Candidate Pancreas Protein Expression and Serum Levels

Promoter and regulatory element optimization demonstrated potential for broad dynamic range of transgene protein production



Preclinical Studies: Feasibility and Toxicity

Feasibility and toxicity studies were conducted in Yucatan pigs because their GI and pancreas anatomy is similar to that of humans, enabling a similar route of administration. In preclinical survival studies in Yucatan pigs, we demonstrated the feasibility and technical success of the Rejuva device and proposed clinical route of administration for local delivery of Rejuva PGTx candidates. We evaluated dose-dependent AAV-transgene expression in the pig pancreas by using green fluorescent protein, or GFP, in our AAV vector. At a dose of 1.5×10^{14} , we observed 41.2% islet cell transduction of GFP and a 3.5 vector copy number, or VCN. The FDA recommends that the VCN should be less than five copies per genome.

Biodistribution analysis demonstrated a 5.1x greater VCN in the pancreas as compared to the liver with our proposed clinical route of administration. According to a study done by Li et al., the same viral vector administered intravenously demonstrated a 0.005x VCN in the pancreas as compared to the liver. We believe this reflects a 1000-fold liver de-targeting with our proposed route of administration as compared to intravenous administration.

We observed no evidence of abnormal adverse events to the pancreas, liver or other tissues after administration of a beta-cell restricted Rejuva PGTx candidate.

Clinical Development Overview: Rejuva Gene Therapy Platform

We plan to complete IND-enabling studies, or its equivalent, for RJVA-001 in the second half of 2024. If the IND, or IND-equivalent, for RJVA-001 is approved, we plan to initiate a first-in-human study in the first half of 2025. In addition, we plan to continue *in vitro* and *in vivo* studies evaluating potential device and gene therapy candidate optimization parameters and route of administration in preclinical safety and efficacy studies on a path toward nominating our first GLP-1 PGTx candidate for obesity.

Commercialization Strategy

We are a commercial-stage company with Revita currently available in Germany. The Revita system is approved in Europe as a medical device under a CE Mark and has received reimbursement authorization in Germany. After securing reimbursement for Revita in the first half of 2023, we initiated a limited commercial pilot in a single center in Dusseldorf, Germany, along with a German Real World Registry, designed to evaluate real-world evidence of Revita's safety and effectiveness in people with inadequately controlled T2D. We elected to launch Revita in Germany only upon first securing reimbursement from statutory health insurers for patients with T2D. We intend to continue to add centers in Germany, focusing on GI endoscopists with a focused interest in metabolic endoscopy and at hospitals that have established reimbursement for Revita with statutory health insurers.

In the United States, we have obtained Breakthrough Device designation from the FDA for the Revita DMR Procedure to improve glycemic control and eliminate insulin needs in T2D patients who are inadequately controlled on long-acting insulin. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and prioritized review of premarket submissions but does not alter or confer any advantage in the regulatory review or approval standard for medical devices. We intend to submit a PMA for Revita after we complete the Revitalize-1 study, including the follow-up study through 48 weeks, in the first half of 2025. If approved, longer term follow-up studies beyond 48 weeks will likely be performed as part of a post-approval study, or PAS, including potentially studying the safety and effectiveness of repeat procedures, should they be necessary. Based on regulatory precedent, we believe a PAS may be conducted in parallel with the commercial launch of Revita. If approved, we intend to execute a targeted, efficient go-to market strategy for Revita, driven by a stepwise approach that will build brand awareness, position Revita as a novel and generally well tolerated procedural therapy alternative to escalating insulin therapy, and ultimately expand procedure volume as attempt to validate Revita in endocrine and endoscopy communities as a durable and potentially repeatable option for patients with T2D and other metabolic diseases.

As we progress our Revita clinical program and generate clinical evidence in support of Revita, we will invest in building a U.S.-based direct salesforce and medical affairs field team to support our U.S. launch ahead of Revita's potential FDA approval. We will seek to strategically recruit representatives with strong backgrounds and experience in the management of T2D as well as those with a deep understanding of the endoscopist workflow. We expect to grow our field force over time to accelerate broad market adoption of Revita, building on the foundational brand awareness we aim to achieve through our initial educational efforts.

As we generate additional clinical data and insights through our Revita clinical program, we plan to carry out an organized medical education effort to inform endocrinologists around the compelling solution provided by our product candidates, as we believe they will serve as the primary prescribing physicians. We believe that the clinical evidence generated from our program will continue to support our messaging to key leaders in the field of endocrinology and gastroenterology.

If Revita is approved, we intend to commercially launch with the PMA approved console design and plan to submit a supplemental PMA for our next generation commercial console design shortly thereafter. We plan to execute an efficient "hub-and spoke" commercialization strategy to position Revita as a novel procedural therapy to treat T2D and drive its rapid adoption. Leveraging key learnings and insights from our Revita clinical program, we plan to have a targeted sales force initially focusing on centers of excellence with metabolically focused endocrinologists and advanced therapeutic endoscopists. We plan to initially target participating physicians from our clinical studies, as we believe their familiarity with our therapies will make them early adopters. Our multi-channel commercialization strategy will include direct marketing campaigns to raise awareness amongst patients for a compelling new treatment alternative in T2D.

We also plan to roll out a robust procedural training and support program for GI endoscopists, ensuring seamless integration of Revita into their workflow. These education and training efforts will be critical in building an installed base in metabolic endoscopy that will begin with providers at large hospitals and expand to outpatient endoscopy centers over time.

Our initial approach will be to focus on insulin-treated T2D patients, and progress to patients with obesity and earlier indications of T2D. Once we are established in T2D through clinical validation, medical education and training, strong procedure volumes and a robust installed base, we plan to leverage our foundational platform, technology and core capabilities to expand indications to other serious diseases, including CVD, among others.

As we expand the adoption of Revita, we will evaluate potential partnerships and/or distributor relationships for its commercialization in other global geographies. Given the high prevalence and rapidly growing incidence of T2D in certain regions, including Africa, India and China, we believe there is a significant unmet need for a scalable, disease-modifying therapy globally. We plan to pursue regulatory approvals and geographic expansion into additional regions as part of our long-term growth strategy.

Because Rejuva is designed to leverage the same console system, physicians, skill sets and same commercialization footprint of Revita, we believe that a successful launch of Revita will enable a more rapid commercialization of Rejuva into that same channel, if both products are approved in the United States.

Research and Development

We have an experienced research and development team with the scientific, engineering, software, operations and clinical talent that we believe is required to grow our business. We have committed, and expect to continue to commit, significant resources to improve product candidate performance and reliability and reduce costs. As of December 31, 2023, our research and development team was comprised of 78 employees. For the years ended December 31, 2022 and 2021, we incurred research and development expenses of approximately \$34.4 million and \$26.4 million, respectively. Major components of the research and development expenses included salaries and benefits, clinical study expenses and production related costs.

We continuously seek to improve Revita, the DMR procedure and our Rejuva gene therapy platform, including improvements in our technology and its accessibility. We believe that technical advantage is important to achieve or sustain a competitive advantage, and therefore our research and development efforts are focused on the continued enhancement of Revita, the DMR procedure and Rejuva. We are dedicated to ongoing innovation with respect to Revita, the DMR procedure, Rejuva, and to expanding our pipeline of product candidates and their applications to treat T2D, obesity, and other metabolic diseases.

Competition

The medical device and biopharmaceutical industries are characterized by rapid advancement of novel technologies, significant competition and a strong defense of intellectual property rights. While we believe that our product candidates and scientific expertise provides us with competitive advantages, we face competition from multiple sources, including larger and better-funded medical device and biopharmaceutical companies, academic institutions, lifestyle and diet service centers, hospitals, surgical centers, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with currently approved therapies, services and procedures, including lifestyle and diet services, bariatric surgeries, in particular gastric bypass surgeries, and new therapies that may become available in the future. Key factors that would affect our ability to effectively compete with other therapeutics include safety, efficacy, ease of administration, pricing, brand recognition and availability of reimbursement and coverage by third party payors.

There are a number of new classes of agents and combination agents in development for T2D and obesity, such as oral GLP-1s and gene therapies, which may offer evidence of significant glycemic improvement, weight loss and broad metabolic benefit. Pharmaceutical companies are heavily invested in their existing and future product platforms for T2D and obesity. They have strong relationships within the clinical community and with prescribing physicians in particular.

Intellectual Property

Our ability to obtain and maintain intellectual property protection for our product candidates and technology is fundamental to the long-term success of our business. We rely on a combination of intellectual property protection strategies, including patents, trademarks, trade secrets, confidentiality policies and procedures, non-disclosure agreements, invention assignment agreements and technical measures designed to protect the intellectual property and commercially valuable confidential information and data used in our business.

As of December 31, 2023, we own: 22 issued U.S. patents; 26 pending U.S. patent applications; 11 pending U.S. provisional patent applications; 2 patent cooperation treaty, or PCT, applications that have not entered national stage; 69 issued foreign patents in Australia, Brazil, Canada, China, Europe, Israel, Japan, Korea, and Russia; and 28 pending foreign patent applications in Australia, Canada, China, Europe, Israel, India, Japan, and Korea. The subject matter covered by our owned patents and patent applications include: Revita and components thereof, methods of using Revita, Rejuva and components thereof, methods of using Rejuva, and other exploratory product candidates. Excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable: our owned issued U.S. patents are expected to expire between January 2032 and June 2037; our owned issued foreign patents are expected to expire between January 2032 and September 2038; any patents that may issue from our owned pending U.S. patent applications are expected to expire between October 2034 and December 2044; any patents that may issue from our owned pending foreign patent applications or PCT applications are expected to expire between January 2032 and February 2042.

With respect to Revita, as of December 31, 2023, we own: 17 issued U.S. patents; 18 pending U.S. patent applications; three pending U.S. provisional patent applications; one PCT application that has not entered national

stage; 61 issued foreign patents in Australia, Brazil, Canada, China, Europe, Israel, Japan, Korea, and Russia; and 19 pending foreign patent applications in Australia, Canada, China, Europe, Israel, India, Japan, and Korea. The issued patents and any patents that may issue from our pending patent applications related to Revita are expected to expire between January 2032 and December 2044, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

With respect to Rejuva, as of December 31, 2023, we own: one pending U.S. patent application; seven pending U.S. provisional patent applications; one PCT application that has not entered national stage; and two pending foreign patent applications in Australia and Europe. Any patents that may issue from our pending patent applications related to Rejuva are expected to expire between February 2042 and November 2044, excluding any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees, as applicable.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. We cannot be sure that our pending patent applications that we have filed or may file in the future will result in issued patents, and we can give no assurance that any patents that have issued or might issue in the future will protect our current or future products, will provide us with any competitive advantage, and will not be challenged, invalidated, or circumvented.

We intend to pursue additional intellectual property protection to the extent we believe it would be beneficial and cost-effective. Our ability to stop third parties from making, using or commercializing any of our patented inventions will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. With respect to our owned intellectual property, we cannot provide any assurance that any of our current or future patent applications will result in the issuance of patents in any particular jurisdiction, or that any of our current or future issued patents will effectively protect any of our product candidates or technology from infringement or prevent others from commercializing infringing products or technology.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. The medical device industry is subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Numerous third-party patents exist in the fields relating to our product candidates, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our product candidates and technologies. We are aware of third-party patents, and patent applications that if issued, may be construed to cover our product candidates or technologies, including Revita.

In addition to our reliance on patent protection for our inventions, products and technologies, we also seek to protect our brand through the procurement of trademark rights. As of December 31, 2023, we own 41 registered trademarks and 10 pending trademark applications for FRACTYL, FRACTYL HEALTH, FRACTYL HEALTH LOGO, REVITA, REVITA DMR and other product related brand names in the United States and certain foreign jurisdictions. Furthermore, we rely on trade secrets, know-how, unpatented technology and other proprietary information, to strengthen our competitive position. We have determined that certain technologies, including certain aspects of our software, are better kept as trade secrets. To mitigate the chance of trade secret misappropriation, we enter into non-disclosure and confidentiality agreements with parties who have access to our trade secrets, such as our employees, consultants, advisors and other third parties. We also enter into invention assignment agreements with our employees and consultants that obligate them to assign to us any inventions they have developed while working for us. We generally control access to our proprietary and confidential information through the use of internal and external controls that are subject to periodic review.

Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. For further discussion of the risks relating to intellectual property, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Manufacturing and Supply

We currently perform final assembly and testing of Revita at our headquarters in Lexington, Massachusetts. We rely upon third-party suppliers for the manufacture of sub-assembly components. We do not have long-term supply agreements with any of our suppliers, some of which are single- or sole-source suppliers. Our purchase order arrangements are terminable at will. We have not yet identified and qualified second-source replacements for many of our critical single-source suppliers. Thus, in the event that our relationship with any of our single- or sole-source suppliers terminates in the future, we may have difficulty maintaining sufficient supplies of key components of our product candidate. Where practicable, we are currently seeking, or intend to seek, second-source manufacturers for our single-source components. We believe that our existing facilities and those of our third-party suppliers are adequate to meet our current manufacturing needs.

Manufacturing facilities that produce medical devices or their component parts are subject to regulation and periodic unannounced inspection by the FDA and other domestic and international regulatory agencies. In the United States, we and some of our sub-assembly component manufacturers will be required to manufacture any products that we sell in compliance with the FDA’s Quality System Regulation, or QSR, or the FDA’s current good manufacturing practices, or cGMPs, which cover the methods used in, and the facilities used for, the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our product candidates. In international markets, we and some of our sub-assembly component manufacturers are and will be required to obtain and maintain various quality assurance and quality management certifications, and are and will continue to be periodically inspected by international regulatory authorities for certification purposes. We believe our manufacturing operations, and those of our suppliers, are in compliance with applicable regulations of the FDA or other applicable regulatory authorities.

Government Regulation

Our product candidates and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. For example, certain of our product candidates are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the FDA, and other product candidates we intend to develop are regulated as biologic-device combination products subject to regulation by the FDA under the FDCA and the Public Health Service Act, or PHSA, and comparable foreign laws and regulations.

United States Regulation of Medical Devices

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a premarket notification submitted under Section 510(k) of the FDCA, classification of FDA’s *de novo* classification process or approval of a PMA. Under the FDCA, medical devices

are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA’s General Controls for medical devices, which include compliance with the applicable portions of the QSR, establishment registration and device listing, reporting of adverse medical events and certain device malfunctions, known as medical device reporting, or MDR, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA’s General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and additional labeling requirements.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA’s permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA’s premarket notification and clearance process in order to be commercially distributed.

510(k) Clearance Marketing Pathway

To obtain 510(k) clearance, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the proposed device is “substantially equivalent” to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA’s 510(k) clearance process usually takes from three to twelve months, but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees for medical device establishment registration.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is “not substantially equivalent” to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the “*de novo*” classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or grant of a *de novo* request for classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) in the first instance, but the FDA can review any such decision and disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until such marketing authorization has been granted. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it

more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in September 2019, the FDA issued revised final guidance describing an optional “safety and performance based” premarket review pathway for manufacturers of “certain, well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list device types appropriate for the “safety and performance based” pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

PMA Approval Pathway

Revita is a Class III device subject to the requirement for PMA approval. Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA’s review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel’s recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers’ or suppliers’ manufacturing facility or facilities to ensure compliance with the QSR, which set forth cGMPs for devices. PMA applications are also subject to the payment of user fees, which are higher than in the 510(k) process.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. None of our medical device products have been approved through the PMA process.

Clinical Trials

Clinical trials are almost always required to support a PMA and *de novo* request for classification, and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may impose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and complying with labeling and record-keeping requirements. In some cases, an IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Expedited Development and Review Programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment and review, while preserving the statutory standards for PMA approval, 510(k) clearance and *de novo* classification.

The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of postmarket data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and prioritized review of premarket submissions.

Post-Market Regulation of Medical Devices

After a product is placed on the market, numerous regulatory requirements continue to apply. These relate to:

- device listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, validation, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations, including regulations pertaining to Unique Device Identification, and FDA prohibitions against the promotion of products for uncleared or unapproved use or indication;
- clearance of product modifications for 510(k)-cleared products that could significantly affect safety or effectiveness or that would constitute a major change in intended use or approval of supplemental PMAs for certain changes to an approved device;
- compliance with MDR regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction and removal reporting regulations, which require that manufacturers report to the FDA certain corrections and removals;
- post-market restrictions or conditions, including post-market study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the medical product;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- regulations pertaining to voluntary recalls.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled and unscheduled inspections by the FDA.

Failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with any marketed products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval, or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products, when and if approved;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance, *de novo* classification or PMA approvals of new products or modified products;
- withdrawing PMA approvals that have already been granted;
- refusal to grant export approvals for our products, when and if approved; or
- criminal prosecution.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes.

Furthermore, under the federal U.S. Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice.

United States Regulation of Biologics and Combination Biologic/Device Products

In the United States, biological products, or biologics, such as those gene therapy candidates we intend to develop through our proprietary Rejuva gene therapy platform, are subject to regulation under the FDCA, PHSA, and other federal, state, local and foreign statutes and regulations.

Combination Biologic/Device Products

We expect our gene therapy candidates developed through our Rejuva gene therapy platform to be subject to regulation in the United States as combination products comprised of a biologic product candidate and a device delivery system. A combination product is the combination of two or more regulated components, such as biologic/device, that are combined or mixed and produced as a single entity, packaged together in a single package or as a unit or a biologic or device packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified biologic or device where both are required to achieve the intended use, indication or effect. If marketed individually, each component would be subject to different regulatory pathways and would require approval of independent marketing applications by the FDA – one for the device component and one for the biologic component of the combination.

A combination product, however, is assigned to a center within FDA that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. To determine which FDA center or centers will review a combination product candidate submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

In the case of our Rejuva gene therapy candidates, we believe that the primary mode of action will be attributable to the biologic component of the combination product. We therefore would expect to seek approval of any such combination biologic/device product candidate through a single Biologics License Application, or BLA, and we do not expect that the FDA will require a separate marketing authorization for the device component.

U.S. Biologics Regulation

The process required by the FDA before biologics may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements, or GLPs;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an IRB or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended use in accordance with good clinical practice requirements, or GCPs;
- preparation of and submission to the FDA of a BLA, after completion of all pivotal clinical trials and other necessary studies;
- satisfactory completion of an FDA advisory committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs (including the QSR in the case of the device component of any biologic/device combination product), and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

The preclinical developmental stage generally involves laboratory evaluations of chemistry, formulation and stability, as well as studies to evaluate the product candidate's toxicity in animals, in an effort to support subsequent clinical testing. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations.

Prior to beginning the first clinical trial with a product candidate in the United States, the trial sponsor must submit an IND to the FDA. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product candidate, chemistry, manufacturing, and controls information, and any available human data or literature to support the use of the product candidate. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

In addition to the IND submission process, under the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant DNA Molecules, or the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring subject safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study, and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing

schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may also be made a condition to approval of the BLA.

While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

In addition, during the development of a new biologic, sponsors are given opportunities to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach alignment on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the product candidate.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product candidate for one or more indications. The BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product candidate, or from a number of alternative sources, including studies initiated by independent investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any

BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether the product candidate is safe, pure and potent for the proposed indication, and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may include limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once a BLA is approved, the FDA may withdraw such approval if compliance with pre-and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety, purity and potency after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the fast track program is intended to expedite or facilitate the process for developing

and reviewing product candidates that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track-designated product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track-designated product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a biologic product candidate submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A BLA is eligible for priority review if the product candidate is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or the FDORA, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under the FDORA, the FDA has increased authority for expedited procedures to withdraw approval of the product receiving accelerated approval if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-Approval Requirements

Biologics are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon them. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved label to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims that are in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for

uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict a manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product.

Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. Whether products deemed "interchangeable" by the FDA are readily substituted by pharmacies is governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Foreign Government Regulation

In addition to U.S. regulations, we are subject to a variety of foreign government regulations applicable to medical devices, medicinal products and combination products.

Regulation of Medical Devices in the European Union

The EU has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices.

Until May 25, 2021, medical devices were regulated by the Council Directive 93/42/EEC or Medical Devices Directive, which has been repealed and replaced by Regulation (EU) No 2017/745, or Medical Devices Regulation. Our current certificates have been granted and renewed under the Medical Devices Directive whose regime is described below. However, as of May 26, 2021, some of the Medical Devices Regulation requirements apply in place of the corresponding requirements of the Medical Devices Directive. Pursuing marketing of medical devices in the EU will notably require that our devices be certified under the new regime set forth in the Medical Devices Regulation.

Medical Devices Directive

Under the Medical Devices Directive, all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I to the Medical Devices Directive, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturer's quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Medical Devices Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues an EC certificate, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the EC certificate, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

Medical Devices Regulation

The regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The Medical Devices Regulation, among other things, establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensures a high level of safety and health while supporting innovation. Unlike the Medical Devices Directive, the Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU.

The Medical Devices Regulation became effective on May 26, 2021. In accordance with its recently extended transitional provisions, both (i) devices lawfully placed on the market pursuant to the Medical Devices Directive prior to May 26, 2021 and (ii) legacy devices lawfully placed on the market after May 26, 2021 in

accordance with the transitional provisions of the Medical Devices Regulation may generally continue to be made available on the market or put into service, provided that the requirements of the transitional provisions are fulfilled (as detailed below). Pursuing marketing of medical devices in the EU will notably require that all our devices be certified under the new regime set forth in the Medical Devices Regulation. Regardless of whether we have already obtained certification under the Medical Devices Regulation, since May 26, 2021, the Medical Devices Regulation requirements apply in place of the corresponding requirements of the Medical Devices Directive with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements (as detailed below).

The Medical Devices Regulation requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (EUDAMED), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The Medical Devices Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier, or UDI, database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier, or UDI-DI, specific to the manufacturer and the device, and a production identifier, or UDI-PI, to identify the unit of device production. Manufacturers are also notably responsible for entering the necessary data on EUDAMED, which includes the UDI database, and for keeping it up to date. EUDAMED is not yet fully functional.

All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the Medical Devices Regulation. Under this system, serious incidents and Field Safety Corrective Actions, or FSCAs must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through EUDAMED – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until EUDAMED is fully functional, the corresponding provisions of the Medical Devices Directive continue to apply. Manufacturers are required to take FSCAs, which are defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. A serious incident is any malfunction or deterioration in the characteristics or performance of a device on the market (e.g., inadequacy in the information supplied by the manufacturer, undesirable side-effect), which, might lead to either the death or serious deterioration of the health of a patient, user, or other persons, or to a serious public health threat. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

Among the new requirements, manufacturers (and authorized representatives) must have available within their organization at least one person responsible for regulatory compliance, or PRRC, who possesses the requisite expertise in the field of medical devices. The PRRC is notably responsible for compliance with post-market surveillance and vigilance requirements.

The advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a

national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU Member States plus Norway, Liechtenstein and Iceland.

Brexit

From January 1, 2021 onwards, the Medicines and Healthcare Products Regulatory Agency, or MHRA, has been the sovereign regulatory authority responsible for the Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the three pre-existing EU directives governing active implantable medical devices, general medical devices and in vitro diagnostic medical devices whereas, broadly, Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA before being placed on the Great Britain market. The MHRA will only register devices where the manufacturer or their United Kingdom, or the UK, Responsible Person has a registered place of business in the UK. Manufacturers based outside the UK need to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA. Following a public consultation on proposed changes to the UK's medical device regulations, the response to which was published on June 26, 2022, the MHRA confirmed that it would bring about changes to the current regulations applicable in Great Britain. It is anticipated that the core aspects of the future regime will now apply from July 1, 2025 so that medical devices placed on the market in Great Britain will require a UK Conformity Assessment, or UKCA, mark. However, the MHRA has recently confirmed that, subject to certain conditions, general medical devices compliant with the (EU) Medical Devices Directive or AIMD with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of expiry of certificate or June 30, 2028. However, UKCA marking will not be recognized in the EU. The rules for placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in the rest of the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, when and if certified, without which they cannot be sold or marketed in Great Britain.

In addition, the Trade and Cooperation Agreement, or the TCA, between the UK and the EU generally provides for cooperation and exchange of information between the parties in the areas of product safety and compliance, including market surveillance, enforcement activities and measures, standardization-related activities, exchanges of officials, and coordinated product recalls. As such, processes for compliance and reporting should reflect requirements from regulatory authorities.

Coverage and Reimbursement

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. In the EU and UK, member states impose controls on whether products are reimbursable by national or regional health service providers and on the prices at which devices are reimbursed under state-run healthcare schemes. More and more, local, product specific reimbursement law is applied as an overlay to Medical Devices Regulation, which has provided an additional layer of clearance requirement.

Regulation of Medicinal Products in the European Union

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies, commercial sales, and distribution of our future products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. In addition, ethical, social and legal concerns about gene-editing technology, gene

therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use.

Most countries outside of the United States, including the EU, require that clinical trial applications, or CTAs, be submitted to and approved by the local regulatory authority for each clinical study. In addition, whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approval from comparable regulatory authorities outside the United States before we can commence clinical studies or marketing of the product candidate in those countries. The requirements and process governing the conduct of clinical trials, approval, product licensing, pricing and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-Clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of GLP as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labelling purposes). GLP principles define a set of rules and criteria for a quality system concerned with the organizational process and the conditions under which these non-clinical studies are planned, performed, monitored, recorded, archived and reported. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on good clinical practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products, or ATMPs. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state’s

decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our future product candidates in the EU, and in many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining a marketing authorization, or MA. To obtain regulatory approval of a product candidate (including an investigational biological product) under EU regulatory systems, we must submit a marketing authorization application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product.

There are two types of MAs:

- “Centralized MAs” are issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the EU. It is compulsory for certain types of products, such as (i) medicinal products derived from biotechnological processes, (ii) designated orphan medicinal products, (iii) ATMPs, such as gene therapy, somatic cell-therapy or tissue-engineered medicines and (iv) medicinal products containing a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for any other medicinal products containing new active substances not authorized in the EU or for product candidates which constitute a significant therapeutic, scientific, or technical innovation or for which the granting of authorization would be in the interests of public health in the EU.
- “National MAs,” which are issued by the competent authorities of the EU member states and only cover their respective territory, are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the Mutual Recognition Procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the Reference member state.

The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT’s opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT’s draft

opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion, if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

Under the centralized procedure the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and/or are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. In March 2016, the EMA launched an initiative, the PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

MAAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance. Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

Data and Marketing Exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving MA, reference product candidates generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA

in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the EEA.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Brexit

The TCA, agreed between the UK and the EU has been provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition cGMP inspections of manufacturing facilities for medicinal products and cGMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. While the TCA has avoided a “no deal” Brexit scenario, and provides for quota and tariff free trading of goods in principle, it is nevertheless expected that the TCA will result in the creation of non-tariff barriers (such as increased shipping and regulatory costs and complexities) to the trade in goods between the UK and EU. Further, the TCA does not provide for the continued free movement of services between the UK and EU and also grants each of the UK and EU the ability, in certain circumstances, to unilaterally impose tariffs on one another.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as “retained EU law”. However, new legislation such as the EU Clinical Trial Regulation (Regulation (EU) No 536/2014) or in relation to orphan medicines will not be applicable. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an ‘appropriate authority’ to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

As of January 1, 2021, the MHRA is the UK’s standalone medicines and medical devices regulator. As a result of the Northern Ireland Protocol, different rules will apply in Northern Ireland than in England, Wales, and Scotland, together, Great Britain, or GB; broadly, Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA. On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the “Windsor Framework”. This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide MA will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the EU will enact legislative measures to bring it into law.

The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder chose to opt-out.

There is no pre-MA orphan designation. Instead, the MHRA will review applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in GB, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in GB.

For MAs, an applicant for a centralized MA must be established in the EU. After Brexit, companies established in the UK can no longer use the centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. The MHRA may rely on a decision taken by the European

Commission on the approval of a new (Centralized Procedure) MA when determining an application for a Great Britain authorization until December 31, 2023. On January 24, 2023, the MHRA announced that a new international recognition framework will be put in place from January 1, 2024, which will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new GB MA. The MHRA's Decentralized or Mutual Recognition Procedures also enables MAs approved in EU member states (or Iceland, Liechtenstein, Norway) to be granted in GB.

The full impact of such arrangements may not yet be fully known.

Coverage and Reimbursement

In some foreign countries, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, in the EU pricing and reimbursement of pharmaceutical products are regulated at a national level under the individual EU member states' social security systems. Some foreign countries provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and can control the prices and reimbursement levels of medicinal products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A country may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Even if approved for reimbursement, historically, product candidates launched in some foreign countries, such as some member states in the EU, do not follow price structures of the United States and prices generally tend to be significantly lower.

Other Healthcare Laws

Healthcare Fraud and Abuse Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, transparency and other healthcare fraud and abuse laws.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including cash, improper discounts, and free or reduced price items and services. Among other things, the Anti-Kickback Statute has been interpreted to apply to arrangements between medical device manufacturers on the one hand and prescribers and purchasers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. The government can exercise enforcement discretion in taking action against unprotected activities. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties. The majority of states also have anti-kickback laws, which establish similar prohibitions, and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers and self-pay patients.

The federal false claims laws, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician’s immediate family members.

Federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products.

Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require manufacturers to implement compliance programs or to comply with the pharmaceutical and medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. Several states also impose other marketing restrictions or require manufacturers to make marketing or price disclosures to the state and require the registration of sales representatives. State and foreign laws, including, for example, the European Union General Data Protection Regulation, which became effective May 2018, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Violations of fraud and abuse laws, including federal and state anti-kickback and false claims laws, may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

European Healthcare Laws

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices and medicinal products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on manufacturers. Certain countries also mandate implementation of commercial compliance programs.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of procedures using any product candidates for which we may obtain regulatory approvals. In the United States, sales of our product candidates, if approved, will depend, in part, on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures in which our product candidates, if approved, are used. In the United States, third-party payors include federal and state healthcare programs, private managed care plans, health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for procedures using our products will be available from government health administration authorities, private insurers and other organizations. In the United States, the principal decisions

about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and certain private payors may follow CMS policies. Coverage and reimbursement by governmental and other third-party payors may depend upon a number of factors, including the third-party payor's determination that use of a product or service and its use for a particular patient is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that coverage and reimbursement will be available for any procedure that uses our product candidate that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which a product candidate is approved by the FDA or comparable foreign regulatory authorities. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical devices and medical services, in addition to questioning their safety and efficacy. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained.

No uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor. Moreover, the process for determining whether a third-party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the procedure using new medical devices and technology. A payor's decision to provide coverage for a procedure does not imply that an adequate reimbursement rate will be approved to also cover the cost of our product candidates, if approved. Further, one payor's determination to provide coverage for a product or procedure does not assure that other payors will also provide coverage for the product or procedure. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to ensure profitability.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. In the European Union, member states are facing increased pressure to limit public healthcare spending. There can be no assurance that procedures using our product candidates, once approved, will be covered for a specific indication or will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidate profitably, once approved. More and more, local, product specific reimbursement law is applied as an overlay to Medical Devices Regulation, which has provided an additional layer of clearance requirement. Historically, products launched in the European Union do not follow the price structures of the United States and product prices in the European Union have generally been significantly lower as compared to the United States.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products, when and if approved. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our future products.

The implementation of the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. In addition, the ACA has subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial, executive and political challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law, including the TCJA, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how any challenge to repeal or replace the ACA will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted:

- The Budget Control Act of 2011, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The Medicare Access and CHIP Reauthorization Act of 2015 repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that began in 2019 that are based on various performance measures and physicians’ participation in alternative payment models, such as accountable care organizations.
- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

There has also been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from \$7,050 to \$2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS

rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Further, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once the regulation becomes applicable, it will have a phased implementation depending on the concerned products. This regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect additional state, federal and foreign healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our future products or additional pricing pressure.

Data Privacy & Security

Numerous state, federal and foreign laws, regulations, and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, including clinical trial data, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the GDPR imposes strict requirements for processing the personal data of individuals within the European Economic Area. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Further, from January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover.

Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that may lead to significant civil and/or criminal penalties and restrictions on data processing.

Facilities

Since 2016, our corporate headquarters has been located at 17 Hartwell Avenue Lexington, Massachusetts 02421, where we currently lease approximately 30,000 square feet of office and manufacturing space. As of December 31, 2023, 68 of our employees are located at our corporate headquarters.

Employees and Human Capital Resources

As of December 31, 2023, we have 94 full-time employees, 78 of whom are dedicated to research and development and 14 of whom hold doctorate degrees (i.e., Ph.D., Pharm.D. or M.D.). None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

We recognize that our continued ability to attract, retain and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- **Talent Development, Compensation and Retention.** We strive to provide our employees with a rewarding work environment, including the opportunity for growth, success and professional development. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package—all designed to attract and retain a skilled and diverse workforce.
- **Health and Safety.** We support the health and safety of our employees by providing health care, retirement planning, paid time off and other additional benefits, which are intended to assist employees to manage their well-being.
- **Inclusion and Diversity.** We believe that much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and focus on extending our diversity and inclusion initiatives across our entire workforce.

Legal Proceedings

We are not subject to any material legal proceedings.

MANAGEMENT

The following table provides information regarding our executive officers and members of our board of directors (ages as of the date of this prospectus):

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Executive Officers		
Harith Rajagopalan, M.D., Ph.D.	47	Co-Founder, Chief Executive Officer, Director
Jay D. Caplan	62	Co-Founder, President, Chief Product Officer
Lisa A. Davidson	57	Chief Financial Officer, Treasurer
Timothy Kieffer, Ph.D.	57	Chief Scientific Officer
Sarah Toomey	49	General Counsel, Corporate Secretary
Non-Employee Directors		
Kelly Barnes	57	Director
William W. Bradley	80	Director
Samuel Conaway	59	Director
Marc Elia	47	Director
Clive Meanwell, M.B., Ch.B., M.D.	66	Director
Ajay Royan	44	Director
Amy W. Schulman	63	Director
Allan R. Will	69	Chairman

Executive Officers

Harith Rajagopalan, M.D. Ph.D. Dr. Rajagopalan co-founded Fractyl in 2010 and has served as our Chief Executive Officer and a member of our board of directors since 2011, while serving as an Entrepreneur-in-Residence at General Catalyst Partners from 2009 to 2011. Prior to founding Fractyl, Dr. Rajagopalan trained in internal medicine and clinical cardiology at Brigham and Women’s Hospital in Boston, Massachusetts from 2005 to 2011, and completed a research fellowship at Harvard Medical School from 2009 to 2011. Dr. Rajagopalan received his B.S. in chemistry from Stanford University, and his M.D. and Ph.D. from Johns Hopkins University School of Medicine. We believe that Dr. Rajagopalan is qualified to serve on our board of directors due to his role as co-founder of Fractyl Health, his management experience as our Chief Executive Officer and his scientific and medical experience.

Jay D. Caplan. Mr. Caplan co-founded Fractyl in 2010 and has served as our President and Chief Product Officer since 2011 and January 2022, respectively. He previously served as a member of our board of directors from 2011 to 2017. Prior to founding Fractyl, Mr. Caplan served as Chief Operating Officer of Candela Corporation from November 2007 to January 2010, which was then a publicly held U.S.-based global medical aesthetic device company. Prior to Candela, he served as Chief Technology Officer and Vice President of Research and Development of InfraReDx, Inc. from September 2001 to October 2007, a privately held company that designs and develops catheter-based coronary imaging devices, that was later acquired by Nipro Corporation (Japan). Mr. Caplan also previously served as Vice President of Operations of Thermo Cardiosystems Inc. (now part of Abbott Laboratories), where he assisted in developing the HeartMate II left ventricular assist device. Mr. Caplan received his B.S. in electrical engineering from the Massachusetts Institute of Technology, or MIT, and his M.B.A. from the University of Pennsylvania’s Wharton School of Business.

Lisa A. Davidson. Ms. Davidson has served as our Chief Financial Officer and Treasurer since August 2015. Prior to joining us, Ms. Davidson was Vice President of Finance and Administration of Flexion Therapeutics, Inc., or Flexion, a publicly held biopharmaceutical company focused on the development and commercialization of novel, injectable pain therapies, from March 2009 to August 2015. Prior to Flexion, Ms. Davidson served as Director of Finance of OmniSonics Medical Technologies, Inc., a privately held

U.S.-based medical device company focused on the treatment of vascular occlusive diseases. Ms. Davidson also previously served as Director of Finance of PerkinElmer Inc., a publicly held company focused on globally providing products and services to customers in health sciences and other advanced technology markets, and as Director of Finance at Citizens Advisers, Inc., an investment adviser to Citizens Funds, an investment company. Ms. Davidson received her B.A. and M.B.A. from the University of New Hampshire.

Timothy Kieffer, Ph.D. Dr. Kieffer has served as our Chief Scientific Officer since September 2023. Prior to joining us, Dr. Kieffer served as the Chief Scientific Officer of ViaCyte Inc., a privately held company at the forefront of stem cell-derived treatments for diabetes, from September 2021 to October 2022. He also currently serves as a Professor of Medicine in the department of cellular and physiological sciences and surgery at the University of British Columbia, a position he has held since 2007. Dr. Kieffer's research is focused on islet biology and the development of novel gene and cell therapy approaches to treat diabetes, and he has co-authored more than 200 publications on these topics and has been cited over 20,000 times. He received his Ph.D. in physiology from the University of British Columbia.

Sarah Toomey. Ms. Toomey has served as our General Counsel and Corporate Secretary since May 2022. Prior to joining us, Ms. Toomey was Senior Vice President of Operations and General Counsel of BERG LLC or BERG (now BPGbio, Inc.), a clinical-stage AI-powered biopharmaceutical company focused on oncology, neurology and rare diseases, from October 2017 to May 2022. Prior to BERG, Ms. Toomey was General Counsel at Metamark Genetics, a molecular diagnostics company focused on urological cancer care, from April 2015 to October 2017. Ms. Toomey also previously served as Senior Vice President and General Counsel at IntelligentMDx, a company that developed and manufactured molecular diagnostics products, from February 2009 to January 2015. Ms. Toomey is a registered patent attorney and practiced patent law before becoming in-house counsel. Prior to law school, Ms. Toomey was employed at Merck as a microbiologist. Ms. Toomey received her B.S. in bacteriology from the University of Wisconsin-Madison and her J.D. from Suffolk University Law School.

Non-Employee Directors

Kelly Barnes. Ms. Barnes has served as a member of our board of directors since January 2022. Prior to joining us, she served in various roles at PricewaterhouseCoopers from 1988 to 2020, most recently serving as a Global Health Industries Leader from 2018 to 2020 and as a U.S. Health Industries Leader from 2009 to 2020, where she oversaw services across all health-related industries. Ms. Barnes currently serves on the board of directors of Included Health and is a member of the executive advisory board of the Walton College of Business at the University of Arkansas. She received her B.S.B.A. and M.S.A in accounting from the University of Arkansas and is a registered certified public accountant in the state of Texas. We believe that Ms. Barnes is qualified to serve on our board of directors due to her strong business and financial acumen, and extensive experience advising companies in the healthcare industry.

William W. Bradley. Senator Bradley has served as a member of our board of directors since March 2017. Since 2000, Sen. Bradley has been a managing director of Allen & Company LLC, an investment banking firm. From 2001 until 2004, he acted as chief outside advisor to McKinsey & Company's non-profit practice. In 2000, Sen. Bradley was a candidate for the Democratic nomination for President of the United States. He served as a senior advisor and vice chairman of the International Council of JP Morgan & Co. from 1997 through 1999. During that time, Sen. Bradley also worked as an essayist for CBS Evening News, and as a visiting professor at Stanford University, the University of Notre Dame and the University of Maryland. Sen. Bradley served in the U.S. Senate from 1979 until 1997, representing the State of New Jersey. Prior to serving in the U.S. Senate, he was an Olympic gold medalist in 1964, and from 1967 through 1977 he played professional basketball for the New York Knicks, during which time they won two world championships. Sen. Bradley previously served on the board of directors of Starbucks Corporation from June 2003 until March 2018. Sen. Bradley also previously served on the board of directors of Seagate Technology, Willis Group Holdings Limited and QuinStreet, Inc. Sen. Bradley received his B.A. in American history from Princeton University and his M.A. in political philosophy and economics from the University of Oxford, Worcester College, where he was a Rhodes Scholar. We believe that Mr. Bradley is qualified

to serve on our board of directors due to his deep understanding of public policy and U.S. governmental and regulatory affairs, and his broad leadership and corporate governance experience.

Samuel Conaway. Mr. Conaway has served as a member of our board of directors since January 2024. Mr. Conaway also currently serves as a director of JD Palatine LLC, a privately held company. Since 2013, Mr. Conaway has held roles of increasing responsibility with Boston Scientific Corporation, a publicly held company focused on global development, manufacturing and marketing of medical devices, and in October 2021, he became President of U.S. cardiology sales. He also currently serves as chair of Close the Gap, Boston Scientific Corporation's health equity program. Prior to joining Boston Scientific Corporation, Mr. Conaway served as the Vice President of U.S. endovascular and coronary sales of Abbott Vascular (formerly Guidant), the cardiovascular device division of Abbott Laboratories, a publicly held biomedical company. Mr. Conaway has over 30 years of experience in the medical device industry. He received his B.S. in business management at the University of Phoenix and his M.B.A. at the University of Maryland. We believe that Mr. Conaway is qualified to serve on our board of directors due to his expertise and experience serving in leadership positions of various medical device companies.

Marc Elia. Mr. Elia has served as a member of our board of directors since June 2021. Mr. Elia also serves as a director and audit committee member at SQZ Biotech, a clinical-stage biotechnology company developing cell therapies for patients with cancer, a director at Invivyd, Inc. (previously Adagio Therapeutics), a publicly-held biotechnology company developing antibodies against viruses, including potentially against COVID-19, and previously served as a director at Adimab LLC, a provider of therapeutic antibody discovery and engineering. Mr. Elia also founded M28 Capital Management, a healthcare sector investment fund, and serves as its Chief Investment Officer. Mr. Elia received his B.A. at Carleton College, graduating with magna cum laude honors. We believe that Mr. Elia is qualified to serve on our board of directors due to his business expertise and experience serving as a director at various life science companies.

Clive Meanwell, M.B., Ch.B., M.D. Dr. Meanwell has served as a member of our board of directors since June 2021. Dr. Meanwell has also been a director and member of the compensation and audit committees at BB Biotech, a publicly held Switzerland-based biotechnology investment company, since 2004, a director at EQRx, a privately held biotechnology company aiming to make medicine more affordable, from January 2021 to August 2023, a director at Comanche BioPharma, a privately held preclinical biopharmaceutical company developing treatments for preeclampsia, since 2021, a director at Hugo Health, a privately held cloud-based healthcare platform, since 2021, a director at Invivyd, Inc., a publicly held biotechnology company developing antibodies against viruses, including potentially against COVID-19, since 2022, and a director at Saama, a privately held company, since 2021. Dr. Meanwell also currently serves as the Chief Executive Officer of a privately held biotechnology company focused on treating metabolic diseases and as Executive Chairman and General Partner at Population Health Partners LP, an investment company focused on innovative therapeutics with the potential to transform health outcomes for populations. Dr. Meanwell also founded The Medicines Company, a biopharmaceutical company focused on addressing cardiovascular disease, and served as Executive Chairman and Chief Executive Officer until 2018 and Chief Innovation Officer until 2020. Dr. Meanwell received his M.B., Ch.B. and M.D. from the University of Birmingham, UK. We believe that Dr. Meanwell is qualified to serve on our board of directors due to his medical background and experience working with and serving on the boards of directors of various pharmaceutical and healthcare companies.

Ajay Royan. Mr. Royan has served as a member of our board of directors since 2014. Mr. Royan is the founder and has served as Managing General Partner at Mithril Capital Management LLC, or Mithril, a venture capital firm investing in technology companies, since June 2012. Mr. Royan serves on the board of directors of several private companies in which Mithril Capital Management LLC or its affiliates have invested, including Adimab, LLC, Oklo Inc., Helion Energy, Inc., AppDirect, Inc. and C2FO. Mr. Royan previously served on the board of directors of Adagio Therapeutics, Inc. Mr. Royan serves on the science advisory board of the Oak Ridge National Laboratory and the board of directors of Fulbright Canada. Mr. Royan received his B.A. from Yale University. We believe that Mr. Royan is qualified to serve on our board of directors due to his experience

working in the venture capital industry and experience working with and serving on the boards of directors of numerous technology companies.

Amy W. Schulman. Ms. Schulman has served as a member of our board of directors since September 2018. Ms. Schulman is a healthcare investor and Managing Partner at Polaris Partners and co-founded and acts as Managing Partner of the Polaris Innovation Fund, which was formed in 2017. Ms. Schulman currently serves as Executive Chair of SQZ Biotech, as well as Lyndra Therapeutics, which she co-founded and served as the company's initial Chief Executive Officer from July 2015 to September 2019. Prior to joining Polaris Partners, Ms. Schulman, held various executive roles at Pfizer, including General Counsel, President of Pfizer Consumer Healthcare and Pfizer Nutrition. Ms. Schulman is currently a member of the board of directors of Alnylam Pharmaceuticals and Mount Sinai Hospital, and also serves as a member of Singapore's Health and Biomedical Sciences International Advisory Council. She previously served as a Senior Lecturer at Harvard Business School and was a partner at DLA Piper. Ms. Schulman received her B.A. in Philosophy and English at Wesleyan University, graduating with Phi Beta Kappa honors, and her J.D. from Yale Law School. We believe that Ms. Schulman is qualified to serve on our board of directors due to her experience working with and serving on the boards of directors of various pharmaceutical and healthcare companies.

Allan R. Will. Mr. Will has served as Chairman of our board of directors since August 2012. Mr. Will has also served as Chairman, President and Chief Executive Officer of EBR Systems, Inc., a privately held company developing a wireless cardiac pacing system for heart failure, from October 2011 to June 2019, and as Executive Chair since June 2019. He also serves as Chair of the board of directors of SetPoint Medical, Inc., a privately held clinical-stage bioelectronics medicine company dedicated to treating patients with chronic autoimmune disease, since March 2011. Since 2014, he has served as a director of Fogarty Innovation, a not-for-profit organization dedicated to advancing human health worldwide. Prior to these roles, Mr. Will served as founding Managing Director of Split Rock Partners' (and its predecessor, St. Paul Venture Capital's) Silicon Valley venture capital office, focusing on the therapeutic medical device field. Previously, Mr. Will founded The Foundry, an incubator dedicated to transforming medical device concepts into companies, where he also served as Chair and Chief Executive Officer from 1998 to 2002 and Chair until 2010, co-founding eleven companies including, among others, Ardian, Inc., a medical device company focused on treating hypertension, which was subsequently acquired by Medtronic plc, and Evalve Inc., a company treating heart failure by repairing mitral valves percutaneously, now a wholly owned subsidiary of Abbott Laboratories. Mr. Will is an inventor on more than 30 issued patents, is a University of Maryland Distinguished Alumnus and a recipient of the ASTIA/Deloitte Excellence in Mentoring Women Executives Award. He served on the MIT Entrepreneurship Center Shareholders' Board and the University of Maryland President's Committee on Innovation and Entrepreneurship. Mr. Will received his M.S. in management from MIT and his B.S. in zoology from the University of Maryland. We believe that Mr. Will is qualified to serve on our board of directors due to his experience as a founder, senior executive and board member of numerous life science companies.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Composition of our Board of Directors

Our board of directors currently consists of nine directors. Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the number of directors on our board of directors will be fixed from time to time by resolution of the board of directors and that our board of directors will be divided into three classes, as nearly equal in number as possible, with the directors in each class serving for a three-year term, and one class being elected each year by our stockholders.

When considering whether directors have the experience, qualifications, attributes or skills, taken as a whole, to enable our board of directors to satisfy its oversight responsibilities effectively in light of our business

and structure, the board of directors focuses primarily on each person's background and experience as reflected in the information discussed in each of the directors' individual biographies set forth above. We believe that our directors provide an appropriate mix of experience and skills relevant to the size and nature of our business.

Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our current directors will be divided among the three classes as follows:

- the Class I directors will be William W. Bradley, Ajay Royan and Amy W. Schulman, and their terms will expire at the annual meeting of stockholders to be held in 2025;
- the Class II directors will be Allan R. Will, Marc Elia and Clive Meanwell, M.B., Ch.B., M.D., and their terms will expire at the annual meeting of stockholders to be held in 2026; and
- the Class III directors will be Kelly Barnes, Samuel Conaway and Harith Rajagopalan, M.D., Ph.D., and their terms will expire at the annual meeting of stockholders to be held in 2027.

Director Independence

Our board of directors has determined that, of our directors, Kelly Barnes, William W. Bradley, Samuel Conaway, Marc Elia, Clive Meanwell, M.B., Ch.B., M.D., Ajay Royan, Amy W. Schulman and Allan R. Will do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of the Nasdaq Stock Market LLC, or the Nasdaq rules.

Board Leadership Structure

Our board of directors is currently chaired by Allan R. Will. Our corporate governance guidelines provide that, if the chairman of the board is a member of management or does not otherwise qualify as independent, the independent directors of the board may elect a lead director. The lead director's responsibilities include, but are not limited to: presiding over all meetings of the board of directors at which the chairman is not present, including any executive sessions of the independent directors; approving board meeting schedules and agendas; and acting as the liaison between the independent directors and the chief executive officer and chairman of the board. Our corporate governance guidelines further provide the flexibility for our board of directors to modify our leadership structure in the future as it deems appropriate.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. Our audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation and human strategy committee, or the compensation committee, assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, our entire board of directors is regularly informed through committee reports about such risks.

Board Committees

Our board of directors has established three standing committees—audit, compensation and nominating and corporate governance—each of which operates under a charter that will be approved by our board of directors. Upon our listing on the Nasdaq Global Market, each committee’s charter has been available under the Corporate Governance section of our website at www.fractyl.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Audit Committee

The audit committee’s responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors’ oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk management policies;
- meeting independently with our internal auditing staff, if any, registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

The members of our audit committee are Kelly Barnes, Marc Elia and Allan R. Will. Kelly Barnes serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable Nasdaq rules. Our board of directors has determined that each of Kelly Barnes, Marc Elia and Allan R. Will meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable Nasdaq rules. Our board of directors has determined that Kelly Barnes is an “audit committee financial expert” as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules.

Compensation Committee

The compensation committee’s responsibilities include:

- reviewing and approving, or recommending for approval by the board of directors, the compensation of our Chief Executive Officer and our other executive officers;
- overseeing and administering our cash and equity incentive plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our “Compensation Discussion and Analysis,” to the extent required; and
- preparing the annual compensation committee report required by SEC rules, to the extent required.

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The members of our compensation committee are Kelly Barnes, Samuel Conaway and Clive Meanwell, M.B., Ch.B., M.D. Clive Meanwell, M.B., Ch.B., M.D. serves as the chairperson of the committee. Our board of directors has determined that each of Kelly Barnes, Samuel Conaway and Clive Meanwell, M.B., Ch.B., M.D. is independent under the applicable Nasdaq rules, including the Nasdaq rules specific to membership on the compensation committee, and is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee’s responsibilities include:

- identifying individuals qualified to become board members;
- recommending to our board of directors the persons to be nominated for election as directors and to each board committee;
- developing and recommending to our board of directors corporate governance guidelines, and reviewing and recommending to our board of directors proposed changes to our corporate governance guidelines from time to time; and
- overseeing a periodic evaluation of our board of directors.

The members of our nominating and corporate governance committee William W. Bradley, Ajay Royan and Amy W. Schulman. William W. Bradley serves as the chairperson of the committee. Our board of directors has determined that each of William W. Bradley, Ajay Royan and Amy W. Schulman are independent under the applicable Nasdaq rules.

Compensation Committee Interlocks and Insider Participation

During 2023, the members of our compensation committee were Ajay Royan, Allan R. Will and Clive Meanwell, M.B., Ch.B., M.D. Mr. Royan is affiliated with one of our principal stockholders, Mithril. See “Certain Relationships and Related Person Transactions” for additional information on the related agreements such stockholder is party to with us. None of our executive officers currently serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the members of our compensation committee has ever been employed by us. For a description of transactions between us and members of our compensation committee and affiliates of such members, please see the section of this prospectus titled “Certain Relationships and Related Person Transactions.”

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Upon our listing on the Nasdaq Global Market, our code of business conduct and ethics will be available under the Corporate Governance section of our website at www.fractyl.com. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the 2023 Summary Compensation Table below. In 2023, our named executive officers and their positions were as follows:

- Harith Rajagopalan, M.D., Ph.D., Chief Executive Officer;
- Timothy Kieffer, Ph.D., Chief Scientific Officer; and
- Jay D. Caplan, President and Chief Product Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

2023 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2023.

Name and Principal Position	Year	Salary (\$)	Bonus (\$) ⁽¹⁾	Stock Awards (\$)	Option Awards (\$) ⁽²⁾	Non-Equity Incentive Plan Compensation (\$) ⁽³⁾	All Other Compensation (\$) ⁽⁴⁾	Total (\$)
Harith Rajagopalan, M.D., Ph.D. <i>Chief Executive Officer</i>	2023	\$550,000		\$2,430,014	\$ 267,990	\$ 313,500	\$ 270	\$3,561,774
Timothy Kieffer, Ph.D. ⁽⁵⁾ <i>Chief Scientific Officer</i>	2023	\$ 92,438	\$25,000	—	\$3,321,650	\$ 23,200	\$ 280	\$3,462,288
Jay D. Caplan <i>President and Chief Product Officer</i>	2023	\$400,000		\$2,097,678	\$ 220,507	\$ 154,000	\$ 1,188	\$2,873,373

- (1) Amount reflects a signing bonus paid to Dr. Kieffer pursuant to the terms of his offer letter. The signing bonus is subject to repayment if Dr. Kieffer is terminated for cause or if he voluntarily leaves our company during the first year following his start date.
- (2) Amounts reflect the full grant-date fair value of option awards granted during the fiscal years shown computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of option awards granted in the fiscal year ended 2022 and option grants in the fiscal year ended 2023 granted on or prior to September 30, 2023 in Note 12 to the consolidated financial statements included in this prospectus. The assumptions used to estimate the grant date fair value of the option awards granted to our named executive officers in November 2023, for such portion qualifying as “incentive stock options,” were as follows:

Risk-free interest rate	4.62%
Expected term (in years)	6.86
Expected volatility	58%
Expected dividend yield	0%
Grant date fair value	\$6.97

The assumptions used to estimate the grant date fair value of the option awards granted to our named executive officers in November 2023, for such portion not qualifying as “incentive stock options,” were as follows:

Risk-free interest rate	4.61%
Expected term (in years)	5.92
Expected volatility	60%
Expected dividend yield	0%
Grant date fair value	\$6.70

- (3) Amounts reported in this column represent the performance bonuses earned for the years shown. Dr. Kieffer’s 2023 annual bonus was prorated to reflect his September 12, 2023 start date. Please refer to “Narrative to Summary Compensation Table—2023 Bonuses” below for additional information regarding our 2023 bonus program.

- (4) With respect to Dr. Rajagopalan and Mr. Caplan, the amounts reported in this column represent annual life insurance premiums paid by the Company on behalf of the executive during the fiscal years shown.
- (5) Dr. Kieffer's employment with our company as Chief Scientific Officer commenced on September 12, 2023. Prior to his commencing employment with us, Dr. Kieffer was engaged by us as a consultant.

Narrative to Summary Compensation Table

2023 Salaries

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. The 2023 annual base salaries for our named executive officers were:

Named Executive Officer	2023 Annual Base Salary (\$)
Harith Rajagopalan, M.D., Ph.D.	\$ 550,000
Timothy Kieffer, Ph.D.	\$ 200,000 ⁽¹⁾
Jay D. Caplan	\$ 400,000

- (1) Pursuant to the terms of his offer letter, Dr. Kieffer's employment with us is initially part-time (approximately 20 hours per week), with the expectation that he will transition to full-time employment within 12 months of his September 12, 2023 start date.

2023 Bonuses

We offer our named executive officers the opportunity to earn annual cash bonuses to compensate them for attaining short-term goals as approved by our board of directors. For 2023, bonuses were based on attaining corporate and individual goals. Corporate goals for 2023 related to Revitalize-1 progress in site activation and enrollment; demonstrating Rejuva pre-clinical progress; and developing our organization for scale. Individual goals for 2023 related to a named executive officer's area of responsibility within the company. For 2023, Dr. Rajagopalan's bonus was based 100% on the achievement of corporate goals, while each of Dr. Kieffer's and Mr. Caplan's bonus was 75% based on the achievement of corporate goals and 25% based on the achievement of individual goals. Our board of directors approved a 2023 annual target bonus as a percent of base salary for each named executive officer as follows:

- Harith Rajagopalan, M.D., Ph.D.: 60%
- Timothy Kieffer, Ph.D.: 40%
- Jay D. Caplan: 40%

The actual amount of performance bonus earned by each of the named executive officers for 2023 is set forth in the "Non-Equity Incentive Plan Compensation" column of the 2023 Summary Compensation Table above.

Equity Compensation

We have historically granted stock options to our employees, including our named executive officers, as the long-term incentive component of our compensation program. Our stock options generally allow employees to purchase shares of our common stock at a price equal to the fair market value of our common stock on the date of grant, as determined by our board of directors. Stock option grants made to new hires typically vest as to 25% of the underlying shares on the first anniversary of the employment commencement date and in equal monthly installments over the following three years. Stock option grants made to existing employees typically vest in 48

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equal monthly installments following the date of grant. Historically, our stock options have been intended to qualify as “incentive stock options” to the extent permitted under the Internal Revenue Code.

The following table sets forth the options granted to our named executive officers during 2023 under our 2011 Stock Incentive Plan, as amended and restated, which we refer to as the 2011 Plan. These stock options have exercise prices equal to the fair market value of our common stock on the date of grant, as determined by the board of directors. These options vest as described in the Outstanding Equity Awards at 2023 Fiscal Year-End table.

<u>Named Executive Officer</u>	<u>2023 Options Granted</u>
Harith Rajagopalan, M.D., Ph.D.	49,649
Timothy Kieffer, Ph.D.	498,005
Jay D. Caplan	40,329

In addition to stock options, in 2023 we also granted RSUs to Dr. Rajagopalan and Mr. Caplan in the amounts set forth in the table below. The RSUs represent the right to receive shares of our common stock upon satisfaction of the applicable vesting conditions. These RSUs vest as described in the Outstanding Equity Awards at 2023 Fiscal Year-End table.

<u>Named Executive Officer</u>	<u>2023 RSUs Granted</u>
Harith Rajagopalan, M.D., Ph.D.	216,924
Timothy Kieffer, Ph.D.	—
Jay D. Caplan	187,257

In connection with this offering, we adopted a 2024 Incentive Award Plan, referred to below as the 2024 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of the Company and certain of its affiliates to enable the Company and certain of its affiliates to obtain and retain services of these individuals, which we consider to be essential to our long-term success. Following the effective date of the 2024 Plan, we will cease making any further grants under the 2011 Plan. However, the 2011 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. For additional information about the 2024 Plan, please see the section titled “Incentive Compensation Plans—2024 Incentive Award Plan” below.

Other Elements of Compensation

Retirement Plan. We currently maintain a 401(k) retirement savings plan for our employees who satisfy certain eligibility requirements. Dr. Rajagopalan and Mr. Caplan, our U.S.-based named executive officers, are eligible to participate in the 401(k) plan on the same terms as other full-time employees. The Internal Revenue Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies. For 2023, we did not make any employer contributions to the 401(k) plan. Dr. Kieffer was not eligible to participate in any Company-sponsored pension or retirement plans during 2023.

Health and Welfare Plans. Dr. Rajagopalan and Mr. Caplan are eligible to participate in our health and welfare plans, including medical, dental and vision benefits, medical and dependent care flexible spending accounts, short-term and long-term disability insurance and life insurance and accidental death & dismemberment insurance, generally on the same terms as our other U.S.-based full time employees, provided that, we provide higher levels of life insurance coverage to our U.S.-based executives, including Dr. Rajagopalan and Mr. Caplan, than is generally available to our other U.S.-based employees. Dr. Kieffer was not eligible to participate in any Company-sponsored health and welfare benefit plans during 2023.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2023.

Name	Vesting Start Date	Option Awards				Number of Shares or Units of Stock that have not Vested (#)	Market Value of Shares of Units of Stock that have not Vested (\$) ⁽¹⁾
		Underlying Un-exercised Options (#) Exercisable	Underlying Un-exercised Options (#) Un-exercisable	Option Exercise Price (\$)	Option Expiration Date		
Harith Rajagopalan, M.D., Ph.D. ⁽²⁾	8/19/2014	190,968	0	1.70	11/10/2024	—	—
	3/01/2015	123,484	0	1.70	2/09/2025	—	—
	12/17/2015	345,078	—	\$ 2.67	12/16/2025	—	—
	6/27/2016	179,868	0	2.67	6/26/2026	—	—
	3/14/2018	422,473	0	3.35	3/13/2028	—	—
	3/26/2020	445,333	29,688	3.89	3/25/2030	—	—
	6/24/2021	164,335	98,602	6.98	6/23/2031	—	—
	9/07/2022	5,096	11,213	8.59	9/06/2032	—	—
	3/16/2023	6,116	26,502	8.18	3/15/2033	—	—
11/10/2023	0	17,031 ⁽³⁾	11.21	11/09/2033	—	—	
							\$ 3,253,860
Timothy Kieffer, Ph.D.	11/10/2023	—	—	—	11/09/2030	216,924 ⁽⁷⁾	0
	10/14/2022	5,436 ⁽⁴⁾	3,883	8.59	12/06/2032	—	—
	9/12/2023	0	498,005 ⁽⁵⁾	11.21	9/12/2033	—	—
Jay D. Caplan ⁽⁶⁾	8/19/2014	95,484	0	0.82	11/10/2024	—	—
	3/01/2015	61,742	0	1.70	2/09/2025	—	—
	12/17/2015	145,875	—	\$ 2.67	12/16/2025	—	—
	6/27/2016	23,298	0	2.67	6/26/2026	—	—
	3/14/2018	94,879	0	3.35	3/13/2028	—	—
	3/26/2020	12,022	802	3.89	3/25/2030	—	—
	6/24/2021	24,358	14,616	6.98	6/23/2031	—	—
	9/07/2022	3,639	8,010	8.59	9/06/2032	—	—
	3/16/2023	4,805	20,823	8.18	3/15/2033	—	—
11/10/2023	0	14,701 ⁽³⁾	11.21	11/09/2033	—	—	
11/10/2023	—	—	—	11/09/2030	187,257 ⁽⁷⁾	\$2,808,855	

- (1) Amounts reflect the value of RSUs outstanding at fiscal year-end, calculated by multiplying the midpoint of the price range set forth on the cover page of this prospectus by the number of RSUs underlying each award.
- (2) Except for the option granted to Dr. Rajagopalan on November 10, 2023, Dr. Rajagopalan's options vest in 48 equal monthly installments following the vesting start date, subject to his continued service through each applicable vesting date.
- (3) The option vests as to 25% of the underlying shares on each of the first four anniversaries of the vesting start date, subject to the named executive officer's continued service through each applicable vesting date.
- (4) Dr. Kieffer's option vests in 24 equal monthly installments following the vesting start date, subject to Dr. Kieffer's continued service through each applicable vesting date.
- (5) Dr. Kieffer's option vests as to 25% of the underlying shares on the first anniversary of the vesting start date and in 36 equal monthly installments over the following three years, subject to Dr. Kieffer's continued service through each applicable vesting date. In the event that Dr. Kieffer does not convert to full-time employment status (40 hours per week) within 12 months of his September 12, 2023 start date, the number of shares subject to the option will be adjusted downward to equal the product of (1) the total number of shares originally subject to the option and (2) a fraction, (a) the numerator of which is the lesser of 40 and the number of hours Dr. Kieffer is providing services to the Company on a weekly basis as of September 12, 2024, and (b) the denominator of which is 40.
- (6) Except for the option granted to Mr. Caplan on November 10, 2023, Mr. Caplan's options vest in 48 equal monthly installments following the vesting start date, subject to his continued service through each applicable vesting date.

- (7) The RSUs vest upon the satisfaction of both a service condition and a performance condition (“dual vesting”). The service condition for the RSUs is satisfied on the first anniversary of the vesting start date, subject to continued service with us through such date. The performance condition for the RSUs will be satisfied upon the earliest of (i) the date six months after the occurrence of our IPO, (ii) such earlier date on or following the occurrence of our IPO that the managing underwriters of such public offering and our company permit open-market transfers of the shares underlying the RSUs and (iii) March 15th of the calendar year following the occurrence of our IPO.

Recent Changes in Executive Compensation

In anticipation and subject to the consummation of this offering, our board of directors approved certain changes to our named executive officers’ compensation arrangements. These include adjusting annual base salaries, entering into new employment agreements and granting, effective upon effectiveness of the registration statement of which this prospectus forms a part, stock options subject to performance-based vesting, each as described in more detail below.

Annual Base Salaries

Our board of directors approved an increase to the annual base salary of Dr. Rajagopalan to \$610,000, of Mr. Caplan to \$475,000, and of Dr. Kieffer to \$225,000 effective upon the date of this offering.

Equity Incentive Awards

Our board of directors approved the following options to purchase shares of our common stock under the 2024 Plan to be granted to our named executive officers effective the day prior to the first public trading date of our common stock:

<u>Named Executive Officer</u>	<u>Options Granted</u>
Harith Rajagopalan, M.D., Ph.D.	435,900
Jay D. Caplan	174,000
Timothy Kieffer, Ph.D.	58,500

These options have an exercise price per share equal to the offering price per share to the public in this offering and become eligible to vest subject to attainment of one or more performance goals during a performance period ending December 31, 2024, with any portion of the option that becomes eligible to vest vesting in four substantially equal installments occurring on the final day of the performance period and each of the first three anniversaries thereof.

Executive Employment Agreements

We entered into new employment agreements with Dr. Rajagopalan and Mr. Caplan that will supersede the named executive officer’s prior employment agreement with us effective on the date of this offering. In addition, we entered into amendments to our offer letter agreement and Severance Agreement and Change in Control Agreement with Dr. Kieffer effective on the date of this offering.

The agreements entitle the named executive officers to the annual base salaries described above under the heading “—Annual Base Salaries” and annual target bonus opportunities equal to those in effect for 2023. If we terminate Dr. Rajagopalan, Mr. Caplan or Dr. Kieffer without “cause” or he resigns for “good reason” (each as defined below), subject to his timely executing a release of claims and his continued compliance with certain restrictive covenants, he is entitled to receive (i) base salary continuation for a period of 12 months, (ii) direct payment of, or reimbursement for, continued health coverage pursuant to COBRA for up to 12 months and (iii) with respect to Dr. Rajagopalan only, a cash lump sum payment equal to 1.0 times his target annual bonus.

If we terminate Dr. Rajagopalan, Mr. Caplan or Dr. Kieffer without “cause” or he resigns for “good reason”, in either case, within 3 months prior to or within 18 months following a change in control, then, in lieu of the severance payments and benefits described above, subject to his timely executing a release of claims and his continued compliance with certain restrictive covenants, he is entitled to receive (i) a cash amount equal to one times (or 1.5 times for Dr. Rajagopalan) his annual base salary for the year of termination, payable over the 12 months (or 18 months for Dr. Rajagopalan) following his termination date; (ii) direct payment of, or reimbursement for, continued health coverage pursuant to COBRA for up to 12 months (or 18 months for Dr. Rajagopalan); (iii) a cash lump sum payment equal to 1.0 times (or 1.5 times for Dr. Rajagopalan) his target annual bonus; and (iv) accelerated vesting of all unvested equity or equity-based awards held by the executive that vest solely based on continued employment or service.

For purposes of the employment agreements, “cause” generally means, subject to certain notice and cure rights, the executive’s (i) refusal to substantially perform the duties associated with the executive’s position or those assigned to him; (ii) material breach of the employment agreement; (iii) conviction, plea of no contest, plea of nolo contendere, or imposition of unadjudicated probation of a felony or a crime involving moral turpitude, or the commission of any act involving fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary against the Company or any of its affiliates; or (iv) unlawful use (including being under the influence) or possession of illegal drugs on the Company’s (or any of its affiliate’s) premises or while performing executive’s duties and responsibilities under the employment agreement.

For purposes of the employment agreements, “good reason” generally means, subject to certain notice and cure rights, (i) any material reduction in annual base salary or target annual bonus, except any reduction in annual base salary that is proportionate to a reduction of base salaries affecting substantially all other executive officers of the Company; (ii) any material reduction in executive’s responsibilities, positions, duties or authority; (iii) the relocation of executive’s primary office to a location more than twenty-five (25) miles from the executive’s primary office as of the date of the employment agreement; or (iv) the Company’s breach of a material provision of the employment agreement.

Clawback Policy

We adopted a compensation recovery policy that is compliant with the listing requirements of Nasdaq.

Director Compensation

None of our non-employee directors received cash compensation from us during 2023. Dr. Rajagopalan does not receive compensation for his service as a director. His compensation for service as an executive officer during 2023 is disclosed in the 2023 Summary Compensation Table and related narrative disclosure.

In March 2023, Mr. Will received an option to purchase 11,649 shares of our common stock and Mr. Bradley and Ms. Barnes and Schulman each received an option to purchase 9,319 shares of our common stock. Each of these options was granted with an exercise price of \$8.18 per share and vests in 36 equal monthly installments following March 16, 2023, subject to continued service with us on each applicable vesting date. In August 2023, Mr. Will received (i) an option to purchase 3,205 shares of our common stock, with an exercise price of \$11.21 per share, that vests in equal installments on each of the first four anniversaries of the grant date, and (ii) an award of 40,829 RSUs that is subject to the same dual vesting conditions as the RSUs issued to our named executive officers in November 2023, except that the vesting start date of Mr. Will’s dual vesting RSU is August 21, 2023. In November 2023, Mr. Will received (i) an option to purchase 12,522 shares of our common stock, with an exercise price of \$11.21 per share, which vests in equal installments on each of the first four anniversaries of the grant date, and (ii) an award of 159,499 RSUs that is subject to the same dual vesting conditions as the RSUs issued to our named executive officers in November 2023.

2023 Director Compensation Table

The following table sets forth information concerning the compensation of non-employee directors for the year ended December 31, 2023.

Name	Stock Awards (\$)⁽²⁾	Options Award⁽¹⁾ ⁽²⁾ (\$)	Total (\$)
Kelly Barnes	—	43,600	43,600
William W. Bradley	—	43,600	43,600
Brian Dovey	—	—	—
Marc Elia	—	—	—
Clive Meanwell, M.B., Ch.B, M.D.	—	—	—
Ajay Royan	—	—	—
Amy W. Schulman	—	43,600	43,600
Allan R. Will	2,244,109	160,953	2,405,062

- (1) Amounts reflect the full grant-date fair value of option awards granted during 2023 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of option awards granted through September 30, 2023 in Note 12 to the consolidated financial statements included in this prospectus. The assumptions used to estimate the grant date fair value of the option awards granted to our non-employee directors in November 2023 were as follows:

Risk-free interest rate	4.62%
Expected term (in years)	6.25
Expected volatility	59%
Expected dividend yield	0%
Grant date fair value	\$6.78

- (2) The table below shows aggregate numbers of option awards (exercisable and unexercisable) and unvested stock awards held as of December 31, 2023 by each of our non-employee directors as of December 31, 2023.

Name	Options Award (#)	Stock Awards (#)
Kelly Barnes	55,917	—
William W. Bradley ⁽¹⁾	418,910	—
Brian Dovey ⁽²⁾	—	—
Marc Elia	—	—
Clive Meanwell, M.B., Ch.B, M.D.	—	—
Ajay Royan	—	—
Amy W. Schulman	140,783	—
Allan R. Will	233,227	200,328

- (1) Includes 186,393 options that are held in the name of a trust for the benefit of a family member.

- (2) Mr. Dovey ceased to serve as a member of our Board of Directors upon his passing on August 27, 2023.

Effective upon the effectiveness of the registration statement of which this prospectus forms a part, we adopted and our stockholders approved a compensation program for our non-employee directors under which each non-employee director will receive the following amounts for their services on our board of directors:

- Upon the director's initial election or appointment to our board of directors that occurs after our initial public offering, an option to purchase 45,000 shares of our common stock;
- If the director has served on our board of directors for at least six months as of the date of an annual meeting of stockholders and will continue to serve as a director immediately following such meeting, an option to purchase 22,500 shares of our common stock on the date of the annual meeting;

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- An annual cash retainer fee of \$43,500 ;
- If the director serves as chair on a committee of our board of directors, an additional annual cash retainer fee as follows:
 - Chair of the board: \$35,000
 - Chair of the audit committee: \$20,000
 - Audit committee member other than the chair: \$10,000
 - Chair of the compensation committee: \$15,000
 - Compensation committee member other than the chair: \$7,500
 - Chair of the nominating and corporate governance committee: \$10,000
 - Nominating and corporate governance committee member other than the chair: \$5,000

Director fees under the program will be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter; provided that the amount of each payment will be prorated for any portion of a quarter that a director is not serving on our board and no fee will be payable in respect of any period prior to the effective date of the registration statement of which this prospectus is a part.

Stock options granted to our non-employee directors under the program will have an exercise price equal to the fair market value of our common stock on the date of grant, as determined under the 2024 Plan (or another applicable equity plan) and will expire not later than ten years after the date of grant. The stock options granted upon a director's initial election or appointment will vest annually over three years. The stock options granted annually to directors will vest in a single installment on the earlier of the date of the next annual meeting of shareholders or the first anniversary of the date of grant, subject to continued service through such vesting date. In addition, all unvested stock options will vest in full upon the occurrence of a sale of the Company.

Incentive Compensation Plans

The following summarizes the material terms of the 2024 Plan and the 2024 Employee Stock Purchase Plan, or the ESPP, which will be the long-term incentive compensation plans in which our directors and named executive officers are eligible to participate following the consummation of this offering, and the 2011 Plan, under which we have previously made periodic grants of equity and equity-based awards to our directors and named executive officers.

2024 Incentive Award Plan

Effective the day prior to the first public trading date of our common stock, we adopted, and our stockholders approved, the 2024 Plan, under which we may grant cash and equity-based incentive awards to eligible service providers in order to attract, retain and motivate the persons who make important contributions to our company. The material terms of the 2024 Plan are summarized below.

Eligibility and Administration

Our employees, consultants and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2024 Plan. The 2024 Plan will be administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of our directors and/or officers

(referred to collectively as the plan administrator below), subject to the limitations imposed under the 2024 Plan, Section 16 of the Exchange Act, stock exchange rules and other applicable laws. The plan administrator will have the authority to take all actions and make all determinations under the 2024 Plan, to interpret the 2024 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2024 Plan as it deems advisable. The plan administrator will also have the authority to grant awards, determine which eligible service providers receive awards and set the terms and conditions of all awards under the 2024 Plan, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2024 Plan.

Shares Available for Awards

An aggregate of 4,298,825 shares of our common stock will initially be available for issuance under the 2024 Plan. The number of shares initially available for issuance will automatically increase on January 1 of each calendar year beginning in 2025 and ending in and including 2034, equal to the lesser of (A) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares determined by our board of directors. No more than 34,740,825 shares of common stock may be issued under the 2024 Plan upon the exercise of incentive stock options. Shares issued under the 2024 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

If an award under the 2024 Plan or the 2011 Plan, expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2024 Plan. Awards granted under the 2024 Plan in substitution for any options or other stock or stock-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the shares available for grant under the 2024 Plan, but will count against the maximum number of shares that may be issued upon the exercise of incentive stock options, or ISOs.

Awards

The 2024 Plan provides for the grant of ISOs, nonqualified stock options, or NSOs, stock appreciation rights, or SARs, restricted stock, dividend equivalents, RSUs, and other stock or cash-based awards. Certain awards under the 2024 Plan may constitute or provide for payment of "nonqualified deferred compensation" under Section 409A of the Code. All awards under the 2024 Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows:

- *Stock Options and SARs.* Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The plan administrator will determine the number of shares covered by each option and SAR, the exercise price of each option and SAR and the conditions and limitations applicable to the exercise of each option and SAR. The exercise price of a stock option or SAR will not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction or if otherwise determined by the plan administrator. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).
- *Restricted Stock and RSUs.* Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met and which may be subject

to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted stock and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2024 Plan.

- *Other Stock or Cash Based Awards.* Other stock or cash-based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock or other property. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other stock or cash-based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

Performance Criteria

The plan administrator may select performance criteria for an award to establish performance goals for a performance period. Performance criteria under the 2024 Plan may include, but are not limited to, the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the company's performance or the performance of a subsidiary, division, business segment or business unit of the company or a subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. When determining performance goals, the plan administrator may provide for exclusion of the impact of an event or occurrence which the plan administrator determines should appropriately be excluded, including, without limitation, non-recurring charges or events, acquisitions or divestitures, changes in the corporate or capital structure, events unrelated to the business or outside of the control of management, foreign exchange considerations, and legal, regulatory, tax or accounting changes.

Certain Transactions

In connection with certain corporate transactions and events affecting our common stock, including a change in control, or change in any applicable laws or accounting principles, the plan administrator has broad

discretion to take action under the 2024 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2024 Plan and replacing or terminating awards under the 2024 Plan. In addition, in the event of certain non-reciprocal transactions with our stockholders, the plan administrator will make equitable adjustments to awards outstanding under the 2024 Plan as it deems appropriate to reflect the transaction.

Notwithstanding the above, if a change in control occurs and a participant's award(s) are not continued, converted, assumed, or replaced with a substantially similar award by (i) the Company, or (ii) a successor entity or its parent or subsidiary, and provided that the participant has not had a termination of service, then immediately prior to the change in control such awards (other than any portion that is subject to performance-based vesting) will become fully vested, exercisable and/or payable, as applicable, and all forfeiture, repurchase and other restrictions thereon will lapse, in which case, such awards shall be canceled upon the consummation of the change in control in exchange for the right to receive the change in control consideration payable to other holders of change in control; provided that the portion of any award subject to performance-based vesting will be governed by the terms and conditions of the applicable award agreement and, in the absence of applicable terms and conditions, the plan administrator's discretion.

Provisions of the 2024 Plan Relating to Director Compensation

The 2024 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2024 Plan's limitations. Prior to commencing this offering, we intend to approve and implement a compensation program for our non-employee directors, which is described above under the heading "Director Compensation." Our board of directors (or its authorized committee) may modify the non-employee director compensation program from time to time in the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value of any equity awards granted under the 2024 Plan as compensation for services as a non-employee director during any fiscal year may not exceed \$1,000,000 in the fiscal year of the non-employee director's initial service and \$750,000 in any other fiscal year. The plan administrator may make exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the plan administrator may determine in its discretion, subject to the limitations in the 2024 Plan.

Plan Amendment and Termination; Repricing

Our board of directors may amend or terminate the 2024 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2024 Plan, may materially and adversely affect an award outstanding under the 2024 Plan without the consent of the affected participant and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the plan administrator may, without the approval of our stockholders, amend any outstanding stock option or SAR to reduce its price per share. The 2024 Plan will remain in effect until the tenth anniversary of its effective date, unless earlier terminated by our board of directors. No awards may be granted under the 2024 Plan after its termination.

Foreign Participants, Claw-Back Provisions, Transferability and Participant Payments

The plan administrator may modify awards granted to participants who are foreign nationals or employed outside the United States or establish subplans or procedures to address differences in laws, rules, regulations or customs of such foreign jurisdictions. All awards will be subject to any company claw-back policy as set forth in such claw-back policy or the applicable award agreement. Except as the plan administrator may determine or provide in an award agreement, awards under the 2024 Plan are generally non-transferrable, except

by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2024 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2024 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, shares of our common stock that meet specified conditions, a promissory note, a "market sell order," such other consideration as the plan administrator deems suitable or any combination of the foregoing.

2024 Employee Stock Purchase Plan

Effective upon the date on which the registration statement of which this prospectus is part is declared effective by the SEC, we adopted, and our stockholders approved, the ESPP, the material terms of which are summarized below.

Shares Available for Awards; Administration

A total of 487,070 shares of our common stock will initially be reserved for issuance under the ESPP. In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2025 and ending in and including 2034, by an amount equal to the lesser of (A) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors, provided that no more than 6,575,470 shares of our common stock may be issued under the ESPP. Our board of directors or a committee of our board of directors will administer and will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the ESPP.

Eligibility

All of our employees are eligible to participate in the ESPP, unless the administrator determines to limit participation in accordance with the terms of the ESPP and provided that an employee may not be granted rights to purchase stock under our ESPP if the employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our stock.

Grant of Rights

The ESPP is intended to qualify under Section 423 of the Code and stock will be offered under the ESPP during offering periods. The length of the offering periods under the ESPP will be determined by the plan administrator and may be up to twenty-seven months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in the offering period or such other date as determined by the administrator and set forth in the offering document. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation or such other maximum percentage determined by the administrator and set forth in the offering document. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period; in the absence of a contrary designation by the administrator, the maximum number of shares that may be purchased by a participant during an offering period is 100,000. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of \$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will expire at the end of the applicable offering period, and

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will be exercised at that time to the extent of the payroll deductions accumulated during the offering period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the ESPP at any time during a specified period prior to the end of the applicable offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer options granted under the ESPP other than by will or the laws of descent and distribution, and options granted under the ESPP are generally exercisable only by the participant.

Certain Transactions

In the event of certain non-reciprocal transactions or events affecting our common stock, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (1) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (2) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (3) the adjustment in the number and type of shares of stock subject to outstanding rights, (4) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (5) the termination of all outstanding rights.

Plan Amendment

The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code.

2011 Stock Incentive Plan

Our board of directors and stockholders have approved the 2011 Plan, under which we may grant stock options and other stock-based awards to employees, directors and consultants of our company or its affiliates. We have reserved a total of 11,994,408 shares of our common stock for issuance under the 2011 Plan.

Following the effectiveness of the 2024 Plan, we will not make any further grants under the 2011 Plan. However, the 2011 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. As discussed above, we anticipate that shares of our common stock subject to awards granted under the 2011 Plan that are forfeited, lapse unexercised or are settled in cash will again be available for issuance under the 2024 Plan.

Eligibility and Administration

Our employees, officers, directors, consultants and advisors are eligible to be granted awards under the 2011 Plan. Our board of directors administers the 2011 Plan and has the authority to determine recipients of awards and the terms of awards granted under the 2011 Plan, to interpret the 2011 Plan and awards outstanding thereunder, and to make changes to awards outstanding under the 2011 Plan, provided that such changes may not impair a participant's rights under the plan without the participant's consent. The board of directors may delegate its authority under the 2011 Plan to a committee.

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Types of Awards

The 2011 Plan provides for the grant of non-qualified and incentive stock options, restricted stock, RSUs and other stock-based awards to eligible participants. As of the date of this prospectus, awards of stock options and RSUs are outstanding under the 2011 Plan.

Certain Transactions

If certain changes are made in, or events occur with respect to, our common stock, the 2011 Plan and outstanding awards will be appropriately adjusted in the class, number and, as applicable, exercise price of securities as determined by the plan administrator. In the event of certain corporate transactions of our company, including a consolidation, merger, or a liquidation, our board of directors may make appropriate provision for the assumption or equitable substitution of outstanding awards, provide for the assumption or replacement of outstanding stock options, terminate awards for a cash payment equal to the excess of the fair market value of the underlying shares over the exercise or purchase price of the applicable award or provide that all stock options will terminate if not exercised within a specified number of days. The vesting and exercisability of awards may accelerate in connection with such a transaction, either by action of the plan administrator or under the terms of the applicable award agreements.

Amendment and Termination

The plan administrator may amend, suspend or terminated the 2011 Plan or any portion thereof from time to time, provided that the board of directors determines that any amendment does not materially and adversely affect the rights of participants under the 2011 Plan. Any amendment the plan administrator determines requires stockholder approval under the Internal Revenue Code will be subject to approval by our stockholders. The 2011 Plan will terminate on June 9, 2031, if not earlier terminated by the board of directors.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2022 to which we have been a party in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock, or 5% Security Holders, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under “Executive and Director Compensation.” We also describe below certain other transactions with our directors, executive officers and stockholders.

Related Party Agreements in Effect Prior to this Offering

July 2023 Warrants

In July 2023, we issued warrants to purchase common stock to lenders under our 2022 Convertible Notes for a variable number of shares based on the principal amount of \$20.9 million. The July 2023 warrants have an exercise price, at the holders’ choice, of (a) \$17.9927 per share, (b) the lowest original issue price of shares of preferred stock we issue in our next bona fide private preferred equity financing round, (c) in the event of any convertible note, or similar convertible security financing, the conversion price contemplated by such convertible security, or (d) in the event of an IPO, the per share offering price to the public in such IPO.

CVF, LLC holds 696,639 shares of common stock issuable upon the exercise of the July 2023 warrants at an assumed exercise price of \$15.00.

Amended and Restated Investors’ Rights Agreement

In connection with the issuance of our Series F Preferred Stock in June and July 2021, we entered into a Fifth Amended and Restated Investors’ Rights Agreement, or the IRA, with certain holders of our preferred stock, many of which are beneficial holders of more than 5% of our capital stock or are entities with which certain of our directors are affiliated. The IRA imposes certain affirmative obligations on us and also grants certain rights to holders, including certain registration rights with respect to the securities held by them, certain information and observer rights, and certain additional rights. Certain provisions of the IRA will terminate in connection with this offering. See “Description of Capital Stock—Registration Rights” for additional information.

Amended and Restated Voting Agreement

We are a party to an amended and restated voting agreement with certain of our stockholders, pursuant to which each of our directors was elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve. Our voting agreement will terminate by its terms in connection with the closing of this offering, and members previously elected to our board of directors pursuant to this voting agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Composition of our Board of Directors.

The Voting Agreement, including its provisions concerning the rights of certain of the holders to designate directors, will automatically terminate upon the consummation of this offering.

Amended and Restated Right of First Refusal and Co-Sale Agreement

In connection with the issuance of our Series F Preferred Stock in June and July 2021, we entered into a Fifth Amended and Restated Right of First Refusal and Co-Sale Agreement, or the ROFR and Co-Sale Agreement, with certain of our preferred stockholders, many of which are beneficial holders of more than 5% of our capital stock or are entities with which certain of our directors are affiliated. The ROFR and Co-Sale

Agreement, among other things: (a) grants our investors certain rights of first refusal and co-sale with respect to proposed transfers of our securities by certain preferred stockholders; and (b) grants us certain rights of first refusal with respect to proposed transfers of our securities by certain preferred stockholders.

The ROFR and Co-Sale Agreement will automatically terminate immediately prior to the completion of this offering.

Employment Agreements

We have entered into employment agreements or consulting agreements with certain of our executive officers. See “Executive and Director Compensation—Executive Compensation Arrangements.”

Director and Officer Indemnification and Insurance

Prior to the consummation of this offering, we intend to enter into separate indemnification agreements with each of our directors and executive officers. We have also purchased directors’ and officers’ liability insurance. See “Description of Capital Stock—Limitations on Liability and Indemnification of Officers and Directors.”

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL STOCKHOLDERS

The following table sets forth information as of December 31, 2023 with respect to the beneficial ownership of our common stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined in accordance with the rules issued by the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any community property laws.

Percentage ownership of our common stock before this offering is based on 38,449,724 shares of common stock outstanding as of December 31, 2023, assuming the conversion of all outstanding shares of our convertible preferred stock into 36,343,909 shares of our common stock, which will occur immediately prior to the closing of this offering. Percentage ownership of our common stock after this offering is based on our issuance of shares of our common stock in this offering and the issuance of 1,824,144 shares of common stock upon the automatic settlement of the 2022 Convertible Notes, including accrued interest, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, in connection with the closing of this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, RSUs, warrants or other rights held by such person that are currently exercisable or vested, or will become exercisable or vest within 60 days of December 31, 2023 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is c/o Fractyl Health, Inc., 17 Hartwell Avenue Lexington, Massachusetts 02421.

Name of Beneficial Owner	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After Offering	
	Number	Percentage	Number	Percentage
5% or Greater Stockholders				
Entities affiliated with Mithril ⁽¹⁾	6,078,868	15.8%	6,078,868	12.8%
Entities affiliated with General Catalyst ⁽²⁾	4,884,186	12.7	4,884,186	10.3
Entities affiliated with Bessemer Venture Partners ⁽³⁾	4,770,901	12.4	4,770,901	10.0
Entities affiliated with Domain Associates, L.L.C. ⁽⁴⁾	4,003,135	10.4	4,003,135	8.4
CVF, LLC ⁽⁵⁾	4,116,515	10.5	5,028,587	10.4
Named Executive Officers and Directors				
Harith Rajagopalan, M.D., Ph.D. ⁽⁶⁾	2,889,438	7.2	2,889,438	5.8
Timothy Kieffer, Ph.D. ⁽⁷⁾	6,212	*	6,212	*
Jay D. Caplan ⁽⁸⁾	947,429	2.4	947,429	2.0
Kelly Barnes	35,206	*	35,206	*
William W. Bradley ⁽⁹⁾	408,749	1.1	408,749	*
Entities affiliated with Marc Elia ⁽¹⁰⁾	1,389,451	3.6	1,389,451	2.9
Entities affiliated with Clive Meanwell, M.B., Ch.B., M.D. ⁽¹¹⁾	277,890	*	277,890	*
Ajay Royan ⁽¹⁾	6,078,868	15.8	6,078,868	12.8
Amy W. Schulman ⁽¹²⁾	130,622	*	130,622	*
Allan R. Will ⁽¹³⁾	205,721	*	205,721	*
All current executive officers and directors as a group (13 persons) ⁽¹⁴⁾	13,110,904	31.0	13,110,904	25.5

* Represents beneficial ownership of less than 1%.

(1) Consists of (a) 1,875,938 shares of common stock issuable upon conversion of Series C-1 Preferred Stock purchased by Mithril LP, (b) 3,030,193 shares of common stock issuable upon conversion of Series C-2 Preferred Stock purchased by Mithril LP, (c) 254,170 shares of common stock issuable upon conversion of Series D Preferred Stock purchased by Mithril LP, (d) 173,821 shares of common stock issuable upon conversion of Series E Preferred Stock purchased by Mithril II LP and (e) 744,746 shares of common stock issuable upon conversion of Series F Preferred Stock purchased by Mithril II LP. Mithril GP LP is the general partner of Mithril LP and Mithril GP LP may be deemed to have shared voting, investment and dispositive power with respect to the securities held by Mithril LP. Mithril II UGP LLC is the general partner of Mithril II GP LP, which is the general partner of Mithril II LP and each of Mithril II UGP LLC and Mithril II GP LP may be deemed to have shared voting, investment and dispositive power with respect to the securities held by Mithril II LP. Ajay Royan is the authorized person of Mithril GP LP and is the sole managing member of Mithril II UGP LLC. Ajay Royan and Peter Thiel are the members of the investment committees of Mithril GP LP and Mithril II GP LP, respectively. Each of the investment committees makes all investment decisions with respect to the shares held by each of Mithril LP and Mithril II LP, respectively, and may be deemed to have shared voting, investment and dispositive power with respect to the securities held by each of Mithril LP and Mithril II LP. The address of the principal offices of each of these entities is c/o Mithril Capital Management LLC, 600 Congress Avenue, Suite 3100, Austin, TX 78701.

(2) Consists of (i) 82,162 shares of common stock held of record by General Catalyst Group V, L.P., or GCGV, (ii) 1,714 shares of common stock held of record by GC Entrepreneurs Fund V, L.P., or GCEV, (iii) 4,702,161 shares of common stock issuable upon conversion of convertible preferred stock purchased by GCGV, and (iv) 98,149 shares of common stock issuable upon conversion of convertible preferred stock purchased by GCEV.

General Catalyst GP V, LLC, or GCGPV, is the general partner of General Catalyst Partners V, L.P., which is the general partner of GCGV and GCEV. GCGPV is controlled by a group of three or more individuals, or the Managing Directors, having shared voting and dispositive control over the shares held by GCGV and GCEV.

Under the so-called “rule of three,” because voting and dispositive decisions are made by a majority of GCGPV Managing Directors, no one of the Managing Directors is deemed to be a beneficial owner of the Company’s securities held by GCGV and GCEV.

The principal business address of the foregoing entities and persons is 20 University Road, Suite 450, Cambridge, MA 02138.

- (3) Consists of (i) 1,526,689 shares of common stock issuable upon the deemed conversion of shares of the convertible preferred stock held of record by Bessemer Venture Partners VII L.P. (BVP VII), (ii) 667,924 shares of common stock issuable upon the deemed conversion of shares of the convertible preferred stock held of record by Bessemer Venture Partners VII Institutional L.P. (BVP VII Institutional) and (iii) 2,576,288 shares of common stock issuable upon the deemed conversion of shares of the convertible preferred stock held of record by BVP VII Special Opportunity Fund L.P. (BVP SOF, and together with BVP VII and BVP VII Institutional, the BVP Entities). Deer VII & Co. L.P. (Deer VII L.P.) is the general partner of the BVP Entities. Deer VII & Co. Ltd. (Deer VII Ltd.) is the general partner of Deer VII L.P. Robert P. Goodman, David Cowan, Jeremy Levine, Byron Deeter and Robert M. Stavis are the directors of Deer VII Ltd. and hold the voting and dispositive power for the BVP Entities. Investment and voting decisions with respect to the shares held by the BVP Entities are made by the directors of Deer VII Ltd. acting as an investment committee. The address of each of these entities is c/o Bessemer Venture Partners, 1865 Palmer Ave., Suite 104, Larchmont, NY 10538.
- (4) Consists of 3,973,653 shares of common stock issuable upon conversion of convertible preferred stock held by Domain Partners VIII, L.P. (Domain VIII) and 29,482 shares of common stock issuable upon conversion of convertible preferred stock held by DP VIII Associates, L.P. (DP VIII). The managing members of One Palmer Square Associates VIII, L.L.C. share voting and investment power with respect to shares beneficially owned by Domain VIII and DP VIII. The address of Domain VIII and DP VIII is 103 Carnegie Center, Suite 300, Princeton, NJ 08540.
- (5) Consists of (i) 3,419,876 shares of common stock issuable upon conversion of convertible preferred stock, (ii) 696,639 shares of common stock issuable upon exercise of the July 2023 warrants at an assumed exercise price of \$15.00, and (iii) 912,072 shares of common stock issuable upon the automatic settlement of the 2022 Convertible Notes in the aggregate principal amount of approximately \$10.9 million, including accrued interest, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, in connection with the closing of this offering held by CVF, LLC. Richard H. Robb, manager of CVF, LLC, exercises voting and investment power with respect to the shares held by CVF, LLC. The address of CVF, LLC is 222 N. LaSalle Street, Suite 2000, Chicago, IL 60601.
- (6) Consists of (i) 663,093 shares of common stock and common stock issuable upon conversion of convertible preferred stock, (ii) 310,809 shares of common stock and common stock issuable upon conversion of convertible preferred stock held by various family trusts for which Harith Rajagopalan serves as the Investment Advisor and, as a result, exercises voting and dispositive power with respect to such shares, and (iii) 1,915,536 shares of common stock underlying options exercisable within 60 days from December 31, 2023.
- (7) Consists of 6,212 shares of common stock underlying options exercisable within 60 days from December 31, 2023.
- (8) Consists of (i) 477,616 shares of common stock and common stock issuable upon conversion of convertible preferred stock held by various family trusts for which Jay D. Caplan serves as the Investment Advisor and, as a result, exercises voting and dispositive power with respect to such shares, and (ii) 469,813 shares of common stock underlying options exercisable within 60 days from December 31, 2023.
- (9) Consists of (i) 186,393 shares of common stock underlying options exercisable within 60 days from December 31, 2023 held of record by the Hillcrest Irrevocable Trust, where Sen. Bradley serves as sole trustee, and (ii) 222,356 shares of common stock underlying options exercisable within 60 days from December 31, 2023.

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- (10) Consists of 944,827 shares of common stock issuable upon conversion of Series F Preferred Stock held by M28 Capital Master Fund LP, or M28 Capital, and 444,624 shares of common stock issuable upon conversion of Series F Preferred Stock held by Sparviero LP. Marc Elia, a member of our Board of Directors, is a managing member of M28 Capital Fund GP LLC, the general partner of M28 Capital and Sparviero LP, and, as a result, may be deemed to share voting and investment power with respect to the shares held by each. Mr. Elia disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. The address of M28 Capital and Sparviero LP is 700 Canal Street, 2nd Floor, Stamford, Connecticut 06902.
- (11) Consists of 277,890 shares of common stock issuable upon conversion of Series F Preferred Stock held by Population Health Capital Partners II, L.P., or PHPII. Clive Meanwell, M.B., Ch.B., M.D., a member of our Board of Directors, is the Founder of Population Health Partners GP, LLC, the general partner of PHPII, and, as a result, may be deemed to share voting and investment power with respect to the shares held by PHPII. Dr. Meanwell disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. The address of PHPII is 50 Mountaintop Road, Bernardsville, New Jersey 07924.
- (12) Consists of 130,622 shares of common stock underlying options exercisable within 60 days from December 31, 2023.
- (13) Consists of 205,721 shares of common stock underlying options exercisable within 60 days from December 31, 2023.
- (14) Consists of (i) 1,307,616 shares of common stock, (ii) 7,897,636 shares of common stock issuable upon conversion of convertible preferred stock, and (iii) 3,905,652 shares of common stock underlying options exercisable within 60 days from December 31, 2023.

DESCRIPTION OF CAPITAL STOCK

Capital Structure

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon the closing of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect changes to our capital structure that will occur upon the closing of this offering.

As of December 31, 2023, 40,273,868 shares of our common stock were outstanding and held by 98 stockholders of record. This amount assumes (i) the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock, which will occur immediately prior to the closing of this offering, and (ii) the issuance of 1,824,144 shares of our common stock upon the automatic settlement of the 2022 Convertible Notes, including accrued interest, assuming an initial public offering price per share of \$15.00, which is the midpoint of the price range set forth on the cover page of this prospectus, in connection with the closing of this offering.

General

At or prior to the consummation of this offering, we will file an amended and restated certificate of incorporation and we will adopt our amended and restated bylaws. Our amended and restated certificate of incorporation will authorize capital stock consisting of:

- 300,000,000 shares of common stock, par value \$0.00001 per share; and
- 10,000,000 shares of preferred stock, par value \$0.00001 per share.

We are selling 7,333,333 shares of common stock in this offering (8,433,332 shares if the underwriters exercise their option to purchase additional shares of our common stock in full). All shares of our common stock outstanding upon consummation of this offering will be fully paid and non-assessable.

The following summary describes the material provisions of our capital stock. We urge you to read our amended and restated certificate of incorporation and our amended and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part.

Certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay or prevent a tender offer or takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares of common stock.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

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Upon our dissolution or liquidation, after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of shares of our common stock will be entitled to receive pro rata our remaining assets available for distribution for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding.

Preferred Stock

Upon the closing of this offering, (i) all outstanding shares of our convertible preferred stock will be converted into shares of our common stock, and (ii) all outstanding shares of our convertible preferred stock will be cancelled.

Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of December 31, 2023, options to purchase 8,721,884 shares of our common stock were outstanding under our 2011 Plan, of which 6,106,422 options were vested of that date.

Restricted Stock Units

As of December 31, 2023, 604,509 shares of common stock issuable upon the vesting and settlement of RSUs were outstanding.

Warrants

2014 Warrants

As of December 31, 2023, 55,211 shares of common stock issuable upon the exercise of warrants issued in 2014 were outstanding.

2019 Warrants

As of December 31, 2023, 119,934 shares of common stock issuable upon the exercise of the 2019 warrants were outstanding.

2020 Warrants

As of December 31, 2023, 41,682 shares of common stock issuable upon the exercise of the 2020 warrants were outstanding.

July 2023 Warrants

As of December 31, 2023, 1,393,277 shares of common stock issuable upon the exercise of the July 2023 warrants, at an assumed exercise price of \$15.00, were outstanding.

The July 2023 warrants have an exercise price, at the holders' choice, of (a) \$17.9927 per share, (b) the lowest original issue price of shares of preferred stock we issue in our next bona fide private preferred equity financing round, (c) in the event of any convertible note, or similar convertible security financing, the conversion price contemplated by such convertible security, or (d) in the event of an IPO, the per share offering price to the public in such IPO.

September 2023 Warrants

As of December 31, 2023, 279,999 shares of common stock issuable upon the exercise of the September 2023 warrants, at an assumed exercise price of \$15.00, were outstanding.

The September 2023 warrants have an exercise price, at the holders' choice, of (a) \$17.9927 per share of common stock or \$8.3843 per share of Series F Preferred Stock, (b) the lowest original issue price of any series of preferred stock we issue after the issuance date of the September 2023 warrants, (c) the conversion or exercise price of any convertible debt security, option, or warrant we issue after the issuance date of the September 2023 warrants, or (d) the price at which our common equity was first sold to the public in a firm-commitment underwritten offering or otherwise.

Registration Rights

Under the IRA, following the consummation of this offering, certain holders of our common stock will be entitled to certain rights with respect to the registration of such shares for public resale under the Securities Act, until the rights otherwise terminate pursuant to the terms of the IRA. Pursuant to the IRA, beginning six months after the completion of this offering, the holders of up to 36,343,909 shares of our common stock, or certain permitted transferees, will be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Form S-1 Registration Rights

Pursuant to the IRA, certain holders of common stock are entitled to certain demand registration rights, including to demand registration of their registrable securities on a registration statement on Form S-1 at any time after 180 days following the completion of this offering. The holders of at least 30% of the registrable securities have the right to require us to file a registration statement on Form S-1 under the Securities Act in order to register the resale of their shares of common stock; *provided*, that no such registration is required to be made (i) during the period that is 60 days before our good faith estimate of the date of filing of, and ending on a date that is 180 days after the effective date of, a Company-initiated registration, (ii) at such time as we have effected two such registration statements, or (iii) if the holders who initiated the registration request propose to dispose of shares of registrable securities that may be immediately registered on Form S-3 pursuant to a request under the IRA. We may, in certain circumstances, defer such registrations, and the underwriters have the right, subject to certain limitations, to limit the number of shares included in such registrations.

Piggyback Registration Rights

If at any time after this offering we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Form S-3 Registration

After we are qualified for registration on Form S-3, the holders, as holders of registrable securities, may make a written request that we register the offer and sale of their shares on a Form S-3 registration statement,

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having an anticipated aggregate offering price of at least \$2,000,000; provided, that no such registration is required to be made (i) during the period that is 30 days before our good faith estimate of the date of filing of, and ending on a date that is 90 days after the effective date of, a Company-initiated registration, or (ii) at such time as we have effected two such registrations within the 12-month period immediately preceding the date of such request. We may, in certain circumstances, defer such registrations, and the underwriters have the right, subject to certain limitations, to limit the number of shares included in such registrations.

Expenses and Indemnification

Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration, filing and qualification fees; printers' and accounting fees; fees and disbursements of our counsel; and reasonable fees and disbursements of a counsel for the selling securityholders. Additionally, we have agreed to indemnify selling stockholders for damages, and any legal or other expenses reasonably incurred, arising from or based upon any untrue statement of a material fact contained in any registration statement, an omission or alleged omission to state a material fact in any registration statement or necessary to make the statements therein not misleading, or any violation or alleged violation by the indemnifying party of securities laws, subject to certain exceptions.

Termination of Registration Rights

The registration rights terminate as to any shares of registrable securities upon the earliest of: (i) such shares have been registered under the Securities Act pursuant to an effective registration statement filed thereunder and disposed of in accordance with the registration statement covering them, (ii) such shares may be publicly sold pursuant to Rule 144 of the Securities Act, (iii) the fifth anniversary of the completion of this offering, or (iv) the closing of a deemed liquidation event.

Choice of Forum

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or stockholders to us or to our stockholders; (iii) any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws (as either may be amended from time to time); and (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. As a result, any action brought by any of our stockholders with regard to any of these matters will need to be filed in the Court of Chancery of the State of Delaware and cannot be filed in any other jurisdiction; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause or causes of action against us or any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any part of this prospectus. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware, or a Foreign Action, in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and amended and restated bylaws and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation and amended and restated bylaws will contain the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Dividends

Declaration and payment of any dividend will be subject to the discretion of our board of directors. The time and amount of dividends will be dependent upon our business prospects, results of operations, financial condition, cash requirements and availability, debt repayment obligations, capital expenditure needs, contractual restrictions, covenants in the agreements governing our current and future indebtedness, industry trends, the provisions of Delaware law affecting the payment of distributions to stockholders and any other factors our board of directors may consider relevant. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business and to repay indebtedness, and therefore do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. See "Dividend Policy" and "Risk Factors—Risks Related to this Offering and Ownership of our Common Stock— We do not currently intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation of the value of our common stock."

Anti-Takeover Provisions

Our amended and restated certificate of incorporation and amended and restated bylaws, as they will be in effect immediately prior to the consummation of this offering, will contain provisions that may delay, defer or discourage another party from acquiring control of us. We expect that these provisions, which are summarized below, will discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors, which we believe may result in an improvement of the terms of any such acquisition in favor of our stockholders. However, they also give our board of directors the power to discourage acquisitions that some stockholders may favor. See "Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock— Provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock."

Authorized but Unissued Shares

The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of the Nasdaq Global Market. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Classified Board of Directors

Our amended and restated certificate of incorporation will provide that our board of directors will be divided into three classes, with the classes as nearly equal in number as possible and each class serving three-year staggered terms. In all other cases and at any other time, directors may only be removed from our board of directors for cause by the affirmative vote of a majority of the shares entitled to vote. See “Management—Composition of our Board of Directors.” These provisions may have the effect of deferring, delaying or discouraging hostile takeovers, or changes in control of us or our management.

Stockholder Action; Special Meeting of Stockholders

Our amended and restated certificate of incorporation will provide that our stockholders will not be able to take action by written consent for any matter and may only take action at annual or special meetings. As a result, a holder controlling a majority of our capital stock would not be able to amend our amended and restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our amended and restated bylaws, unless previously approved by our board of directors. Our amended and restated certificate of incorporation will further provide that special meetings of our stockholders may be called only by the chairman of our board of directors, our chief executive officer, our president or another officer selected by a majority of our board of directors, thus limiting the ability of a stockholder to call a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

In addition, our amended and restated bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. In order for any matter to be “properly brought” before a meeting, a stockholder will have to comply with advance notice and duration of ownership requirements and provide us with certain information. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a qualified stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder’s intention to bring such business before the meeting. These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of our outstanding voting securities until the next stockholder meeting.

Amendment of Certificate of Incorporation or Bylaws

The DGCL provides generally that the affirmative vote of the holders of a majority in voting power of the shares entitled to vote is required to amend a corporation’s certificate of incorporation, unless a corporation’s certificate of incorporation requires a greater percentage. Upon consummation of this offering, our bylaws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders a majority of the votes which all our stockholders would be eligible to cast in an election of directors.

Section 203 of the DGCL

We are subject to Section 203 of the DGCL, which prohibits persons deemed “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other

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transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Limitations on Liability and Indemnification of Officers and Directors

Our amended and restated bylaws provide indemnification for our directors and officers to the fullest extent permitted by the DGCL, along with the right to have expenses incurred in defending proceedings paid in advance of their final disposition. Prior to the consummation of this offering, we intend to enter into indemnification agreements with each of our directors and executive officers that may, in some cases, be broader than the specific indemnification and advancement provisions contained under our amended and restated bylaws and provided under Delaware law. In addition, as permitted by Delaware law, our amended and restated certificate of incorporation includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders to recover monetary damages against a director for breach of fiduciary duties as a director.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our stockholders will have appraisal rights in connection with a merger or consolidation of Fractyl Health, Inc. Pursuant to the DGCL, stockholders who properly demand and perfect appraisal rights in connection with such mergers or consolidations will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery, subject to certain limitations.

Stockholders' Derivative Actions

Under the DGCL, any of our stockholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action, in certain circumstances. Among other things, either the stockholder bringing any such action must be a holder of our shares at the time of the transaction to which the action relates or such stockholder's stock must have thereafter devolved by operation of law, and such stockholder must continuously hold shares through the resolution of such action.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

Trading Symbol and Market

We have applied to list our common stock on the Nasdaq Global Market under the symbol "GUTS."

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although we have applied to have our common stock listed on the Nasdaq Global Market, we cannot assure you that there will be an active public market for our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of 47,607,201 shares of common stock (48,707,200 shares if the underwriters exercise their option to purchase additional shares from us in full). Of these shares, all shares of common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

Lock-Up Agreements

We, our officers and directors and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed that, without the prior written consent of BofA Securities, Inc., Morgan Stanley & Co. LLC and Evercore Group L.L.C., as representatives of the underwriters, we and they will not, subject to certain exceptions, during the period ending 180 days after the date of this prospectus:

- directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, any shares of our common stock, or any securities convertible into or exchangeable for shares of our common stock; or
- enter into any swap or any other agreement or transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock,

whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise. These agreements are subject to certain exceptions, as described in the section of this prospectus entitled “Underwriting.”

The representatives of the underwriters have advised us that they have no present intent or arrangement to release any shares subject to a lock-up, and will consider the release of any lock-up on a case-by-case basis. Upon a request to release any shares subject to a lock-up, the representatives of the underwriters would consider the particular circumstances surrounding the request, including, but not limited to, the length of time before the lock-up expires, the number of shares requested to be released, reasons for the request, the possible impact on the market or our common stock and whether the holder of our shares requesting the release is an officer, director or other affiliate of ours.

Upon the expiration of the applicable lock-up periods, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Rule 144

Affiliate Resales of Restricted Securities

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days

before a sale, who has beneficially owned shares of our common stock for at least 180 days would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding; and
- the average weekly trading volume in our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the SEC and Nasdaq concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

Under Rule 144, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the 90 days preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory stock or option plan or other written agreement before the effective date of the registration statement of which this prospectus forms a part is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. Our affiliates can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

Registration Rights

Pursuant to our IRA, beginning six months after the completion of this offering, the holders of up to _____ shares of our common stock, or certain transferees, will be entitled to certain rights with respect to the registration of the offer and sale of those shares under the Securities Act. See the section titled “Description of Capital Stock—Registration Rights” for a description of these registration rights. If the offer and sale of these shares of our common stock are registered, the shares will be freely tradable without restriction under the Securities Act, subject to the Rule 144 limitations applicable to affiliates, and a large number of shares may be sold into the public market.

Registration Statements on Form S-8

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options, RSUs, warrants and common stock issuable under our equity incentive plans. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences for Non-U.S. Holders (as defined below) of the purchase, ownership, and disposition of our common stock issued pursuant to this offering. This discussion does not purport to be a complete analysis of all potential tax effects relating thereto. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not requested and will not seek any ruling from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules under the U.S. federal income tax laws, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions, regulated investment companies, or real estate investment trusts;
- brokers or dealers in securities or currencies;
- traders in securities or other persons that elect to use a mark-to-market method of accounting for their holdings in our stock;
- controlled foreign corporations (as defined in Section 957 of the Code), passive foreign investment companies (as defined in Section 1297 of the Code), and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes and other pass-through entities (and investors in such entities);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- pension plans or tax-exempt retirement plans;
- persons that own, or are deemed to own, more than five percent of our capital stock;

- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the common stock being taken into account in an applicable financial statement (as defined in Section 451(b) of the Code).

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “United States person” nor an entity treated as a partnership for U.S. federal income tax purposes. A United States person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and which has one or more “United States persons” (as defined in Section 7701(a)(30) of the Code) that have the authority to control all substantial decisions of the trust, or (2) has a valid election in effect to be treated as a United States person under the applicable Treasury Regulations.

Distributions

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “—Sale or other taxable disposition.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder timely

furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may be able to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder generally will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must timely furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to United States persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate provided for by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussion below on information reporting, backup withholding and foreign accounts, a Non-U.S. Holder will generally not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for a period or periods aggregating 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or aUSRPI, by reason of our status as a U.S. real property holding corporation, or aUSRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the rates applicable to United States persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate provided for by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate provided for by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, aUSRPHC. Because the determination of whether we are aUSRPHC depends, however, on the fair market value of ourUSRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not aUSRPHC or will not become one in the future.

Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is “regularly traded,” as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder’s holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock, if any, will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by timely furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder’s U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA), on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a “foreign financial institution” or a “non-financial foreign entity” (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any “substantial United States owners” (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain “specified United States persons” or “United States-owned foreign entities” (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

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Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. The U.S. Department of the Treasury has issued proposed Treasury Regulations providing that the withholding provisions under FATCA do not apply with respect to the gross proceeds from a sale or other disposition of our common stock. In its preamble to such proposed regulations, the U.S. Department of the Treasury stated that taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

BofA Securities, Inc., Morgan Stanley & Co. LLC and Evercore Group L.L.C. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
BofA Securities, Inc.	
Morgan Stanley & Co. LLC	
Evercore Group L.L.C.	
Total	<u>7,333,333</u>

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ _____ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	<u>Per Share</u>	<u>Without Option</u>	<u>With Option</u>
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discount, are estimated at \$3.3 million and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to \$30,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,099,999 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of the representatives. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- exercise any right with respect to the registration of any of the common stock, or file, cause to be filed or cause to be confidentially submitted any registration statement in connection therewith; or
- enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock, whether any such swap or transaction is to be settled by delivery of shares of common stock or other securities, in cash or otherwise.

The exceptions to the restrictions in the immediately preceding paragraph permit our executive officers and directors, subject to certain restrictions, to transfer the common stock:

- as a bona fide gift or gifts;
- to any immediate family member or any trust;
- as a distribution to any limited partners, members, stockholders or other equity holders;
- to affiliates or to any investment fund or other entity controlled or managed by the person subject to the lock-up;
- by will or intestate succession; or
- pursuant to a court order, a qualified domestic order or in connection with a divorce settlement.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Nasdaq Global Market Listing

We have applied to list our common stock on the Nasdaq Global Market under the symbol "GUTS."

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a

decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each a “Relevant State”), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation), except that offers of Shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of coordinator for any such offer; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of Shares shall require the Issuer or any Manager to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

References to the Prospectus Regulation includes, in relation to the UK, the Prospectus Regulation as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018.

The above selling restriction is in addition to any other selling restrictions set out below.

In connection with the offering, the underwriters are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

Notice to Prospective Investors in the United Kingdom

In relation to the United Kingdom, or the UK, no Shares have been offered or will be offered pursuant to the offering to the public in the UK prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority in the UK in accordance with the UK Prospectus Regulation and the FSMA, except that offers of Shares may be made to the public in the UK at any time under the following exemptions under the UK Prospectus Regulation and the FSMA:

- a. to any legal entity which is a qualified investor as defined under the UK Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of coordinator for any such offer; or
- c. at any time in other circumstances falling within section 86 of the FSMA,

provided that no such offer of Shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

Each person in the UK who initially acquires any Shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the Managers that it is a qualified investor within the meaning of the UK Prospectus Regulation.

In the case of any Shares being offered to a financial intermediary as that term is used in Article 5(1) of the UK Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the Shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the UK to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in the UK means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018, and the expression “FSMA” means the Financial Services and Markets Act 2000.

In connection with the offering, the underwriters are not acting for anyone other than the issuer and will not be responsible to anyone other than the issuer for providing the protections afforded to their clients nor for providing advice in relation to the offering.

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the “Financial Promotion Order”), (ii) are persons falling within Article 49(2)(a) to (d) (“high net worth companies, unincorporated associations etc.”) of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as “relevant persons”). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or the DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a. a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- b. a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- a. to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- b. where no consideration is or will be given for the transfer;
- c. where the transfer is by operation of law; or
- d. as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of

the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* NI 33-105, the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Goodwin Procter LLP has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

EXPERT

The consolidated financial statements of Fractyl Health, Inc. at December 31, 2022 and 2021, and for each of the two years in the period ended December 31, 2022, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed with the registration statement. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits filed with the registration statement. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC also maintains an internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

Upon the closing of this offering, we will be required to file periodic reports, proxy statements, and other information with the SEC pursuant to the Exchange Act. These reports, proxy statements, and other information will be available on the website of the SEC referred to above.

We also maintain a website at www.fractyl.com, through which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessed through our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Fractyl Health, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Fractyl Health, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2022 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations, expects the losses to continue and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Boston, Massachusetts
August 22, 2023,
except for Note 17,
as to which the date is January 26, 2024

Fractyl Health, Inc.
Consolidated Balance Sheets
(in thousands, except for share and per share information)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 49,269	\$ 95,473
Prepaid expenses and other current assets	2,360	915
Total current assets	51,629	96,388
Restricted cash	4,255	—
Property and equipment, net	326	723
Right-of-use lease assets	1,321	622
Other long-term assets	3,425	4,815
Total assets	<u>\$ 60,956</u>	<u>\$ 102,548</u>
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 980	\$ 970
Accrued expenses and other current liabilities	5,081	6,010
Lease liabilities, current	1,250	950
Note payable, current	—	15,724
Total current liabilities	7,311	23,654
Lease liabilities, long-term	465	334
Convertible notes payable, long-term	17,760	—
Convertible preferred stock warrant liability	407	544
Other long-term liabilities	2	11
Total liabilities	25,945	24,543
Commitments and contingencies		
Convertible preferred stock (Series A, B, C-1, C-2, D, E and F), \$0.00001 par value; 78,112,639 shares authorized at December 31, 2022 and 2021; 77,994,156 shares issued and outstanding at December 31, 2022 and 2021; aggregate liquidation preference of \$361,901 and \$344,734 at December 31, 2022 and 2021, respectively	287,330	287,330
Stockholders' deficit:		
Common stock, \$0.00001 par value; 107,000,000 shares authorized at December 31, 2022 and 2021; 2,055,399 and 1,887,117 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	17,206	13,747
Accumulated deficit	(269,525)	(223,072)
Total stockholders' deficit	(252,319)	(209,325)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 60,956</u>	<u>\$ 102,548</u>

The accompanying notes are an integral part of these consolidated financial statements.

Fractyl Health, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share information)

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 34,354	\$ 26,435
General and administrative	15,031	10,493
Total operating expenses	<u>49,385</u>	<u>36,928</u>
Loss from operations	<u>(49,385)</u>	<u>(36,928)</u>
Other income (expense), net:		
Interest income (expense), net	797	(1,442)
Loss from debt extinguishment	(313)	0
Change in fair value of convertible notes payable	2,315	0
Change in fair value of convertible preferred stock warrant liability	137	(356)
Other expenses, net	<u>(4)</u>	<u>(9)</u>
Total other income (expense), net	<u>2,932</u>	<u>(1,807)</u>
Net loss and comprehensive loss	<u>(46,453)</u>	<u>(38,735)</u>
Accretion of dividends on convertible preferred stock	(17,180)	(14,486)
Net loss attributable to common stockholders	\$ (63,633)	\$ (53,221)
Net loss per share attributable to common stockholders, basic and diluted	\$ (31.97)	\$ (28.62)
Weighted-average number of common shares outstanding, basic and diluted	<u>1,990,419</u>	<u>1,859,582</u>

The accompanying notes are an integral part of these consolidated financial statements.

Fractyl Health, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except for share information)

	Series A, B, C-1, C-2, D, E and F Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	66,067,108	\$ 187,484	1,853,827	\$ —	\$ 11,616	\$ (184,337)	\$ (172,721)
Issuance of Series F convertible preferred stock, net of issuance costs of \$154	11,927,048	99,846	—	—	—	—	—
Exercise of common stock options	—	—	33,290	—	40	—	40
Stock-based compensation expense	—	—	—	—	2,091	—	2,091
Net loss	—	—	—	—	—	(38,735)	(38,735)
Balance at December 31, 2021	77,994,156	287,330	1,887,117	—	13,747	(223,072)	(209,325)
Exercise of common stock options	—	—	168,282	—	321	—	321
Stock-based compensation expense	—	—	—	—	3,138	—	3,138
Net loss	—	—	—	—	—	(46,453)	(46,453)
Balance at December 31, 2022	<u>77,994,156</u>	<u>\$ 287,330</u>	<u>2,055,399</u>	<u>\$ —</u>	<u>\$ 17,206</u>	<u>\$ (269,525)</u>	<u>\$ (252,319)</u>

The accompanying notes are an integral part of these consolidated financial statements.

Fractyl Health, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$(46,453)	\$(38,735)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	452	676
Loss on disposal of fixed assets	1	8
Loss on debt extinguishment	313	—
Stock-based compensation expense	3,138	2,091
Non-cash interest expense	0	431
Change in fair value of convertible preferred stock warrant liability	(137)	356
Change in fair value of convertible notes payable	(2,315)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,445)	860
Accounts payable	10	666
Accrued expenses and other current liabilities	(929)	3,097
Lease assets and lease liabilities, net	(268)	(618)
Other long-term assets and liabilities	1,390	(2,294)
Net cash used in operating activities	<u>(46,243)</u>	<u>(33,462)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(56)	(51)
Net cash used in investing activities	<u>(56)</u>	<u>(51)</u>
Cash flows from financing activities:		
Proceeds from issuance of convertible notes	20,075	—
Proceeds from exercise of stock options	321	40
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	99,846
Repayment of notes payable	(16,037)	—
Principal payments on capital lease obligations	(9)	(7)
Net cash provided by financing activities	<u>4,350</u>	<u>99,879</u>
Net increase in cash, cash equivalents and restricted cash	<u>(41,949)</u>	<u>66,366</u>
Cash, cash equivalents and restricted cash at beginning of period	95,473	29,107
Cash, cash equivalents and restricted cash at end of period	<u>\$ 53,524</u>	<u>\$ 95,473</u>
Supplemental disclosure of cash flow information:		
Interest paid	\$ 7	\$ 1,028
Non-cash investing and financing activities:		
Remeasurement of right-of-use asset on lease modification	\$ 1,352	\$ —

The accompanying notes are an integral part of these consolidated financial statements.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements
(in thousands, except share and per share information)

1. Nature of the Business and Basis of Presentation

Fractyl Health, Inc. (the “Company”) was incorporated on August 30, 2010 under the name MedCatalyst, Inc. The Company subsequently changed its name to Fractyl Laboratories Inc. on January 10, 2012 and subsequently to Fractyl Health, Inc. on June 9, 2021. The Company is a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including type 2 diabetes (“T2D”) and obesity. The Company’s goal is to transform metabolic disease treatment from chronic symptomatic management to durable disease-modifying therapies that target the organ-level root causes of T2D and obesity. The Revita DMR System (“Revita”), the Company’s lead product candidate, is an outpatient procedural therapy designed to durably modify duodenal dysfunction, a major pathologic consequence of a high fat and high sugar diet, which can initiate T2D and obesity in humans. Led by the Company’s ongoing Revitalize-1 pivotal study, the Company has initiated a broad clinical program designed to evaluate Revita in multiple clinical studies across a range of patient populations from prediabetes and obesity to advanced T2D patients on long-acting insulin. In addition, the Company is developing Rejuva, a novel, locally administered, adeno-associated virus delivered pancreatic gene therapy platform. Rejuva is designed to enable long-term remission of T2D and obesity by durably altering metabolic hormone function in the pancreatic islet cells of patients. The Company believes Revita and Rejuva, if approved, have the potential to revolutionize treatment across the spectrum of T2D and obesity, align the clinical and economic interest of key stakeholders around the long-term regression of metabolic disease, and, at their fullest potential, significantly reduce the burden of metabolic disease globally.

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASUs”), promulgated by the Financial Accounting Standards Board (“FASB”).

Liquidity

The Company has financed its operations to date primarily through sales of its convertible preferred stock and debt financing. As of December 31, 2022, the Company had cash and cash equivalents totaling \$49,269 and net working capital of \$44,318. The Company has a history of operating losses and had an accumulated deficit of \$269,525 as of December 31, 2022.

Under ASC 205-40, *Going Concern*, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved by the Company’s Board of Directors (“Board”) before the date that the financial statements are issued.

The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain profitable operations. The Company is subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful discovery and development of

its product candidates, raising additional capital with favorable terms, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products. The successful discovery and development of product candidates requires substantial working capital which may not be available to the Company on favorable terms or not at all.

The Company has generated insignificant revenue from product sales since its limited pilot commercial launch in Germany in the first quarter of 2023. The Company does not anticipate generating revenue from product sales in the United States unless and until it successfully completes clinical development and obtains marketing approvals from one or more of the product candidates. As a result, management expects continuing operating losses in the future. As of December 31, 2022, the Company had available cash and cash equivalents of \$49,269, which is not sufficient to fund the Company's current operating plan for at least twelve months after the date the consolidated financial statements are issued. The Company expects to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. The Company is currently pursuing financing through a debt facility with lenders that would extend its cash runway, however there can be no assurances that management will be successful in securing this debt financing. The Company may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions and, if necessary, the Company will be required to implement cost reduction strategies which could curtail or delay its current clinical activities. As a result, substantial doubt exists about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates relied upon in preparing these consolidated financial statements include, but are not limited to, the fair value of common stock, the fair value of preferred and common stock warrants, the fair value of convertible notes payable, the fair value of stock-based awards, the incremental borrowing rate for lease accounting and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ materially from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents, which consist of money market funds, are stated at fair value.

Restricted Cash

The Company opened a cash collateral bank account in August 2022 in conjunction with the maintenance of a letter of credit required under its new facility lease (See Note 7). The letter of credit was issued for an original effective period of 12 months with automatic annual renewal until the expiration date.

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Concentration of Credit Risk

The Company's financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. As of December 31, 2022, substantially all of the Company's cash and cash equivalents were maintained at one financial institution. The Company's deposits at times may significantly exceed federally insured limits. Potential failure of the financial institution could impact access to our cash and cash equivalents and could adversely impact our operating liquidity and financial performance. To date, the Company has not experienced any losses related to its cash and cash equivalents.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's chief executive officer, views the Company's operations and manages its business as a single operating segment. All of the Company's long-lived assets are held in the United States.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

<u>Asset Category</u>	<u>Estimated Useful Life</u>
Computer and office equipment	3 to 5 years
Laboratory and manufacturing equipment	3 years
Website development costs	3 years
Leasehold improvements	Shorter of remaining lease term or the estimated useful life of 5 to 8 years

Costs of major additions and betterments are capitalized and amortized on a straight-line basis over the shorter of the remaining lease term or the estimated useful life of the asset. Upon retirement or sale, the cost of assets disposed of and the related accumulated amortization are removed from the accounts and any resulting gain or loss is included in the determination of net income or loss. Repairs and maintenance costs are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and right-of-use operating lease assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Deferred Public Offering Costs

Deferred public offering costs, which primarily consist of direct, incremental legal and accounting fees relating to the planned Initial Public Offering (“IPO”), are capitalized within other long-term assets. The deferred public offering costs will be offset against IPO proceeds upon the consummation of the offering. The Company had incurred \$2,195 in IPO costs as of December 31, 2021. In 2022, the Company delayed its IPO plan due to adverse market conditions. The delay was considered an aborted IPO and associated deferred offering costs of \$2,704 were expensed within general and administrative expenses on the consolidated statement of operations. The decision to abort the IPO does not preclude the Company from pursuing alternative financing options or future capital market transactions.

Other Long-term Assets

At December 31, 2022, other long-term assets consisted of vendor deposits of \$2,562 and implementation costs incurred in a cloud computing arrangement that is a service contract of \$863. At December 31, 2021, other long-term assets consisted of vendor deposits of \$2,562, deferred public offering costs of \$2,195 and long-term prepaid expenses of \$58.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company’s cash equivalents, 2022 Convertible Notes and convertible preferred stock warrant liability are carried at fair value, determined according to the fair value hierarchy above (See Note 3). The carrying values of the Company’s accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities. The carrying value of the Company’s outstanding 2019 Note approximates fair value (a Level 2 fair value measurement), reflecting interest rates currently available to the Company (See Note 6).

Leases

The Company adopted ASC 842, *Leases*, with an initial application date of January 1, 2021, using the modified retrospective method.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company’s finance lease is immaterial.

At the lease commencement date, the Company recognizes a right-of-use asset and a lease liability for all leases, except short-term leases with an original term of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is a reasonable certainty that the Company will renew. The operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of fixed lease payments over the expected lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in the lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. The Company recognizes operating lease expense on a straight-line basis over the lease term.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

See Note 7—"Leases" and Note 9—"Commitments and Contingencies" for additional information about the Company's leases.

Debt Issuance Costs

Debt issuance costs are recorded as a direct reduction to the carrying amount of the related debt liability rather than an asset in accordance with the simplified presentation of debt issuance costs provided by ASU No. 2015-03, *Interest – Imputation of Interest*. Debt issuance costs are amortized as additional interest expense using the effective interest rate method over the term of the debt.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include salaries, stock-based compensation and employee-related benefits, product development, clinical trial and related clinical manufacturing costs, allocation of facility-related expenses, overhead expenses and other outside expenses. Nonrefundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with companies and individuals globally. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or projects, including the phase or completion of events, invoices received and contracted costs. Judgments and estimates are made in determining the accrued balance at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

Convertible Preferred Stock Warrant Liability

The Company classifies a warrant to purchase shares of its Series B convertible preferred stock as a liability on its consolidated balance sheets as the warrant is a free-standing financial instrument that may require the Company to transfer assets upon exercise. The warrant was initially recorded at fair value on the grant date, and it is subsequently remeasured to fair value at each balance sheet date. Changes in fair value of the warrant are recognized as a component of other expenses, net in the consolidated statements of operations and comprehensive loss. The Company will continue to adjust the liability until the earlier of exercise or expiration of the warrant.

The Company uses the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the convertible preferred stock warrant. The Company has assessed these assumptions and estimates at each financial reporting period as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying Series B convertible preferred stock, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying convertible preferred stock. The Company determines the fair value per share of the underlying convertible preferred stock by taking into consideration the most recent sales of its convertible preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. Expected dividend yield is determined considering that the underlying Series B convertible preferred stock is entitled to dividends of 6.0% per year, whether or not declared.

Convertible Notes Payable

The Company elected to apply the fair value option (“FVO”) to its convertible notes payable in accordance with ASC 825, Financial Instruments. Accordingly, the convertible notes payables will be marked to market at each reporting period end. The primary reason for electing the fair value option was to address simplification and cost-benefit considerations that result from accounting for a hybrid financial instrument at fair value in its entirety versus bifurcation of the embedded derivatives from the debt host. See Note 6.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards based on their fair value on the date of the grant. Those awards typically have a graded vesting schedule and compensation expense for awards with only service conditions are recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. Compensation costs recognized for performance-based awards reflect the number of awards that are expected to vest during the requisite service period, and are adjusted to reflect those awards that ultimately vest upon final determination of the performance conditions achieved. Historical performance patterns, to the extent that they are indicative to the performance conditions to be achieved, are used in developing estimates for the probability of attaining these performance conditions.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient’s payroll costs are classified or in which the award recipient’s service payments are classified.

The Company uses the Black-Scholes option pricing model, which incorporates assumptions and estimates, to measure the fair value of its option awards on the date of grant of each stock option award. The Company determines the fair value per share of the underlying common stock by taking into consideration the results obtained from third-party valuations and additional factors that are deemed relevant. The Company historically

has been a private company and lacks company-specific historical and implied volatility information. Therefore, the Company estimates its expected stock volatility based on an analysis of reported data for a publicly traded peer group of companies that granted options with substantially similar terms and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term assumption for employee grants is determined by using the “simplified” method for awards that qualify as “plain-vanilla” options. The risk-free interest rate is based on the rate of the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future. Forfeitures are accounted for as they occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company’s tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and the tax basis of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Convertible Preferred Stock

The Company records its convertible preferred stock at fair value on the dates of issuance, net of issuance costs. All shares of convertible preferred stock have been presented outside of stockholders’ deficit as the redemption of such shares is outside the Company’s control (See Note 10). The Company does not adjust the carrying values of the convertible preferred stock to the redemption value of such stock until such time as a redemption event is probable of occurring.

Comprehensive Loss

Comprehensive loss is comprised of two components: net loss and other comprehensive loss, which includes other changes in stockholders’ deficit that result from transactions and economic events other than those with stockholders. The Company had no items qualifying as other comprehensive loss; accordingly, comprehensive loss equaled total net loss for each of the years ended December 31, 2022 and 2021.

Net Loss Per Share

Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company’s common shares

and participating securities. The Company's Series A, Series B, Series C-1, Series C-2, Series D, Series E, and Series F convertible preferred stock contain participating rights in any dividend paid by the Company and are therefore participating securities. Net loss attributable to common stockholders and participating securities is allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. However, the participating securities do not include a contractual obligation to share in the losses of the Company and were not included in the calculation of net loss per share in the periods that had a net loss.

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method and treasury stock method, as applicable. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Diluted net loss per share is equivalent to basic net loss per share for the years presented herein because common stock equivalent shares from the Series A, Series B, Series C-1, Series C-2, Series D, Series E, and Series F convertible preferred stock, stock option awards and outstanding warrants to purchase common stock and convertible preferred stock (see Note 15) were anti-dilutive.

Emerging Growth Company Status

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company may take advantage of these exemptions until the Company is no longer an "emerging growth company." Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, its consolidated financial statements may not be comparable to companies that comply with public company effective dates. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that it is no longer an "emerging growth company".

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2019-12, Income Taxes—Simplifying the Accounting for Income Taxes ("ASU 2019-12"). The ASU simplifies the accounting for income taxes by removing certain exceptions to the general principles as well as clarifying and amending existing guidance to improve consistent application. The Company adopted ASU 2019-12 on January 1, 2022 using the prospective basis approach. The adoption of the standard did not have a material impact on the company's consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06"), as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. Among other changes, the new guidance removes from GAAP separation models for convertible debt that require the convertible debt to be separated into a debt and equity component, unless the conversion feature is required to be bifurcated and accounted for as a derivative or the debt is issued at a substantial premium. As a result, after adopting the guidance, entities will no longer separately present such embedded conversion features in equity, and will instead account for the convertible debt wholly as debt. The new guidance also requires use of the "if-converted" method when calculating the dilutive impact of convertible debt on earnings per share, which is consistent with the Company's current accounting treatment under the current guidance. The Company

adopted ASU 2020-06 on January 1, 2022, using the modified retrospective approach and upon adoption there was no cumulative effect to retained earnings and no impact to other paid in capital as there were no conversion options previously recorded to equity. There was no impact to the Company's statements of operations or cash flows as the result of the adoption of ASU 2020-06.

In October 2020, the FASB issued ASU No. 2020-10, Codification Improvements ("ASU 2020-10"). The ASU contains improvements to the Codification by ensuring that all guidance that requires or provides an option for an entity to provide information in the notes to financial statements is codified in the disclosure section of the Codification. The ASU also improves various topics in the Codification so that entities can apply guidance more consistently on codifications that are varied in nature where the original guidance may have been unclear. The Company adopted ASU 2020-06 on January 1, 2022. The adoption of the standard did not have a material impact on the company's consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements

The Company has evaluated recently issued accounting pronouncements and determined that there are no such pronouncements that have a material impact on its consolidated financial statements and related disclosures.

3. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of fair value hierarchy utilized to determine such fair values:

	Fair Value measurements as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	\$ 1	\$ —	\$ —	\$ 1
	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1</u>
Liabilities:				
Convertible notes payable	\$ —	\$ —	\$ 17,760	\$ 17,760
Convertible preferred stock warrant liability	—	—	407	407
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 18,167</u>	<u>\$ 18,167</u>

	Fair Value measurements as of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	\$ 2	\$ —	\$ —	\$ 2
	<u>\$ 2</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2</u>
Liabilities:				
Convertible preferred stock warrant liability	\$ —	\$ —	\$ 544	\$ 544
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 544</u>	<u>\$ 544</u>

During the years ended December 31, 2022 and 2021, there were no transfers between Level 1, Level 2 and Level 3.

See Note 6—"Notes Payable" for the discussion of the fair value methodology of the convertible notes payable and a rollforward of the fair value.

See Note 8—“Convertible Preferred Stock Warrant Liability” for the discussion of the fair value methodology of the convertible preferred stock warrants and a rollforward of the fair value.

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2022	2021
Computer and office equipment	\$ 844	\$ 927
Laboratory and manufacturing equipment	521	812
Website development costs	40	40
Leasehold improvements	3,466	3,473
	<u>4,871</u>	<u>5,252</u>
Less: accumulated depreciation	<u>(4,545)</u>	<u>(4,529)</u>
	<u>\$ 326</u>	<u>\$ 723</u>

Depreciation expense for the years ended December 31, 2022 and 2021 were \$452 and \$676, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2022	2021
Payroll and payroll-related expenses	\$2,760	\$1,851
External research and development services	1,519	1,784
Professional fees and consulting services	766	2,272
Other current liabilities	36	103
	<u>\$5,081</u>	<u>\$6,010</u>

6. Notes Payable

2019 Note

In February 2019, the Company entered into a loan and security agreement (the “2019 Note”) with a lender that provided for borrowings of up to \$15,000 in two term loan advances defined as “Term A Loan” and “Term B Loan”, collectively referred to as “Term Loans”. Under Term A Loan, the Company may borrow up to \$10,000 by June 30, 2019 with an initial draw of \$3,000 upon execution of the 2019 Note and optional additional borrowings at a minimum increment of \$2,500. Under Term B Loan, the Company may borrow \$5,000 upon achieving certain clinical milestones as defined in the 2019 Note, by December 31, 2019. On February 5, 2019, the Company drew down \$3,000 under Term A Loan, and on May 31, 2019, the Company drew down an additional \$7,000 under Term A Loan. On October 3, 2019, the Company drew down \$5,000 under Term B Loan.

The outstanding balances under the Term Loans bear interest at a floating annual rate that equals the greater of 1.5% above the Wall Street Journal prime rate or 6.75%. The Term Loans initially required interest-only repayments through December 31, 2020. After the interest-only period, the Term Loans require 24 equal monthly principal repayments of the outstanding balances plus accrued interest through the maturity date on December 1, 2022. Borrowings under the 2019 Note are secured by substantially all assets of the Company and assets the Company may acquire in the future, other than intellectual property, except for proceeds from intellectual property outstanding.

There are no financial covenants associated with the 2019 Note; however, there are certain operating and negative covenants restricting the Company's activities, including limitations on dispositions, mergers or acquisitions, encumbering or granting a security interest in its intellectual property, incurring indebtedness or liens, paying dividends, making certain investments and engaging in certain other business transactions. The obligations under the 2019 Note are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in the Company's business, operations or financial or other condition.

The 2019 Note provides for certain prepayment premiums should the Company make early payments of any principal balances prior to the maturity date. Upon occurrence of either payment default or covenant default, the lender may take one of the following actions: i) declare that all obligations are immediately due and payable; ii) stop advancing money; iii) demand that the Company deposit cash collateral with the lender.

On the date that the 2019 Note is paid in full or becomes due and payable, the Company will make a payment (the "Final Payment"), in addition to the regular monthly payments of principal plus accrued interest, equal to 6% of the original principal amount of the Term Loans extended by the lender. The Final Payment is being accreted as additional interest expense over the term of the respective Term Loans using the effective interest rate method.

In February 2019, in connection with entering into the 2019 Note, the Company issued to the lender and an affiliated investor warrants to purchase up to an aggregate of 119,934 shares of the Company's common stock with par value of \$0.00001 per share, at an exercise price of \$3.3263 per share (the "2019 Warrants"). Of the 119,934 shares, 79,965 shares were exercisable upon the issuance of the warrants and an additional 39,969 shares became exercisable upon the drawdown of the Term B Loan. The warrants have a contractual term of ten years from issuance. The Company recorded the total fair value of the warrants of \$284 as debt discount and additional paid-in capital. The debt discount recorded by the Company also included \$24 of fees paid to lenders and \$25 of debt issuance costs. The debt discount is being amortized as additional interest expense over the term of the respective Term Loans using the effective interest rate method. The 2019 Warrants were not exercised from its inception through December 31, 2022.

First Amendment to 2019 Note

On December 31, 2020, the Company entered into the First Amendment to the 2019 Note (the "First Amendment") whereby the Term Loans were amended to revise the interest-only repayment terms.

The First Amendment extended interest-only payments through January 31, 2021. After the interest-only period, the First Amendment requires 23 equal monthly principal repayments of the outstanding balance plus accrued interest starting from February 1, 2021 through the maturity date of December 1, 2022. Upon achieving certain milestones as specified in the First Amendment, the interest-only payment may be extended through July 31, 2021 with the principal to be repaid equally over 17 consecutive calendar months starting August 1, 2021 and may be further extended through December 31, 2021 with principal to be repaid equally over 12 consecutive calendar months starting January 1, 2022.

In connection with entering into the First Amendment, the Company issued to the lender and an affiliated investor, warrants to purchase up to an aggregate of 41,682 shares of the Company's common stock, par value \$0.00001 per share, at an exercise price of \$3.8843 per share (the "2020 Warrants"). The 2020 Warrants expire ten years from the date of issuance on December 30, 2030.

The Company accounted for the First Amendment as a debt modification in accordance with ASC 470-50, *Modifications and Extinguishments*. As such, unamortized fees will continue to be deferred and amortized, any new creditor fees were capitalized and amortized as part of the effective yield and new fees paid to third parties were expensed.

The Company recorded the total fair value of the 2020 Warrants of \$105 as debt discount and additional paid-in capital. The debt discount recorded by the Company also included \$8 of debt issuance costs. The debt discount was being amortized as additional interest expense over the term of the respective Term Loans using the effective interest rate method. The 2020 Warrants were not exercised through December 31, 2022.

The fair value of the 2020 Warrants was determined using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	0.9%
Weighted average expected term (in years)	10.0
Weighted average expected volatility	57%
Weighted average expected dividend yield	0%
Fair value of common stock per share	\$3.8843

Second Amendment to 2019 Note

On February 26, 2021, the Company entered into the Second Amendment to the 2019 Note (the “Second Amendment”) to further revise the interest-only repayment terms amended by the First Amendment.

The Second Amendment extended interest-only payments through July 31, 2021, upon the achievement of a certain milestone event, as defined in the Second Amendment. After the interest-only period, the Second Amendment requires 17 equal monthly principal repayments of the outstanding balance plus accrued interest through the maturity date of December 1, 2022. Upon achieving additional milestone events as specified in the Second Amendment, the interest-only payment may be extended to December 31, 2021, with principal to be repaid equally over 12 consecutive calendar months through the maturity date of December 1, 2022.

The Company accounted for the Second Amendment as a debt modification in accordance with ASC 470-50, *Modifications and Extinguishments*. As such, unamortized fees will continue to be deferred and amortized. New creditor fees related to the Second Amendment were immaterial.

In June 2021, upon achievement of certain milestones in the Second Amendment, the interest-only payment was extended through January 1, 2022. All principal under the Term Loans will be repaid over 12 consecutive calendar months in the year ending December 31, 2022.

For the year ended December 31, 2021, the Company recognized total interest expense of \$1,457 related to the 2019 Note, which included additional interest expense of \$431 associated with the accretion of the Final Payment and the amortization of the debt discount. The effective annual interest rate of the 2019 Note was 9.72% for the year ended December 31, 2021.

On January 3, 2022, the Company fully paid off the 2019 Note by making a lump-sum payment to the lender of the Term Loans for a total amount of \$16,130, which consisted of the outstanding principal balance of the Term Loans of \$15,000, the Final Payment of \$900, the prepayment premium of \$137 and accrued interest of \$93. A loss from debt extinguishment of \$313 was recognized as a nonoperating expense in the consolidated statement of operations during the year ended December 31, 2022 as a result of the early payoff of the 2019 Note.

2022 Convertible Notes

On January 11, 2022, the Company entered into a financing arrangement with certain lenders (the “Lenders”) in which the Company issued convertible promissory notes in exchange for an aggregate principal amount of \$20,075 (the “2022 Convertible Notes”). Interest accrues on the unpaid principal balance of the 2022 Convertible Notes at the rate of 3% per year until it is paid or converted in full. Subject to the conversion provisions set forth, all principal and accrued interest shall be due and payable on July 11, 2023 (the “Maturity Date”).

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Effective upon the closing of an equity financing event, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes will automatically be converted into shares of the same class and series of capital stock of the Company issued to other investors in the financing event at a conversion price equal to (i) in the event of an IPO, 80% of the price per share of the public company securities paid by other investors in the IPO; or (ii) in the event of a non-IPO, 80% of the opening price on the applicable stock exchange on the closing date; or (iii) in the event of a private financing round, 80% of the price per share of the financing securities paid by other investors in the financing round. In no event should the conversion price be a) less than the amount equal to \$875,000 divided by our fully diluted capitalization as of immediately prior to the closing of the financing event (the “Floor Valuation”); or (b) more than an amount equal to \$1,100,000 divided by the Company’s fully diluted capitalization as of immediately prior to the closing of the financing event (the “Valuation Cap”).

In the event of a Change of Control of the Company, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes will, at the option of the Lenders, (1) be repaid in cash as of the closing of such Change of Control; or (2) be converted into common stock of the Company at a conversion price equal to 80% of the fair market value of the Company’s common stock as determined in good faith by the Company’s Board of Directors, provided that, if the successor company is a publicly traded issuer, the conversion price will be determined by a volume-weighted average price per share of the successor company’s stock on the applicable stock exchange for the five trading days prior to the Change of Control; and provided further that, in the event stockholders are to receive any non-cash consideration pursuant to the Change of Control, the Lenders shall receive the same non-cash consideration, in the same proportion, and the value of such non-cash consideration received by the Lenders shall be determined in accordance with the agreement governing such Change of Control. In no event should the conversion price be less than the Floor Valuation or more than the Valuation Cap.

In the event the 2022 Convertible Notes is still outstanding on the Maturity Date, or from and after the date and during the continuation of an Event of Default, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes will be converted, at the option of the holders, into shares of the Company’s Series F Preferred Stock at a conversion price equal to the lesser of (a) \$8.3843 per share or (b) the Valuation Cap.

There are no financial covenants associated with the 2022 Convertible Notes, however the 2022 Convertible Notes do contain customary events of default, subject to rights and remedies generally applicable to federal law or the laws of the State of Delaware. As of December 31, 2022, the Company was in compliance with the terms of the arrangement.

The fair value of the 2022 Convertible Notes was estimated using a scenario-weighted binomial lattice model to calculate equity values at different points in time leading up to a conversion event. Assumptions in the model include but are not limited to the following: equity value, volatility, time to conversion event (IPO or non-IPO), scenario weightings and risk-free rate.

This fair value measurement was based on significant inputs that were not observable in the market and represented a Level 3 measurement. The following table provides a rollforward of the fair value of the 2022 Convertible Notes:

	<u>Fair Value</u>
Original balance at issuance as of January 11, 2022	\$20,075
Change in fair value	<u>(2,315)</u>
Balance as of December 31, 2022	<u>\$17,760</u>

Transaction costs incurred during the years ended December 31, 2022 and 2021 related to the issuance of the 2022 Convertible Notes were immaterial and were expensed as incurred. Accrued interest on the 2022 Convertible Notes was incorporated into the determination of the fair value of the 2022 Convertible Notes.

7. Leases

Lexington Lease

In November 2015, the Company entered into a lease agreement for office and laboratory space in Lexington, Massachusetts with the lease term covering a seven-year period from May 1, 2016 through April 30, 2023 (the “Lexington Lease”). The Lexington facility includes 30,000 square feet of office and laboratory space and has been occupied by the Company since August 2016. The Lexington Lease includes a provision for a \$3,000 tenant improvement allowance, which was funded by the lessor in 2016. The Lexington Lease does not contain any material residual value guarantees or material restrictive covenants. The Company is not involved in the construction or design of the additional underlying asset, aside from constructing leasehold improvements. The Company is obligated to pay its portion of real estate taxes and costs, including costs of operations, maintenance, repair, replacement, and management of the Lexington Lease.

The Company recognized right-of-use assets and lease liabilities for such leases in connection with its adoption of ASC 842 as of January 1, 2021. The Company reports operating lease right-of-use assets in right-of-use lease assets and the current and non-current portions of its operating lease liabilities in lease liabilities, current and lease liabilities, long-term, respectively, on its Consolidated Balance Sheet. The discount rate used to calculate lease liabilities was the Company’s estimated incremental borrowing rate of 6.75%.

In June 2022, the Company extended the term of the Lexington Lease for twelve months commencing on May 1, 2023 and expiring on April 30, 2024. The extended term will expire on April 30, 2024 unless terminated earlier in accordance with the terms of the lease and the Company shall have no option to further extend the lease upon the expiration date. The total fixed lease payment during the extended term is \$1,590.

The extension of the lease has resulted in a revision to the lease term, which has been accounted for as a modification in accordance with ASC 842. As a result of the lease modification, the Company has reassessed the lease liability and right-of-use asset related to the lease. The reassessment involves the remeasurement of the present value of future lease payments, considering the revised lease term and any changes in lease payments, including any adjustments due to changes in discount rate. The Company reassessed its incremental borrowing rate at the time of the lease modification to be 11.75%, which was used as the discount rate in the remeasurement of the lease liabilities. The lease extension resulted in an addition of the operating right-of-use asset and lease liability of \$1,352 on the date of the modification.

Burlington Lease

In August 2022, the Company entered into a lease agreement for office and laboratory space in Burlington, Massachusetts, encompassing a rentable area of 78,000 square feet (the “Burlington Lease”). The lease contains a total lease term of 128 months, which includes an initial eight-month period of free rent and a remaining lease term of 10 years, subject to total lease payments of \$59,284. Additionally, the Burlington Lease incorporates a five-year renewal option exercisable at the Company’s discretion.

The commencement of the Burlington Lease is contingent upon the substantial completion of the lessor’s construction of the facility. As of December 31, 2022, the leased space was still undergoing construction and the Company had not yet taken control and possession. The estimated lease commencement date is November 1, 2023, upon which the Company will recognize the right-of-use asset and lease liability associated with the Burlington Lease on its Consolidated Balance Sheet in accordance with ASC 842.

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The following table is a summary of the components of lease expenses for the years ended December 31, 2022 and 2021:

	<u>2022</u>	<u>2021</u>
Operating lease cost	\$ 805	\$510
Short-term lease cost	155	—
Variable lease cost	223	234
Total lease cost	<u>\$1,183</u>	<u>\$744</u>

Supplemental cash flow information related to leases for the years ended December 31, 2022 and 2021 are as follows:

	<u>2022</u>	<u>2021</u>
Operating cash flows paid for operating leases	\$1,268	\$1,043

The following table summarizes the maturity of lease liabilities under operating leases as of December 31, 2022:

Year Ending December 31,	
2023	\$1,463
2024	397
Total future minimum lease payments	1,860
Less: Imputed interest	145
Total lease liabilities	<u>\$ 1,715</u>

Future minimum payments under operating leases above do not include those committed under short-term leases and leases not yet commenced.

The Company has an obligation to maintain letters of credit as security deposits for its office space leases, which are held in favor of the respective lessors. These letters of credit were initially issued for a period of 12 months, with automatic annual renewal until the expiration date specified in the lease agreements. As of December 31, 2022, the Company had a total of \$4,555 outstanding in letters of credit associated with its leases, of which \$4,255 is collateralized by cash maintained in collateral bank accounts. The balance of the cash maintained in the collateral bank accounts has been included in restricted cash on the Company's Consolidated Balance Sheet.

8. Convertible Preferred Stock Warrant Liability

In January 2014, the Company issued a fully vested warrant to purchase 118,483 shares of the Company's Series B convertible preferred stock in connection with the 2014 Note. The warrant was immediately exercisable at an exercise price of \$1.266 per share and has a contractual term of ten years from issuance. The fair value of the warrant at issuance was \$48 and was recorded as a convertible preferred stock warrant liability. This amount was recorded as a debt discount and was being amortized to interest expense over the term of the note. The warrant was not exercised from its inception through December 31, 2022.

The Company re-measures the fair value of the liability for this convertible preferred stock warrant at each reporting date, with any adjustments being recorded as a component of other expenses in the Company's consolidated statements of operations and comprehensive loss. The Company recorded related expense of \$137 and \$356 for the years ended December 31, 2022 and 2021, respectively.

Due to the lack of market quotes relating to the Company's convertible preferred stock warrants, the fair value of the convertible preferred stock warrants was determined using the Black-Scholes model, which is based on Level 3 inputs. The following table provides a rollforward of the fair value of the Company's warrant liability:

	Fair Value
Balance as of December 31, 2021	\$ 544
Change in fair value	(137)
Balance as of December 31, 2022	<u>\$ 407</u>

The fair value was determined using the Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	4.7%	0.7%
Expected term (in years)	1.1	2.1
Expected volatility	51%	66%
Expected Dividend yield	6%	6%
Fair value of Series B convertible preferred stock per share	\$4.93	\$6.55

9. Commitments and Contingencies

Guarantees and Indemnification Obligations

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, the Company indemnifies and agrees to reimburse the indemnified party for losses and costs incurred by the indemnified party in connection with any patent, copyright, trade secret or other intellectual property or personal right infringement claim by any third party with respect to the Company's technology. The term of these indemnification agreements is generally perpetual after execution of the agreement. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of its status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. To date, the Company has not incurred any losses or any material costs related to this indemnification obligation and no claims with respect thereto were outstanding. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations and cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2022 and 2021.

10. Convertible Preferred Stock

The Company has issued Series A, Series B, Series C-1, Series C-2, Series D, Series E and Series F convertible preferred stock (collectively, the "Convertible Preferred Stock"). The holders of Convertible Preferred Stock have liquidation rights in the event of a deemed liquidation that, in certain circumstances, is not solely within the control of the Company. Therefore, the Convertible Preferred Stock is classified outside of stockholders' deficit. The Company's certificate of incorporation, as amended and restated, authorized the Company to issue 78,112,639 shares of \$0.00001 par value convertible preferred stock as of December 31, 2022 and 2021.

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In June 2021 through July 2021, the Company issued a total of 11,927,048 shares of Series F convertible preferred stock (the “Series F Convertible Preferred Stock”) at \$8.3843 per share to investors for net proceeds of \$99,846, net of issuance costs of \$154. The Series F Convertible Preferred Stock has the same rights and preferences as the Series A, Series B, Series C-1, Series C-2, Series D and Series E Convertible Preferred Stock.

In June 2021, contemporaneous with the Series F Convertible Preferred Stock financing, the shareholders of the Company approved a reduction of the authorized shares of Series E Convertible Preferred Stock by 4,646,797 shares to 12,838,573 shares.

As of each balance sheet date, Convertible Preferred Stock consisted of the following:

	December 31, 2022				
	Convertible Preferred Shares Authorized	Convertible Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Convertible Preferred Stock	5,500,000	5,500,000	\$ 6,510	\$ 9,303	2,562,900
Series B Convertible Preferred Stock	11,451,453	11,332,970	15,459	22,798	5,280,969
Series C-1 Convertible Preferred Stock	9,064,640	9,064,640	20,114	30,428	4,223,960
Series C-2 Convertible Preferred Stock	15,336,464	15,336,464	47,129	67,383	7,146,525
Series D Convertible Preferred Stock	11,994,461	11,994,461	43,899	58,460	5,589,207
Series E Convertible Preferred Stock	12,838,573	12,838,573	54,373	64,223	5,982,550
Series F Convertible Preferred Stock	11,927,048	11,927,048	99,846	109,306	5,557,798
	<u>78,112,639</u>	<u>77,994,156</u>	<u>\$ 287,330</u>	<u>\$ 361,901</u>	<u>36,343,909</u>

	December 31, 2021				
	Convertible Preferred Shares Authorized	Convertible Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Convertible Preferred Stock	5,500,000	5,500,000	\$ 6,510	\$ 8,974	2,562,900
Series B Convertible Preferred Stock	11,451,453	11,332,970	15,459	21,939	5,280,969
Series C-1 Convertible Preferred Stock	9,064,640	9,064,640	20,114	29,216	4,223,960
Series C-2 Convertible Preferred Stock	15,336,464	15,336,464	47,129	64,561	7,146,525
Series D Convertible Preferred Stock	11,994,461	11,994,461	43,899	55,821	5,589,207
Series E Convertible Preferred Stock	12,838,573	12,838,573	54,373	60,917	5,982,550
Series F Convertible Preferred Stock	11,927,048	11,927,048	99,846	103,306	5,557,798
	<u>78,112,639</u>	<u>77,994,156</u>	<u>\$ 287,330</u>	<u>\$ 344,734</u>	<u>36,343,909</u>

In January 2014, the Company issued a fully vested warrant to purchase 118,483 shares of the Company’s Series B Convertible Preferred Stock in connection with the 2014 Note (See Note 8).

The holders of the Convertible Preferred Stock have the following rights and preferences:

Voting

The holders of the Convertible Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote and have the right to vote the number of shares equal to the number of shares of common stock into which such Convertible Preferred Stock could convert on the record date for determination of stockholders entitled to vote. In addition, holders of Series A, Series B, Series C-1, Series C-2, Series D, Series E and Series F convertible preferred stock, voting as a separate class, are entitled to elect four directors of the Company.

Dividends

The holders of Convertible Preferred Stock are entitled to receive cumulative dividends in preference to any dividend on common stock at the rate of 6.0% of the Original Issue Price (as defined below) per share, per annum. Dividends are payable only when, as, and if declared by the board of directors. No dividends have been declared or paid by the Company since its inception in August 2010. The Original Issue Price is \$1.00 per share for Series A convertible preferred stock, \$1.266 per share for Series B convertible preferred stock, \$2.2356 per share for Series C-1 convertible preferred stock, \$3.0756 per share for Series C-2 convertible preferred stock, \$3.6667 per share for Series D convertible preferred stock, \$4.2893 per share for Series E convertible preferred stock and \$8.3843 per share for Series F convertible preferred stock subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to Convertible Preferred Stock.

Liquidation Preference

In the event of any liquidation, voluntary or involuntary, dissolution or winding up of the Company or Deemed Liquidation Event (as defined below), holders of the Convertible Preferred Stock are entitled to receive, in preference to all other stockholders, and to the extent available, an amount equal to the Original Issue Price per share, adjusted for any stock dividends, stock splits or reclassifications, plus any accruing dividends accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid. In the event that proceeds are not sufficient to permit payment in full to these holders, the proceeds will be ratably distributed among the holders of the Convertible Preferred Stock on a *pari passu* basis to the full preferential amount each such holder is otherwise entitled to receive.

After payments have been made in full to the holders of the Convertible Preferred Stock, then, to the extent available, holders of the common stock will receive the remaining amounts available for distribution ratably in proportion to the number of common shares held by them provided, however, if the holders of any series of the Convertible Preferred Stock would receive a greater amount of the proceeds if they had converted their shares of the Convertible Preferred Stock, then such holders shall not receive any proceeds under the preceding paragraph and will receive proceeds on an as converted to common stock basis.

Unless the holders of at least 60.0% of the then outstanding shares of the Convertible Preferred Stock, voting together as single class, elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Conversion

Each share of Series A, Series B, Series C-1, Series C-2, Series D, Series E and Series F convertible preferred stock is convertible into common stock. Prior to authorization of the Series C-1 Convertible Preferred Stock, Series A Convertible Preferred Stock and Series B Convertible Preferred Stock was convertible into common stock, at the option of the stockholder at any time after the date of issuance. Upon authorization of the Series C-1 Convertible Preferred Stock, each class of the Convertible Preferred Stock is convertible into common stock, at the option of the stockholder, beginning two years after the effective issuance date, or August 2016. Each share of Series A, Series B, Series C-1, Series C-2, Series D, Series E and Series F convertible preferred stock will automatically be converted into shares of common stock, at the applicable conversion ratio of each series then in effect, (i) upon a qualified public offering, defined as the closing of a firm commitment underwritten public offering in which the gross proceeds raised equal or exceed \$60,000; (ii) the consummation of a qualified SPAC transaction; or (iii) a date and time, or occurrence of an event specified by vote or written consent of 60.0% of the holders of the then outstanding shares of Convertible Preferred Stock.

The conversion ratio of each series of the Convertible Preferred Stock is determined by dividing the Original Issue Price of each series of convertible preferred stock by the Conversion Price of each series. The

Conversion Price is \$2.146 for Series A Convertible Preferred Stock, \$2.7168 for Series B Convertible Preferred Stock, \$4.7976 for Series C-1 Convertible Preferred Stock, \$6.6002 for Series C-2 Convertible Preferred Stock, \$7.8687 for Series D Convertible Preferred Stock, \$9.2048 per share for Series E Convertible Preferred Stock and \$17.9927 per share for Series F Convertible Preferred Stock, resulting in a conversion ratio of 1-for-2.146 for each series of the Convertible Preferred Stock.

Redemption

Prior to August 19, 2014, the carrying values of the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock were being accreted to their redemption values through March 8, 2018. Upon the closing of the Series C-1 convertible preferred stock financing, the redemption rights of the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock were removed. As a result of the removal of the redemption rights, as of August 19, 2014, the Company ceased the periodic recording of adjustments to accrete the carrying values of Series A Convertible Preferred Stock and Series B Convertible Preferred Stock to each of their redemption values. None of the series of the Company's convertible preferred stock are redeemable as of December 31, 2022.

11. Common Stock

The Company's certificate of incorporation, as amended and restated, authorized the Company to issue 107,000,000 shares of \$0.00001 par value common stock as of December 31, 2022 and 2021. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Convertible Preferred Stock set forth above.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of the Convertible Preferred Stock equivalent to the dividend amount they would receive if each preferred share were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Convertible Preferred Stock have been paid in full. No dividends have been declared to date.

As of December 31, 2022, the Company had 104,944,601 shares of common stock available for the conversion of outstanding shares of the Convertible Preferred Stock (See Note 10), the exercise of outstanding stock options and the number of shares remaining available for grant under the Company's 2011 Stock Incentive Plan (See Note 12) as well as the exercise of the warrant to purchase common stock (See Note 6) and Series B convertible preferred stock (See Note 8), assuming the warrant to purchase Series B convertible preferred stock became a warrant to purchase common stock at the applicable Series B convertible preferred stock conversion ratio.

12. Stock-Based Compensation

The Company's 2011 Stock Incentive Plan, as amended, (the "Plan") provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, officers, directors, consultants and advisors of the Company. Incentive stock options may only be granted to employees. The Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The Company values its common stock by taking into consideration its most recently available valuation of common

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stock performed by an independent valuation analyst engaged by management and the board of directors, as well as additional factors which may have changed since the date of the most recently available valuation through the date of grant. The Company generally grants stock-based awards with service conditions only (“service-based” awards).

Stock options granted under the Plan generally vest over four years, with some options having a 25% vesting after one year and the balance vesting pro rata each month and others vesting pro rata each month. The Company also issues performance-based awards from time to time, which are expensed based on the number of options ultimately expected to vest.

The total number of shares of common stock that may be issued under the Plan was 11,994,408 as of December 31, 2022 and 2021, of which 1,440,745 and 1,925,297 were available for future grant as of December 31, 2022 and 2021, respectively.

Stock Option Valuation

The assumptions that the Company used to determine the fair value of stock options granted were as follows:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	1.8%—4.2%	0.9%—1.2%
Weighted average expected term (in years)	5.9	6.0
Weighted average expected volatility	58%	59%
Weighted average expected dividend yield	0%	0%
Fair value of common stock per share	8.82	6.97

Stock Options

The following table summarizes the Company’s stock option activity since December 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2021	8,265,575	\$ 3.25	5.9	\$ 71,070
Grant	2,006,862	9.37		
Exercised	(168,282)	1.91		
Forfeited	(1,522,310)	6.61		
Outstanding at December 31, 2022	8,581,845	\$ 4.11	5.6	\$ 35,496
Options exercisable at December 31, 2022	6,407,920	\$ 3.00	4.4	\$ 33,245

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2022 and 2021 was \$4.49 and \$3.78 per share, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2022 and 2021, was \$1,568 and \$324, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company’s common stock for those stock options that had exercise prices lower than the fair value of the Company’s common stock. The total fair value of stock options vested during the years ended December 31, 2022 and 2021 was \$2,662 and \$2,084, respectively.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense related to stock options in the following expense categories within its consolidated statements of operations and comprehensive loss:

	Year Ended December 31,	
	2022	2021
Research and development expenses	\$1,486	\$1,034
General and administrative expenses	1,652	1,057
	<u>\$3,138</u>	<u>\$2,091</u>

Total unrecognized stock-based compensation expense for all stock-based awards was \$8,786 as of December 31, 2022, which is expected to be recognized over a weighted average period of 3.0 years.

13. Income Taxes

During the years ended December 31, 2022 and 2021, the Company recorded no income tax benefits for the net operating losses incurred in each year due to its uncertainty of realizing a benefit from those items. The majority of the Company's losses before income taxes were generated in the United States.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	8.0	4.8
Research and development tax credits	4.3	3.9
Permanent differences	—	(0.6)
Change in fair value of convertible notes payable	1.0	—
Non-deductible stock compensation	(0.9)	—
Return to provision	0.1	—
Change in valuation allowance	(33.5)	(29.1)
Effective income tax rate	<u>—%</u>	<u>—%</u>

Net deferred tax assets as of December 31, 2022 and 2021 consisted of the following:

	<u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 58,314	\$ 53,593
Research and development tax credit carryforwards	11,330	8,616
Lease liabilities	461	349
Stock-based compensation expense	1,924	1,827
Accrued expenses and other	247	409
Capitalized patent and trademark costs	1,161	1,056
Capitalized research and development	8,293	—
Other	38	157
Total deferred tax assets	<u>81,768</u>	<u>66,007</u>
Deferred tax liabilities:		
Right-of-use lease assets	(355)	(169)
Valuation allowance	<u>(81,413)</u>	<u>(65,838)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2022, the Company had federal net operating loss carryforwards of \$215,270, of which \$82,672 begin to expire in 2030 and \$132,598 will carryforward indefinitely. In addition, the Company had state net operating loss carryforwards of \$207,826 which begin to expire at various dates beginning in 2030. As of December 31, 2022, the Company also had available research and development tax credit carryforwards for federal and state income tax purposes of \$8,493 and \$3,590, respectively, which begin to expire in 2031 and 2027, respectively.

Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not currently completed an evaluation of ownership changes through December 31, 2022 to assess whether utilization of the Company's net operating loss or research and development credit carryforwards would be subject to an annual limitation under Section 382. To the extent an ownership change occurs in the future, the net operating loss and credit carryforwards may be subject to limitation. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has not yet conducted a study of its research and development credit carryforwards. This study may result in an increase or decrease to the Company's credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A valuation allowance has been provided against the Company's credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. As a result, there would be no impact to the consolidated statements of operations and comprehensive loss or consolidated statements of cash flows if an adjustment were required.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which are comprised principally of net operating losses and research and development tax credit carryforwards. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of

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the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2022 and 2021. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the year ended December 31, 2022 and 2021 related primarily to the increase in federal and state net operating loss carryforwards and available research and development credits and were as follows:

	Year Ended December 31,	
	2022	2021
Valuation allowance at beginning of year	\$ 65,838	\$ 54,579
Increases recorded to income tax provision	15,575	11,259
Valuation allowance at end of year	<u>\$ 81,413</u>	<u>\$ 65,838</u>

The Company's policy is to recognize interest and penalties for uncertain tax position as a component of income tax expense. The Company has not recorded any amounts for unrecognized tax benefits, interest, or penalties historically through December 31, 2022.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax returns are still open under statute from 2019 to the present, however carryforward attributes that were generated prior to January 1, 2019 may still be adjusted upon examination by federal or state tax authorities if they have been or will be utilized in a future period.

14. 401(k) Savings Plan

The Company maintains a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax and or after-tax basis. Company contributions to the plan may be made at the discretion of the Board of Directors. The Company has not made any matching or discretionary contributions to date under the 401(k) savings plan.

15. Net Loss Per Share

The following securities that could potentially dilute basic net loss per share in the future were not included in the computation of diluted net loss per share for the periods presented, because to do so would have been antidilutive:

	Year Ended December 31,	
	2022	2021
Series A Convertible Preferred Stock	2,562,900	2,562,900
Series B Convertible Preferred Stock	5,280,969	5,280,969
Series C-1 Convertible Preferred Stock	4,223,960	4,223,960
Series C-2 Convertible Preferred Stock	7,146,525	7,146,525
Series D Convertible Preferred Stock	5,589,207	5,589,207
Series E Convertible Preferred Stock	5,982,550	5,982,550
Series F Convertible Preferred Stock	5,557,798	5,557,798
Outstanding stock options	8,581,845	8,265,575
Common stock warrants	161,616	161,616
Series B Convertible Preferred Stock warrants	55,211	55,211
Total	<u>45,142,581</u>	<u>44,826,311</u>

16. Subsequent Events

On July 11, 2023, the Company paid \$78 to settle in full the outstanding principal and accrued interest owed to one of the lenders under the 2022 Convertible Notes and issued amended and restated convertible promissory notes to certain of the lenders in replacement of, but not in payment of, the remainders of the 2022 Convertible Notes (see Note 6). As part of these amendments, among other changes, such lenders agreed to extend the maturity date of the outstanding principal and accrued but unpaid interest on the 2022 Convertible Notes to December 31, 2024 and remove the Floor Valuation. Following these amendments, \$20,899 in aggregate principal under the 2022 Convertible Notes will remain outstanding and accrue interest at the rate of 10% per year until they are paid or converted in full. In connection with entering into these amendments, the Company issued to such lenders warrants to purchase shares of the Company's common stock with par value of \$0.00001 per share. The warrants are immediately exercisable for a variable number of shares based on the principal amount of the 2022 Convertible Notes, as amended, and an exercise price, at the holders' choice, of (a) \$17.9927 per share, (b) the lowest original issue price of shares of Preferred Stock of the Company issued in the Company's next bona fide private preferred equity financing round, (c) in the event of any convertible note or similar convertible security financing, the conversion price contemplated by such convertible security, or (d) in the event of an IPO, the per share offering price to the public in such IPO. The warrants have a contractual term of ten years from issuance.

17. Reverse Common Stock Split

On January 26, 2024, the Company's board of directors approved a 1-for-2.146 reverse stock split of its issued and outstanding shares of common stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse common stock split and adjustment of the Convertible Preferred Stock conversion ratios.

Fractyl Health, Inc.
Consolidated Balance Sheets (Unaudited)
(in thousands, except for share and per share information)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 44,500	\$ 49,269
Accounts Receivable	24	—
Inventory	76	—
Restricted cash, current	315	—
Prepaid expenses and other current assets	1,896	2,360
Total current assets	46,811	51,629
Restricted cash, long-term	4,255	4,255
Property and equipment, net	322	326
Right-of-use lease assets	615	1,321
Other long-term assets	4,779	3,425
Total assets	<u>\$ 56,782</u>	<u>\$ 60,956</u>
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 746	\$ 980
Accrued expenses and other current liabilities	6,334	5,081
Lease liabilities, current	768	1,250
Warrant liabilities, current	549	—
Total current liabilities	8,397	7,311
Notes payable, long-term	54,743	17,760
Lease liabilities, long-term	—	465
Warrant liabilities, long-term	13,487	407
Other long-term liabilities	—	2
Total liabilities	<u>76,627</u>	<u>25,945</u>
Commitments and contingencies		
Convertible preferred stock (Series A, B, C-1, C-2, D, E and F), \$0.00001 par value; 78,112,639 shares authorized at September 30, 2023 and December 31, 2022; 77,994,156 shares issued and outstanding at September 30, 2023 and December 31, 2022; aggregate liquidation preference of \$374,750 and \$361,901 at September 30, 2023 and December 31, 2022, respectively	287,330	287,330
Stockholders' deficit:		
Common stock, \$0.00001 par value; 107,000,000 shares authorized at September 30, 2023 and December 31, 2022; 2,095,129 and 2,055,399 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	20,261	17,206
Accumulated deficit	(327,436)	(269,525)
Total stockholders' deficit	(307,175)	(252,319)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 56,782</u>	<u>\$ 60,956</u>

See accompanying notes to consolidated financial statements (unaudited).

Fractyl Health, Inc.
Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands, except for share and per share information)

	Nine Months Ended September 30,	
	2023	2022
Revenue	\$ 113	\$ —
Cost of goods sold	75	—
Gross profit	38	—
Operating expenses:		
Research and development	27,872	25,737
Selling, general and administrative	10,021	12,235
Total operating expenses	37,893	37,972
Loss from operations	(37,855)	(37,972)
Other income (expense), net:		
Interest income, net	797	386
Loss from debt extinguishment	—	(313)
Change in fair value of notes payable	(19,676)	2,185
Change in fair value of warrant liabilities	(1,161)	122
Other expense, net	(16)	(3)
Total other income (expense), net	(20,056)	2,377
Net loss and comprehensive loss	(57,911)	(35,595)
Accretion of dividends on convertible preferred stock	(12,850)	(12,850)
Net loss attributable to common stockholders	\$ (70,761)	\$ (48,445)
Net loss per share attributable to common stockholders-basic and diluted	\$ (34.11)	\$ (24.61)
Weighted-average number of common shares outstanding-basic and diluted	2,074,223	1,968,521

See accompanying notes to consolidated financial statements (unaudited).

Fractyl Health, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit (Unaudited)
(in thousands, except for share information)

	Series A, B, C-1, C-2, D, E and F Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2022	77,994,156	\$287,330	2,055,399	\$ —	\$ 17,206	\$ (269,525)	\$ (252,319)
Exercise of common stock options	—	—	39,730	—	35	—	35
Stock-based compensation expense	—	—	—	—	3,020	—	3,020
Net loss	—	—	—	—	—	(57,911)	(57,911)
Balance at September 30, 2023	<u>77,994,156</u>	<u>\$287,330</u>	<u>2,095,129</u>	<u>\$ —</u>	<u>\$ 20,261</u>	<u>\$ (327,436)</u>	<u>\$ (307,175)</u>
	Series A, B, C-1, C-2, D, E and F Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2021	77,994,156	\$287,330	1,887,117	\$ —	\$ 13,747	\$ (223,072)	\$ (209,325)
Exercise of common stock options	—	—	168,282	—	321	—	321
Stock-based compensation expense	—	—	—	—	2,231	—	2,231
Net loss	—	—	—	—	—	(35,595)	(35,595)
Balance at September 30, 2022	<u>77,994,156</u>	<u>287,330</u>	<u>2,055,399</u>	<u>—</u>	<u>16,299</u>	<u>(258,667)</u>	<u>(242,368)</u>

See accompanying notes to consolidated financial statements (unaudited).

Fractyl Health, Inc.
Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (57,911)	\$ (35,595)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	248	371
Loss on disposal of fixed assets	—	1
Loss on debt extinguishment	—	313
Stock-based compensation expense	3,020	2,231
Change in fair value of warrant liabilities	1,161	(122)
Change in fair value of notes payable, non-cash	19,526	(2,185)
Issuance costs related to notes payable	1,934	—
Changes in operating assets and liabilities:		
Accounts Receivable	(24)	—
Inventory	(76)	—
Prepaid expenses and other current assets	464	(160)
Lease assets and lease liabilities, net	(241)	(273)
Accounts payable	(504)	(375)
Accrued expenses and other current liabilities	176	334
Other long term assets and liabilities	3	1,750
Net cash used in operating activities	<u>(32,224)</u>	<u>(33,710)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(223)	(56)
Net cash used in investing activities	<u>(223)</u>	<u>(56)</u>
Cash flows from financing activities:		
Proceeds from issuance of notes payable, net	28,432	20,075
Proceeds from exercise of stock options	35	321
Payments related to debt issuance costs	(327)	—
Payments related to offering costs	(66)	—
Principal payments on capital lease obligations	(6)	(6)
Repayment of notes payable	(75)	(16,037)
Net cash provided by financing activities	<u>27,993</u>	<u>4,353</u>
Net increase in cash, cash equivalents and restricted cash	(4,454)	(29,413)
Cash, cash equivalents and restricted cash at beginning of period	53,524	95,473
Cash, cash equivalents and restricted cash at end of period	<u>\$ 49,070</u>	<u>\$ 66,060</u>
Supplemental disclosure of cash flow information:		
Interest paid	\$ 150	\$ 6
Non-cash investing and financing activities:		
Remeasurement of right-of-use asset on lease modification	\$ —	\$ 1,352
Purchases of property and equipment included in accounts payable or accrued expenses	\$ 21	\$ —
Debt issuance costs included in accrued expenses	\$ 39	\$ —
Deferred offering costs included in accounts payable or accrued expenses	\$ 1,287	\$ —
Fair value of warrant liabilities recognized in connection with amendment of convertible notes payable	\$ 9,876	\$ —
Fair value of warrant liabilities recognized in connection with issuance of notes payable	\$ 2,592	\$ —

See accompanying notes to consolidated financial statements (unaudited).

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited)
(in thousands, except share and per share information)

1. Nature of the Business and Basis of Presentation

Fractyl Health, Inc. (the “Company”) was incorporated on August 30, 2010 under the name MedCatalyst, Inc. The Company subsequently changed its name to Fractyl Laboratories Inc. on January 10, 2012 and subsequently to Fractyl Health, Inc. on June 9, 2021. The Company is a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including type 2 diabetes (“T2D”) and obesity. The Company’s goal is to transform metabolic disease treatment from chronic symptomatic management to durable disease-modifying therapies that target the organ-level root causes of T2D and obesity. The Revita DMR System (“Revita”), the Company’s lead product candidate, is an outpatient procedural therapy designed to durably modify duodenal dysfunction, a major pathologic consequence of a high fat and high sugar diet, which can initiate T2D and obesity in humans. Led by the Company’s ongoing Revitalize-1 pivotal study, the Company has initiated a broad clinical program designed to evaluate Revita in multiple clinical studies across a range of patient populations from prediabetes and obesity to advanced T2D patients on long-acting insulin. In addition, the Company is developing Rejuva, a novel, locally administered, adeno-associated virus delivered pancreatic gene therapy platform. Rejuva is designed to enable long-term remission of T2D and obesity by durably altering metabolic hormone function in the pancreatic islet cells of patients. The Company believes Revita and Rejuva, if approved, have the potential to revolutionize treatment across the spectrum of T2D and obesity, align the clinical and economic interest of key stakeholders around the long-term regression of metabolic disease, and, at their fullest potential, significantly reduce the burden of metabolic disease globally.

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASUs”), promulgated by the Financial Accounting Standards Board (“FASB”).

Liquidity

The Company has financed its operations to date primarily through sales of its convertible preferred stock and debt financing. As of September 30, 2023, the Company had cash and cash equivalents totaling \$44,500 and net working capital of \$38,414. The Company has a history of operating losses and had an accumulated deficit of \$327,436 as of September 30, 2023.

Under ASC 205-40, *Going Concern*, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved by the Company’s Board of Directors (“Board”) before the date that the financial statements are issued.

The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain profitable operations. The Company is subject to a number of risks similar to

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

other early-stage life science companies, including, but not limited to, successful discovery and development of its product candidates, raising additional capital with favorable terms, development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products. The successful discovery and development of product candidates requires substantial working capital which may not be available to the Company on favorable terms or not at all.

The Company has generated insignificant revenue from product sales since its limited pilot commercial launch in Germany in the first quarter of 2023. The Company does not anticipate generating revenue from product sales in the United States unless and until it successfully completes clinical development and obtains marketing approvals from one or more of the product candidates. As a result, management expects continuing operating losses in the future. As of September 30, 2023, the Company had available cash and cash equivalents of \$44,500, which is not sufficient to fund the Company's current operating plan for at least twelve months after the date the interim consolidated financial statements are issued. The Company expects to seek additional funds through equity or debt financings or through additional collaboration, licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into additional collaboration or licensing transactions and, if necessary, the Company will be required to implement cost reduction strategies which could curtail or delay its current clinical activities. As a result, substantial doubt exists about the Company's ability to continue as a going concern. The accompanying interim consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The interim consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. Significant Accounting Policies

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States, or GAAP, for interim financial reporting and as required by Regulation S-X, Rule 10-01. The consolidated financial statements have been prepared in accordance with GAAP and include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated. These interim financial statements, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair presentation of the Company's financial position and results of operations for the nine-month interim periods ended September 30, 2023 and 2022. The results of operations for the interim periods are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates relied upon in preparing these consolidated financial statements include, but are not limited to, the fair value of common stock, the fair value of preferred and common stock warrants, the fair value of notes payable, the fair value of stock-based awards, the incremental borrowing rate for lease accounting and the accrual of research and development expenses. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ materially from those estimates.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash equivalents. Cash equivalents, which consist of money market funds, are stated at fair value.

Restricted Cash

The Company's restricted cash primarily represented cash held in separate collateral bank accounts in conjunction with the maintenance of letters of credit required under the Company's facility leases (See Note 7). The letters of credit were issued for an original effective period of 12 months with automatic annual renewal until the expiration date.

Concentration of Credit Risk

The Company's financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. As of September 30, 2023, substantially all of the Company's cash deposits are maintained at large, creditworthy financial institutions. The Company's deposits at times may significantly exceed federally insured limits. The Company has not experienced any losses related to its cash and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Segment information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's chief executive officer, views the Company's operations and manages its business as a single operating segment. Substantially all of the Company's long-lived assets are held in the United States.

Revenue

The Company records revenue under the guidance of ASC 606, *Revenue from Contracts with Customers (Topic 606)* which requires a company to recognize revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those good or services. During the nine months ended September 30, 2023, the Company has recognized an insignificant amount of revenue from the sales and leasing of Revita in Germany. During the nine months ended September 30, 2022, the Company did not generate any revenues.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, the Company satisfies a performance obligation

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

Accounts Receivable

The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in customer credit profiles. The Company reserves against accounts receivables for estimated losses that may arise from a customer's inability to pay, and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. There was no reserve amount for estimated losses as of September 30, 2023.

Inventory and Cost of Goods Sold

Inventories are stated at the lower of cost or estimated net realizable value with cost based on the first-in first-out method. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in clinical trials. Cost of goods sold is based on the sale of inventory used in commercial products.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

<u>Asset Category</u>	<u>Estimated Useful Life</u>
Computer and office equipment	3 to 5 years
Laboratory and manufacturing equipment	3 years
Website development costs	3 years
Leasehold improvements	Shorter of remaining lease term or the estimated useful life of 5 to 8 years

Costs of major additions and betterments are capitalized and amortized on a straight-line basis over the shorter of the remaining lease term or the estimated useful life of the asset. Upon retirement or sale, the cost of assets disposed of and the related accumulated amortization are removed from the accounts and any resulting gain or loss is included in the determination of net income or loss. Repairs and maintenance costs are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and right-of-use operating lease assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

Deferred Public Offering Costs

Deferred public offering costs, which primarily consist of direct, incremental legal and accounting fees relating to the planned Initial Public Offering (“IPO”), are capitalized within other long-term assets. The deferred public offering costs will be offset against IPO proceeds upon the consummation of the offering. The Company had incurred \$2,195 in IPO costs as of December 31, 2021. In 2022, the Company delayed its IPO plan due to adverse market conditions. The delay was considered an aborted IPO and associated deferred offering costs of \$2,704 were expensed within selling, general and administrative expenses on the consolidated statements of operations and comprehensive loss during the nine months ended September 30, 2022. In the third quarter of 2023, the Company re-initiated its effort for a planned IPO and had incurred offering-related costs of \$1,353 as of September 30, 2023, which were capitalized as deferred public offering costs within other long-term assets.

Other Long-term Assets

At September 30, 2023, other long-term assets consisted of vendor deposits of \$2,522, deferred public offering costs of \$1,353 and implementation costs incurred in a cloud computing arrangement that is a service contract of \$904. At December 31, 2022, other long-term assets consisted of vendor deposits of \$2,562 and implementation costs incurred in a cloud computing arrangement that is a service contract of \$863.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company’s cash equivalents, notes payable and warrant liabilities are carried at fair value, determined according to the fair value hierarchy above (See Note 3). The carrying values of the Company’s accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Leases

The Company applies the provisions of ASC 842, *Leases*, (“ASC 842”) to account for its leases.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company’s finance lease is immaterial.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

At the lease commencement date, the Company recognizes a right-of-use asset and a lease liability for all leases, except short-term leases with an original term of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is a reasonable certainty that the Company will renew. The operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of fixed lease payments over the expected lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in the lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. The Company recognizes operating lease expense on a straight-line basis over the lease term.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

See Note 7—"Leases" and Note 9—"Commitments and Contingencies" for additional information about the Company's leases.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include salaries, stock-based compensation and employee-related benefits, product development, clinical trial and related clinical manufacturing costs, allocation of facility-related expenses, overhead expenses and other outside expenses. Nonrefundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with companies and individuals globally. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or projects, including the phase or completion of events, invoices received and contracted costs. Judgments and estimates are made in determining the accrued balance at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are recorded as general and administrative expenses as incurred, as recoverability of such expenditures is uncertain.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

Notes Payable

The Company elected to apply the fair value option to its notes payable in accordance with ASC 825, *Financial Instruments* (“ASC 825”). Accordingly, the notes payable are remeasured at the end of each reporting period with changes in fair value recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. Changes in fair value resulting from changes in instrument-specific credit risk, if any, will be recognized separately in other comprehensive income. The primary reason for electing the fair value option was to address simplification and cost-benefit considerations that result from accounting for hybrid financial instruments at fair value in their entirety versus bifurcation of the embedded derivatives from the debt hosts.

The fair values of the notes payable are determined using valuation models that incorporate assumptions and estimates. The Company assesses these assumptions and estimates at each financial reporting period as additional information impacting the assumptions is obtained. Assumptions in the models include but are not limited to equity value, volatility, time to conversion event, risk-free rate and scenario weightings. The fair value measurements of the notes payable are based on significant inputs that are not observable in the market and represent a Level 3 measurement. See Note 6.

Warrant Liabilities

The Company classifies warrants to purchase shares of its convertible preferred stock as liabilities on its consolidated balance sheets as the underlying shares are contingently redeemable. In addition, the Company classifies certain warrants to purchase shares of its common stock as liabilities on its consolidated balance sheets as such warrants embody an obligation to issue a variable number of shares for which the monetary value is predominantly fixed. These warrants were initially recorded at fair value on the grant date, and are subsequently remeasured to fair value at the end of each reporting period with changes in fair value recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. The Company will continue to adjust the liabilities until the earlier of exercise or expiration of the warrant.

The fair values of these warrant liabilities are determined using either a Black-Scholes option-pricing model or a Monte Carlo simulation model, depending on the nature of the warrants. The valuation model used incorporates assumptions and estimates, which the Company assesses at each financial reporting period as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying shares, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying shares. The Company determines the fair value per share of the underlying shares by taking into consideration the most recent sales of its convertible preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. Expected dividend yield for the convertible preferred stock warrants is determined considering that the underlying shares are entitled to dividends of 6.0% per year, whether or not declared. Expected dividend yield for the common stock warrants is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends on common stock in the foreseeable future.

This fair value measurement of the warrant liabilities is based on significant inputs that are not observable in the market and represent a Level 3 measurement. See Note 8.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

Stock-Based Compensation

The Company measures all stock-based awards based on their fair value on the date of the grant. Those awards typically have a graded vesting schedule and compensation expense for awards with only service conditions are recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. Compensation costs recognized for performance-based awards reflect the number of awards that are expected to vest during the requisite service period, and are adjusted to reflect those awards that ultimately vest upon final determination of the performance conditions achieved. Recognition of compensation costs related to performance-based awards with performance condition based on occurrence of certain events is deferred until these events are probable of occurring.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The Company uses the Black-Scholes option pricing model, which incorporates assumptions and estimates, to measure the fair value of its option awards on the date of grant of each stock option award. The Company determines the fair value per share of the underlying common stock by taking into consideration the results obtained from third-party valuations and additional factors that are deemed relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, the Company estimates its expected stock volatility based on an analysis of reported data for a publicly traded peer group of companies that granted options with substantially similar terms and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term assumption for employee grants is determined by using the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is based on the rate of the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future. Forfeitures are accounted for as they occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and the tax basis of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Convertible Preferred Stock

The Company records its convertible preferred stock at fair value on the dates of issuance, net of issuance costs. All shares of convertible preferred stock have been presented outside of stockholders' deficit as the redemption of such shares is outside the Company's control (See Note 10). The Company does not adjust the carrying values of the convertible preferred stock to the redemption value of such stock until such time as a redemption event is probable of occurring.

Comprehensive Loss

Comprehensive loss is comprised of two components: net loss and other comprehensive loss, which includes other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. The Company had no items qualifying as other comprehensive loss; accordingly, comprehensive loss equaled total net loss for each of the nine months ended September 30, 2023 and 2022.

Net Loss Per Share

Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's Series A, Series B, Series C-1, Series C-2, Series D, Series E, and Series F convertible preferred stock contain participating rights in any dividend paid by the Company and are therefore participating securities. Net loss attributable to common stockholders and participating securities is allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. However, the participating securities do not include a contractual obligation to share in the losses of the Company and were not included in the calculation of net loss per share in the periods that had a net loss.

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method and treasury stock method, as applicable. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Diluted net loss per share is equivalent to basic net loss per share for the years presented herein because common stock equivalent shares from the Series A, Series B, Series C-1, Series C-2, Series D, Series E, and Series F convertible preferred stock, outstanding stock options and restricted stock units and outstanding warrants to purchase common stock and convertible preferred stock (see Note 15) were anti-dilutive.

Emerging Growth Company Status

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company may take advantage of these exemptions until the Company is no longer an "emerging growth company." Section 107 of the JOBS Act

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provides that an “emerging growth company” can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, its consolidated financial statements may not be comparable to companies that comply with public company effective dates. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that it is no longer an “emerging growth company”.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments*, which has been subsequently amended by ASU No. 2018-19, ASU No. 2019-04, ASU No. 2019-05, ASU No. 2019-10, ASU No. 2019-11 and ASU No. 2021-03 (“ASU 2016-13”). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 was effective for the Company on January 1, 2023 and had no material impact on the Company’s Consolidated Financial Statements and did not record any effects through retained earnings.

Recently Issued Accounting Pronouncements

On October 9, 2023, the FASB issued ASU 2023-06 *Disclosure Improvements: Codification Amendments in Response to the SEC’s Disclosure Update and Simplification Initiative (“ASU 2023-06”)*, which modifies certain disclosure and presentation requirements of a variety of Topics in the Codification and is intended to both clarify or improve such requirements and align the requirements with the SEC’s regulations. The Company is in the process of evaluating the amendments provided in the Update and believes certain of the disclosure improvements may be applicable to the Company’s interim or annual disclosures, for example, disclosures related to earnings-per-share computation for dilutive securities and preferred stock. The effective date for each amendment is the effective date of the removal of the related disclosure from Regulation S-X or Regulation S-K, with early adoption prohibited. The Company will apply the provisions prospectively as such provisions become effective, and does not expect ASU 2023-06 to have a material impact on the consolidated financial statements.

3. Fair Value Measurements

The following tables present information about the Company’s financial assets and liabilities measured at fair value on a recurring basis and indicate the level of fair value hierarchy utilized to determine such fair values:

	Fair Value measurements as of			
	September 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	\$ 1	\$ —	\$ —	\$ 1
	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1</u>
Liabilities:				
Warrant liabilities, current	\$ —	\$ —	\$ 549	\$ 549
Warrant liabilities, long-term	—	—	13,487	13,487
Notes payable, long-term	—	—	54,743	54,743
	<u>\$ —</u>	<u>\$ —</u>	<u>\$68,779</u>	<u>\$68,779</u>

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	Fair Value measurements as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	\$ 1	\$ —	\$ —	\$ 1
	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1</u>
Liabilities:				
Warrant liabilities, long-term	\$ —	\$ —	\$ 407	\$ 407
Notes payable	—	—	17,760	17,760
	<u>\$ —</u>	<u>\$ —</u>	<u>\$18,167</u>	<u>\$18,167</u>

During the nine months ended September 30, 2023 and year ended December 31, 2022, there were no transfers between Level 1, Level 2 and Level 3.

See Note 6—“Notes Payable” for the discussion of the fair value methodology of the notes payable and a rollforward of the fair value. See Note 8—“Warrant Liabilities” for the discussion of the fair value methodology of the stock warrants and a rollforward of the fair value.

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2023	December 31, 2022
Computer and office equipment	\$ 844	\$ 844
Laboratory and manufacturing equipment	605	521
Website development costs	59	40
Leasehold improvements	3,607	3,466
	<u>5,115</u>	<u>4,871</u>
Less: Accumulated depreciation	(4,793)	(4,545)
	<u>\$ 322</u>	<u>\$ 326</u>

Depreciation expense for the nine months ended September 30, 2023 and 2022 was \$248 and \$371, respectively.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2023	December 31, 2022
Payroll and payroll-related expenses	\$ 3,223	\$ 2,760
External research and development services	1,302	1,519
Professional fees and consulting services	1,761	766
Other current liabilities	48	36
	<u>\$ 6,334</u>	<u>\$ 5,081</u>

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6. Notes Payable

Notes payable, long-term consisted of the following:

	September 30, 2023	December 31, 2022
2019 Note	\$ —	\$ —
2022 Convertible Notes	27,225	17,760
2023 Notes	27,518	—
	<u>\$ 54,743</u>	<u>\$ 17,760</u>

2019 Note

In February 2019, the Company entered into a loan and security agreement (the “2019 Note”) with a lender that provided for borrowings of up to \$15,000, all of which were drawn down during 2019. The outstanding balances under the 2019 Note bear interest at a floating annual rate that equals the greater of 1.5% above the Wall Street Journal prime rate or 6.75%. The 2019 Note provides for certain prepayment premiums should the Company make early payments of any principal balances prior to the maturity date. On the date that the 2019 Note is paid in full or becomes due and payable, the Company is required to make a payment (the “Final Payment”), in addition to the regular monthly payments of principal plus accrued interest, equal to 6% of the original principal amount.

In connection with entering into the 2019 Note, the Company issued to the lender and an affiliated investor warrants to purchase up to an aggregate of 119,934 shares of the Company’s common stock with par value of \$0.00001 per share, at a weighted average exercise price of \$3.3263 per share. The fair value of the warrants at issuance was \$285 and was recorded as an equity on the consolidated balance sheet. The warrants expire ten years from the date of issuance. They were not exercised from their inception through September 30, 2023.

In 2020 and 2021, the Company entered into two amendments to the 2019 Note to revise certain interest-only repayment terms. In connection with entering into the first amendment, the Company issued to the lender and an affiliated investor, warrants to purchase up to an aggregate of 41,682 shares of the Company’s common stock, par value \$0.00001 per share, at an exercise price of \$3.8843 per share. The fair value of the warrants at issuance was \$105 and was recorded as an equity on the consolidated balance sheet. The warrants expire ten years from the date of issuance. They were not exercised from their inception through September 30, 2023.

On January 3, 2022, the Company fully paid off the 2019 Note by making a lump-sum payment to the lender for a total amount of \$16,130, which consisted of the outstanding principal balance of \$15,000, the Final Payment of \$900, the prepayment premium of \$137 and accrued interest of \$93. A loss from debt extinguishment of \$313 was recognized as other expense in the consolidated statements of operations and comprehensive loss during the nine months ended September 30, 2022 as a result of the early payoff of the 2019 Note.

2022 Convertible Notes

On January 11, 2022, the Company entered into a financing arrangement with certain lenders (the “2022 Lenders”) in which the Company issued convertible promissory notes in exchange for an aggregate principal amount of \$20,075 (the “2022 Convertible Notes”). Under the original terms of the 2022 Convertible Notes, interest accrued on the unpaid principal balance of the 2022 Convertible Notes at the rate of 3% per year until paid or converted in full. Subject to the conversion provisions set forth below, all principal and accrued interest on the 2022 Convertible Notes was to be due and payable on July 11, 2023 (the “Original Maturity Date”).

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Effective upon the closing of an equity financing event, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes will automatically be converted into shares of the same class and series of capital stock of the Company issued to other investors in the financing event at a conversion price equal to (i) in the event of an IPO, 80% of the price per share of the public company securities paid by other investors in the IPO; or (ii) in the event of a non-IPO, 80% of the opening price on the applicable stock exchange on the closing date; or (iii) in the event of a private financing round, 80% of the price per share of the financing securities paid by other investors in the financing round. In no event should the conversion price be a) less than the amount equal to \$875,000 divided by our fully diluted capitalization as of immediately prior to the closing of the financing event (the “Floor Valuation”); or (b) more than an amount equal to \$1,100,000 divided by the Company’s fully diluted capitalization as of immediately prior to the closing of the financing event (the “Valuation Cap”).

In the event of a Change of Control of the Company, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes will, at the option of the 2022 Lenders, (1) be repaid in cash as of the closing of such Change of Control; or (2) be converted into common stock of the Company at a conversion price equal to 80% of the fair market value of the Company’s common stock as determined in good faith by the Company’s Board of Directors, provided that, if the successor company is a publicly traded issuer, the conversion price will be determined by a volume-weighted average price per share of the successor company’s stock on the applicable stock exchange for the five trading days prior to the Change of Control; and provided further that, in the event stockholders are to receive any non-cash consideration pursuant to the Change of Control, the 2022 Lenders shall receive the same non-cash consideration, in the same proportion, and the value of such non-cash consideration received by the 2022 Lenders shall be determined in accordance with the agreement governing such Change of Control. In no event should the conversion price be less than the Floor Valuation or more than the Valuation Cap.

Under the original terms of the 2022 Convertible Notes, in the event the 2022 Convertible Notes was still outstanding on the Original Maturity Date, or from and after the date and during the continuation of an Event of Default, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes was to be converted, at the option of the holders, into shares of the Company’s Series F convertible preferred stock at a conversion price equal to the lesser of (a) \$8.3843 per share or (b) the Valuation Cap.

The Company elected to apply the fair value option (“FVO”) to the 2022 Convertible Notes in accordance with ASC 825. Accordingly, the 2022 Convertible Notes are marked to market at the end of each reporting period, with changes in fair value recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss. The fair value was estimated using a Monte Carlo simulation model to calculate equity values at different points in time leading up to a conversion event. The Company assesses the assumptions and estimates used in the valuation model at each financial reporting period as additional information impacting the assumptions is obtained. Assumptions and estimates impacting the fair value measurement include the fair value per share of the underlying shares, the expected time to conversion events (IPO or non-IPO), risk-free interest rate, expected volatility of the price of the underlying shares and scenario weightings. The Company determines the fair value per share of the underlying shares by taking into consideration the most recent sales of its convertible preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the expected time to conversion events. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the expected time to conversion events. Scenario weightings are based on management’s best estimate of the probabilities of the occurrence of each conversion event considered.

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On July 11, 2023 (the “reissuance date”), the Company paid \$78 to settle in full the outstanding principal and accrued interest owed to one of the lenders under the 2022 Convertible Notes and issued amended and restated convertible promissory notes to certain of the lenders (the “Continuing 2022 Lenders”) in replacement of, but not in payment of, the remainder of the 2022 Convertible Notes. As part of these amendments, among other changes, the Continuing 2022 Lenders agreed to extend the maturity date of the outstanding principal and accrued but unpaid interest on the 2022 Convertible Notes to December 31, 2024 and remove the Floor Valuation. Following these amendments, \$20,899 in aggregate principal under the 2022 Convertible Notes remained outstanding and accrues interest at the rate of 10% per year until they are paid or converted in full. In connection with entering into these amendments, the Company issued to the Continuing 2022 Lenders warrants to purchase shares of the Company’s common stock with par value of \$0.00001 per share. The warrants were recorded as part of the warrant liabilities on the consolidated balance sheet. The fair value of the warrants was estimated using a Monte-Carlo simulation model. See Note 8.

The Company evaluated the amendments to the 2022 Convertible Notes that were not settled in full under the debt modification and extinguishment guidance and concluded that the amendments resulted in terms that were substantially different and therefore resulted in debt extinguishments. Because the Company elected to apply the FVO to the 2022 Convertible Notes, the net carrying value of the extinguished debt should be equal to its fair value at the reissuance date. As a result, no gain or loss on extinguishment was recognized at the reissuance date as the carrying value of the extinguished debt was remeasured to be equal to the fair value of the reissued debt, which represented a combination of the fair value of the notes payable reissued and the fair value of the associated warrants issued, at the reissuance date. The resulting changes in the fair value from the remeasurement was recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss and the fair value of the warrants issued was reclassified to warrant liabilities immediately after the reissuance of the 2022 Notes. In addition, due to the proximity of the reissuance date to the last reporting date of June 30, 2023, the fair value of the 2022 Convertible Notes as of June 30, 2023 already considered the known and knowable terms of the subsequently amended convertible notes, as described above, along with warrants that were issued with the amended convertible notes.

This fair value measurement is based on significant inputs that are not observable in the market and represent a Level 3 measurement. The following table provides a rollforward of the fair value of the 2022 Convertible Notes:

	Fair Value
Balance as of December 31, 2022	\$17,760
Increase in fair value	18,689
Partial repayment of notes	(78)
Balance as of reissuance date of July 11, 2023	\$36,371
Fair value of warrants issued in connection with the reissuance of 2022 Convertible Notes	(9,876)
Increase in fair value	730
Balance as of September 30, 2023	<u>\$27,225</u>

Transaction costs incurred during the nine months ended September 30, 2022 related to the issuance of the 2022 Convertible Notes were immaterial and were expensed as part of the selling, general and administrative expenses as incurred. Accrued interest on the 2022 Convertible Notes is incorporated into the determination of the fair value of the 2022 Convertible Notes.

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There are no financial covenants associated with the 2022 Convertible Notes, however the 2022 Convertible Notes do contain customary events of default, subject to rights and remedies generally applicable to federal law or the laws of the State of Delaware. As of September 30, 2023, the Company was in compliance with the terms of the arrangement.

2023 Notes

On September 7, 2023, the Company entered into a credit agreement with certain lenders (the “2023 Lenders”) that provides for term loans in an aggregate principal amount of \$45,000 (the “Applicable Commitments”) in two tranches (the “2023 Notes”). The first tranche with a principal amount of \$30,000 was extended on September 7, 2023. The second tranche with a principal amount of \$15,000 may be extended upon the Company’s achievement of certain funding milestones as defined in the 2023 Notes, by July 31, 2024. The 2023 Notes also provide for a third tranche with an uncommitted principal amount of \$20,000 that may be extended to the Company, subject to the lenders’ prior written consent in their sole discretion.

The outstanding balances under the 2023 Notes bear interest at a floating annual rate equal to the greater of 5.5% above the Wall Street Journal prime rate or 13.25%. On and prior to September 30, 2024, 6.0% of the interest is payable in kind (the “PIK interest”) and added to the outstanding principal amount of the loans. Beginning September 30, 2026, the Company is required to make principal payments in the amount of 1.5% of the aggregate principal amount outstanding, including accrued PIK interest, each month. The first principal payment date can be extended to September 30, 2027, at the Company’s option, if certain financing milestones as defined in the 2023 Notes are achieved on or prior to September 30, 2026. In addition, upon any principal payment, the Company is required to make an additional payment to the 2023 Lenders a 6.0% fee (the “Exit Fee”) over the principal and accrued PIK interest paid. The aggregate Exit Fee of the 2023 Notes should equal to 6.0% of the total Applicable Commitments of \$45,000 plus all accrued PIK interest. All remaining outstanding principal balance, accrued interest and Exit Fee on the 2023 Notes shall be due and payable on the maturity date of September 7, 2028.

In connection with the issuance of the 2023 Notes, the Company issued to the 2023 Lenders warrants to purchase, at the holders’ choice, shares of the Company’s Series F convertible preferred stock, the most senior series of Preferred Stock of the Company that is then authorized, or the Company’s common stock. The warrants were recorded as part of the warrant liabilities on the consolidated balance sheet. The fair value of the warrants was estimated using a Monte-Carlo simulation model. See Note 8.

The Company elected to apply the FVO to the 2023 Notes in accordance with ASC 825. The Company considers that the fair value of the notes and warrants at issuance equated to the \$30,000 total proceeds of the 2023 Notes as the credit agreement of the 2023 Notes were entered into with the 2023 Lenders in an arm’s-length transaction. Therefore, the balance of the 2023 Notes as of the issuance date of September 7, 2023 was estimated at the difference between the total proceeds of \$30,000 and the estimated fair value of the warrants of \$2,592.

This fair value measurement is based on significant inputs that are not observable in the market and represent a Level 3 measurement. The following table provides a rollforward of the fair value of the 2023 Notes:

	Fair Value
Fair value at issuance date of September 7, 2023	\$27,408
Increase in fair value	257
Payment of interest	(147)
Balance as of September 30, 2023	<u>\$27,518</u>

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Transaction costs incurred during the nine months ended September 30, 2023 related to the issuance of the 2023 Notes were approximately \$1,934 and were expensed as part of the selling, general and administrative expenses as incurred. Accrued interest on the 2023 Notes is incorporated into the determination of the fair value of the 2023 Notes. Fair value of the 2023 Notes as of September 30, 2023 approximated the fair value as of issuance date of September 7, 2023. The increase in fair value represented interests accrued.

The 2023 Notes are subject to specific financial covenants, which include (i) a minimum liquidity covenant that requires the Company to maintain a minimum \$10,000 balance in cash and/or certain permitted cash equivalent investments, subject to certain exceptions, and (ii) a financing milestone covenant requiring that (a) we have received proceeds from an equity financing or series of financings of at least \$40,000 during the period commencing on September 7, 2023, or the Closing Date, and ending on or prior to February 15, 2024, and (b) we have received equity financing or series of financings of at least \$100,000 (inclusive of such equity financing or series of financings in the preceding clause (a)) during the period commencing as of the Closing Date and prior to June 30, 2024. In addition, the 2023 Notes also contain customary events of default, subject to rights and remedies generally applicable to federal law or the laws of the State of Delaware. As of September 30, 2023, the Company was in compliance with the financial covenants and other terms of the arrangement.

7. Leases

Lexington Lease

In November 2015, the Company entered into a lease agreement for office and laboratory space in Lexington, Massachusetts with the lease term covering a seven-year period from May 1, 2016 through April 30, 2023 (the "Lexington Lease"). The Lexington facility includes 30,000 square feet of office and laboratory space and has been occupied by the Company since August 2016. The Lexington Lease includes a provision for a \$3,000 tenant improvement allowance, which was funded by the lessor in 2016. The Lexington Lease does not contain any material residual value guarantees or material restrictive covenants. The Company is not involved in the construction or design of the additional underlying asset, aside from constructing leasehold improvements. The Company is obligated to pay its portion of real estate taxes and costs, including costs of operations, maintenance, repair, replacement, and management of the Lexington Lease.

The Company reports operating lease right-of-use assets in right-of-use lease assets and the current and non-current portions of its operating lease liabilities in lease liabilities, current and lease liabilities, long-term, respectively, on its Consolidated Balance Sheet. The discount rate used to calculate lease liabilities was the Company's estimated incremental borrowing rate of 6.75%.

In June 2022, the Company extended the term of the Lexington Lease for twelve months commencing on May 1, 2023 and expiring on April 30, 2024. The extended term will expire on April 30, 2024 unless terminated earlier in accordance with the terms of the lease and the Company shall have no option to further extend the lease upon the expiration date. The total fixed lease payment during the extended term is \$1,590.

The extension of the lease has resulted in a revision to the lease term, which has been accounted for as a modification in accordance with ASC 842. As a result of the lease modification, the Company has reassessed the lease liability and right-of-use asset related to the lease. The reassessment involves the remeasurement of the present value of future lease payments, considering the revised lease term and any changes in lease payments, including any adjustments due to changes in discount rate. The Company reassessed its incremental borrowing rate at the time of the lease modification to be 11.75%, which was used as the discount rate in the remeasurement of the lease liabilities. The lease extension resulted in an addition of the operating right-of-use asset and lease liability of \$1,352 on the date of the modification.

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Burlington Lease

In August 2022, the Company entered into a lease agreement for office and laboratory space in Burlington, Massachusetts, encompassing a rentable area of 78,000 square feet (the “Burlington Lease”). The lease contains a total lease term of 128 months, which includes an initial eight-month period of free rent and a remaining lease term of 10 years, subject to total lease payments of \$59,284. Additionally, the Burlington Lease incorporates a five-year renewal option exercisable at the Company’s discretion.

The commencement of the Burlington Lease is contingent upon the substantial completion of the lessor’s construction of the facility. As of September 30, 2023, the leased space was still undergoing construction and the Company had not yet taken control and possession. The lease has subsequently commenced on November 1, 2023 and the Company will recognize the right-of-use asset and lease liability associated with the Burlington Lease on its consolidated balance sheet in accordance with ASC 842, *Leases*.

The following table is a summary of the components of lease expenses for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	2022
Operating lease cost	\$ 824	\$ 530
Short-term lease cost	362	82
Variable lease cost	234	167
Total lease cost	<u>\$ 1,420</u>	<u>\$ 779</u>

Supplemental cash flow information related to leases for the nine months ended September 30, 2023 and 2022 are as follows:

	Nine Months Ended September 30,	
	2023	2022
Operating cash flows paid for operating leases	<u>\$ 1,427</u>	<u>\$ 914</u>

The following table summarizes the maturity of lease liabilities under operating leases as of September 30, 2023:

Fiscal Period Ended September 30, 2023	
Remaining three months of fiscal 2023	\$397
2024	398
Total future minimum lease payments	795
Less: Imputed interest	27
Total lease liabilities	<u>\$768</u>

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8. Warrant Liabilities**2014 Warrant**

In January 2014, the Company issued a fully vested warrant to purchase 118,483 shares of the Company's Series B convertible preferred stock (the "2014 Warrant") in connection with a loan and security agreement entered into in January 2014. The 2014 Warrant was immediately exercisable at an exercise price of \$1.266 per share and has a contractual term of ten years from issuance. The fair value of the 2014 Warrant at issuance was \$48 and was recorded as part of the warrant liabilities in the consolidated balance sheet. The 2014 Warrant was not exercised from its inception through September 30, 2023.

The Company remeasures the fair value of the 2014 Warrant at the end of each reporting period, with any adjustments being recorded as a component of other expense in the consolidated statements of operations and comprehensive loss. The fair value of the 2014 Warrant was determined using the Black-Scholes option-pricing model with the following assumptions:

	September 30, 2023	December 31, 2022
Risk-free interest rate	5.4%	4.7%
Expected term (in years)	0.3	1.1
Expected volatility	49%	51%
Expected Dividend yield	6%	6%
Fair value of Series B convertible preferred stock per share	\$5.99	\$4.93

This fair value measurement of the 2014 Warrant was based on significant inputs that are not observable in the market and represented a Level 3 measurement. The following table provides a rollforward of the fair value of the Company's warrant liability:

	Fair Value
Balance as of December 31, 2022	\$407
Increase in fair value	142
Balance as of September 30, 2023	<u>\$549</u>

July 2023 Warrants

In July 2023, the Company issued fully vested warrants to purchase shares of the Company's common stock in connection with the issuance of the amended and restated 2022 Convertible Notes (the "July 2023 Warrants"). The July 2023 Warrants were immediately exercisable for a variable number of shares based on the principal amount of the 2022 Convertible Notes, as amended, of \$20,899, and an exercise price, at the holders' choice, of (a) \$17.9927 per share, (b) the lowest original issue price of shares of Preferred Stock of the Company issued in the Company's next bona fide private preferred equity financing round, (c) in the event of any convertible note or similar convertible security financing, the conversion price contemplated by such convertible security, or (d) in the event of an IPO, the per share offering price to the public in such IPO. The July 2023 Warrants have a contractual term of ten years from issuance. They were not exercised from their inception through September 30, 2023.

The fair value of the July 2023 Warrants at issuance was \$9,876 and was recorded as part of the warrant liabilities on the consolidated balance sheet. The Company remeasures the fair value at the end of each reporting

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period, with any adjustments being recorded as a component of other expense in the consolidated statements of operations and comprehensive loss.

The fair value was determined using the Monte-Carlo simulation model, which was based on significant inputs that are not observable in the market and represented a Level 3 measurement. See Note 2 for a discussion of the assumptions and estimates used in the fair value measurement. The following table provides a rollforward of the fair value of the July 2023 Warrants:

	<u>Fair Value</u>
Fair value at issuance date of July 11, 2023	\$ 9,876
Increase in fair value	1,019
Balance as of September 30, 2023	<u>\$ 10,895</u>

September 2023 Warrants

In September 2023, in connection with the issuance of the 2023 Notes, the Company issued fully vested warrants to purchase, at the holders' choice, shares of the Company's Series F convertible preferred stock, the most senior series of Preferred Stock of the Company that is then authorized, or the Company's common stock (the "September 2023 Warrants"). The September 2023 Warrants are immediately exercisable for a variable number of shares based on a total fixed dollar value, of \$4,200, and an exercise price, at the holders' choice, of (a) \$17.9927 per share of common stock or \$8.3843 per share of Series F Convertible Preferred Stock, (b) the lowest original issue price of any series of Preferred Stock issued by the Company after the issuance date of the September 2023 Warrants, (c) the conversion or exercise price of any convertible debt security, option, or warrant issued by the Company after the issuance date of the September 2023 Warrants, or (d) the price at which the Company's common equity was first sold to the public by the Company in a firm-commitment underwritten offering or otherwise. The September 2023 Warrants have a contractual term of ten years from issuance. They were not exercised from their inception through September 30, 2023.

The fair value of the September 2023 Warrants at issuance was \$2,592 and was recorded as part of the warrant liabilities on the consolidated balance sheet. The Company remeasures the fair value at the end of each reporting period, with any adjustments being recorded as a component of other expense in the consolidated statements of operations and comprehensive loss.

The fair value was determined using the Monte-Carlo simulation model, which was based on significant inputs that are not observable in the market and represented a Level 3 measurement. See Note 2 for a discussion of the assumptions and estimates used in the fair value measurement. No change in fair value was recorded for the September 2023 Warrants during the nine months ended September 30, 2023 as the fair value as of September 30, 2023 approximated the fair value at issuance date of September 7, 2023.

9. Commitments and Contingencies

Guarantees and Indemnification Obligations

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, the Company indemnifies and agrees to reimburse the indemnified party for losses and costs incurred by the indemnified party in connection with any patent, copyright, trade secret or other intellectual property or personal right infringement claim by any third party with respect to the Company's technology. The term of these indemnification agreements is generally perpetual after execution of the agreement. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of its

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Notes to Consolidated Financial Statements (Unaudited) (continued)
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status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. To date, the Company has not incurred any losses or any material costs related to this indemnification obligation and no claims with respect thereto were outstanding. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations and cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of September 30, 2023 and December 31, 2022.

10. Convertible Preferred Stock

The Company has issued Series A, Series B, Series C-1, Series C-2, Series D, Series E and Series F convertible preferred stock (collectively, the “Convertible Preferred Stock”). The holders of Convertible Preferred Stock have liquidation rights in the event of a deemed liquidation that, in certain circumstances, is not solely within the control of the Company. Therefore, the Convertible Preferred Stock is classified outside of stockholders’ deficit. The Company’s certificate of incorporation, as amended and restated, authorized the Company to issue 78,112,639 shares of \$0.00001 par value convertible preferred stock as of September 30, 2023 and December 31, 2022.

As of each balance sheet date, Convertible Preferred Stock consisted of the following:

	September 30, 2023				
	Convertible Preferred Shares Authorized	Convertible Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Convertible Preferred Stock	5,500,000	5,500,000	\$ 6,510	\$ 9,550	2,562,900
Series B Convertible Preferred Stock	11,451,453	11,332,970	15,459	23,442	5,280,969
Series C-1 Convertible Preferred Stock	9,064,640	9,064,640	20,114	31,337	4,223,960
Series C-2 Convertible Preferred Stock	15,336,464	15,336,464	47,129	69,500	7,146,525
Series D Convertible Preferred Stock	11,994,461	11,994,461	43,899	60,433	5,589,207
Series E Convertible Preferred Stock	12,838,573	12,838,573	54,373	66,694	5,982,550
Series F Convertible Preferred Stock	11,927,048	11,927,048	99,846	113,794	5,557,798
	<u>78,112,639</u>	<u>77,994,156</u>	<u>\$ 287,330</u>	<u>\$ 374,750</u>	<u>36,343,909</u>

	December 31, 2022				
	Convertible Preferred Shares Authorized	Convertible Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Convertible Preferred Stock	5,500,000	5,500,000	\$ 6,510	\$ 9,303	2,562,900
Series B Convertible Preferred Stock	11,451,453	11,332,970	15,459	22,798	5,280,969
Series C-1 Convertible Preferred Stock	9,064,640	9,064,640	20,114	30,428	4,223,960
Series C-2 Convertible Preferred Stock	15,336,464	15,336,464	47,129	67,383	7,146,525
Series D Convertible Preferred Stock	11,994,461	11,994,461	43,899	58,460	5,589,207
Series E Convertible Preferred Stock	12,838,573	12,838,573	54,373	64,223	5,982,550
Series F Convertible Preferred Stock	11,927,048	11,927,048	99,846	109,306	5,557,798
	<u>78,112,639</u>	<u>77,994,156</u>	<u>\$ 287,330</u>	<u>\$ 361,901</u>	<u>36,343,909</u>

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

In January 2014, the Company issued a fully vested warrant to purchase 118,483 shares of the Company's Series B Convertible Preferred Stock. In September 2023, the Company issued fully vested warrants to purchase, at the holders' choice, a variable number of shares of the Company's Series F Convertible Preferred Stock, the most senior series of Preferred Stock of the Company that is then authorized, or the Company's common stock. The number of shares exercisable under these warrants is based on a fixed dollar value and an exercise price at the holders' choice, as defined in the warrant agreement. See Note 8.

The holders of the Convertible Preferred Stock have the following rights and preferences:

Voting

The holders of the Convertible Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote and have the right to vote the number of shares equal to the number of shares of common stock into which such Convertible Preferred Stock could convert on the record date for determination of stockholders entitled to vote. In addition, holders of Series A, Series B, Series C-1, Series C-2, Series D, Series E and Series F convertible preferred stock, voting as a separate class, are entitled to elect four directors of the Company.

Dividends

The holders of Convertible Preferred Stock are entitled to receive cumulative dividends in preference to any dividend on common stock at the rate of 6.0% of the Original Issue Price (as defined below) per share, per annum. Dividends are payable only when, as, and if declared by the board of directors. No dividends have been declared or paid by the Company since its inception in August 2010. The Original Issue Price is \$1.00 per share for Series A convertible preferred stock, \$1.266 per share for Series B convertible preferred stock, \$2.2356 per share for Series C-1 convertible preferred stock, \$3.0756 per share for Series C-2 convertible preferred stock, \$3.6667 per share for Series D convertible preferred stock, \$4.2893 per share for Series E convertible preferred stock and \$8.3843 per share for Series F convertible preferred stock subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to Convertible Preferred Stock.

Liquidation Preference

In the event of any liquidation, voluntary or involuntary, dissolution or winding up of the Company or Deemed Liquidation Event (as defined below), holders of the Convertible Preferred Stock are entitled to receive, in preference to all other stockholders, and to the extent available, an amount equal to the Original Issue Price per share, adjusted for any stock dividends, stock splits or reclassifications, plus any accruing dividends accrued but unpaid, whether or not declared, together with any other dividends declared but unpaid. In the event that proceeds are not sufficient to permit payment in full to these holders, the proceeds will be ratably distributed among the holders of the Convertible Preferred Stock on a *pari passu* basis to the full preferential amount each such holder is otherwise entitled to receive.

After payments have been made in full to the holders of the Convertible Preferred Stock, then, to the extent available, holders of the common stock will receive the remaining amounts available for distribution ratably in proportion to the number of common shares held by them provided, however, if the holders of any series of the Convertible Preferred Stock would receive a greater amount of the proceeds if they had converted their shares of the Convertible Preferred Stock, then such holders shall not receive any proceeds under the preceding paragraph and will receive proceeds on an as converted to common stock basis.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

Unless the holders of at least 60.0% of the then outstanding shares of the Convertible Preferred Stock, voting together as single class, elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Conversion

Each share of Series A, Series B, Series C-1, Series C-2, Series D, Series E and Series F convertible preferred stock is convertible into common stock. Prior to authorization of the Series C-1 Convertible Preferred Stock, Series A Convertible Preferred Stock and Series B Convertible Preferred Stock was convertible into common stock, at the option of the stockholder at any time after the date of issuance. Upon authorization of the Series C-1 Convertible Preferred Stock, each class of the Convertible Preferred Stock is convertible into common stock, at the option of the stockholder, beginning two years after the effective issuance date, or August 2016. Each share of Series A, Series B, Series C-1, Series C-2, Series D, Series E and Series F convertible preferred stock will automatically be converted into shares of common stock, at the applicable conversion ratio of each series then in effect, (i) upon a qualified public offering, defined as the closing of a firm commitment underwritten public offering in which the gross proceeds raised equal or exceed \$60,000; (ii) the consummation of a qualified SPAC transaction; or (iii) a date and time, or occurrence of an event specified by vote or written consent of 60.0% of the holders of the then outstanding shares of Convertible Preferred Stock.

The conversion ratio of each series of the Convertible Preferred Stock is determined by dividing the Original Issue Price of each series of convertible preferred stock by the Conversion Price of each series. The Conversion Price is \$2.146 for Series A Convertible Preferred Stock, \$2.7168 for Series B Convertible Preferred Stock, \$4.7976 for Series C-1 Convertible Preferred Stock, \$6.6002 for Series C-2 Convertible Preferred Stock, \$7.8687 for Series D Convertible Preferred Stock, \$9.2048 per share for Series E Convertible Preferred Stock and \$17.9927 per share for Series F Convertible Preferred Stock, resulting in a conversion ratio of 1-for-2.146 for each series of the Convertible Preferred Stock.

Redemption

Prior to August 19, 2014, the carrying values of the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock were being accreted to their redemption values through March 8, 2018. Upon the closing of the Series C-1 convertible preferred stock financing, the redemption rights of the Series A Convertible Preferred Stock and Series B Convertible Preferred Stock were removed. As a result of the removal of the redemption rights, as of August 19, 2014, the Company ceased the periodic recording of adjustments to accrete the carrying values of Series A Convertible Preferred Stock and Series B Convertible Preferred Stock to each of their redemption values. None of the series of the Company's convertible preferred stock are redeemable as of September 30, 2023.

11. Common Stock

The Company's certificate of incorporation, as amended and restated, authorized the Company to issue 107,000,000 shares of \$0.00001 par value common stock as of September 30, 2023 and December 31, 2022. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Convertible Preferred Stock set forth above.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of all classes of stock outstanding. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of the Convertible Preferred Stock equivalent to the dividend amount they would receive if each preferred share were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Convertible Preferred Stock have been paid in full. No dividends have been declared to date.

As of September 30, 2023 the Company had 104,904,871 shares of common stock available for the conversion of outstanding shares of the Convertible Preferred Stock (See Note 10), the exercise of outstanding stock options, the vesting of restricted stock units and the number of shares remaining available for grant under the Company's 2011 Stock Incentive Plan (See Note 12) as well as the exercise of the warrants to purchase common stock and convertible preferred stock (See Note 8), assuming the warrant to purchase convertible preferred stock became a warrant to purchase common stock at the applicable convertible preferred stock conversion ratio.

12. Stock-Based Compensation

The Company's 2011 Stock Incentive Plan, as amended, (the "Plan") provides for the Company to sell or issue restricted stock or restricted stock units, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, officers, directors, consultants and advisors of the Company. Incentive stock options may only be granted to employees. The Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The Company values its common stock by taking into consideration its most recently available valuation of common stock performed by an independent valuation analyst engaged by management and the board of directors, as well as additional factors which may have changed since the date of the most recently available valuation through the date of grant. The Company generally grants stock-based awards with service conditions only, but also grants stock-based awards with both performance and service conditions from time to time.

The total number of shares of common stock that may be issued under the Plan was 11,994,408 as of September 30, 2023 and December 31, 2022, of which 724,262 and 1,440,745 were available for future grant as of September 30, 2023 and December 31, 2022, respectively.

Stock Options

Stock options granted under the Plan generally vest over four years, with some options having a 25% vesting after one year and the balance vesting pro rata each month and others vesting pro rata each month.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options awards and determine the related compensation expense. The assumptions that the Company used to determine the fair value of stock options granted to employees and directors were as follows:

	Nine Months Ended September 30,	
	2023	2022
Risk-free interest rate	3.7% - 4.3%	1.8% - 3.4%
Weighted average expected term (in years)	6.0	5.8
Weighted average expected volatility	59%	58%
Weighted average expected dividend yield	0%	0%
Fair value of common stock per share	9.16	9.55

The following table summarizes the Company's stock option activity from December 31, 2022 to September 30, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2022	8,581,845	\$ 4.11	5.6	\$ 35,496
Granted	1,682,147	9.18		
Exercised	(39,730)	0.88		
Forfeited/Cancelled	(962,458)	5.25		
Expired	(44,035)	0.82		
Outstanding at September 30, 2023	<u>9,217,769</u>	\$ 4.95	5.6	\$ 57,707
Options exercisable at September 30, 2023	6,430,629	\$ 3.38	4.0	\$ 50,323

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2023 and 2022 was \$5.37 and \$4.42 per share, respectively. The total fair value of stock options vested during the nine months ended September 30, 2023 and 2022 was \$2,972 and \$1,876, respectively.

The total intrinsic value of stock options exercised during the nine months ended September 30, 2023 and 2022 was \$308 and \$1,568, respectively. The intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

As of September 30, 2023, total unrecognized stock-based compensation expense for stock options was \$13,230, which is expected to be recognized over a weighted average period of 3.1 years.

Restricted Stock Units

No Restricted stock units ("RSU"s) were granted under the Plan prior to January 1, 2023. The RSUs granted under the Plan during the nine months ended September 30, 2023 have a one-year cliff vesting with performance conditions based on the timing of occurrence of certain changes in control or financing events.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

The following table summarizes the Company's RSU activity from December 31, 2022 to September 30, 2023:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Outstanding at December 31, 2022	—	\$ —
Granted	40,829	11.21
Outstanding at September 30, 2023	<u>40,829</u>	<u>\$ 11.21</u>

No RSUs have vested during the nine months ended September 30, 2023 as the vesting conditions have not been met as of September 30, 2023. Total unrecognized stock-based compensation expense for RSUs as of September 30, 2023 was \$457, the period over which the expense is going to be recognized is dependent on the achievement of the underlying performance conditions.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense in the following expense categories within its consolidated statements of operations and comprehensive loss:

	<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>
Research and development	<u>\$1,868</u>	<u>\$1,069</u>
Selling, general and administrative	<u>1,152</u>	<u>1,162</u>
	<u>\$3,020</u>	<u>\$2,231</u>

13. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2023 as the Company incurred losses for the nine months ended September 30, 2023, and is forecasting additional losses through the remainder of fiscal year ending December 31, 2023, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2023. Therefore, no federal or state income taxes are expected and none have been recorded at this time. Income taxes have been accounted for using the liability method.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a full valuation allowance, since the Company does not currently believe that realization of its deferred tax assets is more likely than not.

As of September 30, 2023, the Company had no unrecognized income tax benefits that would reduce the Company's effective tax rate if recognized.

Fractyl Health, Inc.
Notes to Consolidated Financial Statements (Unaudited) (continued)
(in thousands, except share and per share information)

14. 401(k) Savings Plan

The Company maintains a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all U.S. employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax and or after-tax basis. Company contributions to the plan may be made at the discretion of the Board of Directors. The Company has not made any matching or discretionary contributions to date under the 401(k) savings plan.

15. Net Loss Per Share

The following securities that could potentially dilute basic net loss per share in the future were not included in the computation of diluted net loss per share for the periods presented, because to do so would have been antidilutive:

	Nine Months Ended	
	September 30,	
	2023	2022
Series A Convertible Preferred Stock	2,562,900	2,562,900
Series B Convertible Preferred Stock	5,280,969	5,280,969
Series C-1 Convertible Preferred Stock	4,223,960	4,223,960
Series C-2 Convertible Preferred Stock	7,146,525	7,146,525
Series D Convertible Preferred Stock	5,589,207	5,589,207
Series E Convertible Preferred Stock	5,982,550	5,982,550
Series F Convertible Preferred Stock	5,557,798	5,557,798
Outstanding stock options	9,217,769	8,875,292
Outstanding restricted stock units	40,829	—
Common stock warrants	161,616	161,616
Series B Convertible Preferred Stock warrants	55,211	55,211
Total	<u>45,819,334</u>	<u>45,436,028</u>

The table presented above does not include the number of shares that may be issued upon exercises of the common stock or preferred stock warrants issued in connection with the 2022 Convertible Notes and the 2023 Notes because the number of shares to be issued under these warrants are variable based on a variable exercise price at the warrant holders' option. See Note 8.

16. Reverse Common Stock Split

On January 26, 2024, the Company's board of directors approved a 1-for-2.146 reverse stock split of its issued and outstanding shares of common stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse common stock split and adjustment of the Convertible Preferred Stock conversion ratios.

Through and including _____, 2024 (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

7,333,333 Shares



Common Stock

PROSPECTUS

BofA Securities

Morgan Stanley

Evercore ISI

, 2024

Part II**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq listing fee.

	<u>Amount</u>
SEC registration fee	\$ 19,916
FINRA filing fee	20,740
Nasdaq listing fee	255,000
Accountants' fees and expenses	729,000
Legal fees and expenses	1,865,000
Transfer agent's fees and expenses	5,000
Printing and engraving expenses	385,000
Miscellaneous expenses	60,000
Total	<u>\$ 3,339,656</u>

Item 14. Indemnification of Directors and Officers.

Fractyl Health, Inc. is incorporated under the laws of the State of Delaware. Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for violations of the director's fiduciary duty, except (1) for any breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends or unlawful stock purchase or redemptions or (4) for any transaction from which the director derived an improper personal benefit.

Section 145(a) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation), because he or she is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Section 145(b) of the DGCL provides, in general, that a corporation may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor because the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses

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(including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, except that no indemnification shall be made with respect to any claim, issue or matter as to which he or she shall have been adjudged to be liable to the corporation unless and only to the extent that the adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, he or she is fairly and reasonably entitled to indemnity for such expenses which the adjudicating court shall deem proper.

Section 145(g) of the DGCL provides, in general, that a corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify the person against such liability under Section 145 of the DGCL.

We expect that the amended and restated certificate of incorporation adopted by us prior to the completion of this offering will provide that no director of our company shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability (1) for any breach of the director's duty of loyalty to us or our stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) in respect of unlawful dividend payments or stock redemptions or repurchases or other distributions pursuant to Section 174 of the DGCL, or (4) for any transaction from which the director derived an improper personal benefit. In addition, our charter will provide that if the DGCL is amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of our company shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

We also expect our charter will further provide that any amendment, repeal or modification of such article unless otherwise required by law will not adversely affect any right or protection existing at the time of such repeal or modification with respect to any acts or omissions occurring before such repeal or amendment of a director serving at the time of such repeal or modification.

We expect that our amended and restated certificate of incorporation adopted by us prior to the completion of this offering, will provide that we shall indemnify each of our directors and executive officers, and shall have power to indemnify our other officers, employees and agents, to the fullest extent permitted by the DGCL as the same may be amended (except that in the case of an amendment, only to the extent that the amendment permits us to provide broader indemnification rights than the DGCL permitted us to provide prior to such the amendment) against any and all expenses, judgments, penalties, fines and amounts reasonably paid in settlement that are incurred by the director, officer or such employee or on the director's, officer's or employee's behalf in connection with any threatened, pending or completed proceeding or any claim, issue or matter therein, to which he or she is or is threatened to be made a party because he or she is or was serving as a director, officer or employee of our company, or at our request as a director, partner, trustee, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of our company and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. We expect the amended and restated certificate of incorporation will further provide for the advancement of expenses to each of our directors and, in the discretion of the board of directors, to certain officers and employees, in advance of the final disposition of such action, suit or proceeding only upon receipt of an undertaking by such person to repay all amounts advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such person is not entitled to be indemnified for such expenses.

In addition, we expect the amended and restated certificate of incorporation will provide that the right of each of our directors and officers to indemnification and advancement of expenses shall not be exclusive of any

other right now possessed or hereafter acquired under any statute, provision of the charter or bylaws, agreement, vote of stockholders or otherwise. Furthermore, our amended and restated certificate of incorporation will authorize us to provide insurance for our directors, officers, employees and agents against any liability, whether or not we would have the power to indemnify such person against such liability under the DGCL or the bylaws.

We intend to enter into indemnification agreements with each of our directors and our executive officers. These agreements will provide that we will indemnify each of our directors and such officers to the fullest extent permitted by law and our amended and restated certificate of incorporation.

We also maintain a general liability insurance policy which covers certain liabilities of directors and officers of our company arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we will enter into in connection with the sale of the common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act, against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

During the past three years, we issued securities that were not registered under the Securities Act as set forth below. The following is a summary of transactions during the preceding three fiscal years involving sales of our securities that were not registered under the Securities Act:

(a) Issuance of Capital Stock

In June and July 2021, we issued and sold to investors in a private placement an aggregate of 11,927,048 shares of Series F Preferred Stock at a purchase price of \$8.3843 per share, for aggregate consideration of approximately \$100.0 million.

In January 2022, we entered into a note purchase agreement with certain individual and institutional accredited investors, pursuant to which we sold and issued approximately \$20.1 million aggregate principal amount of 2022 Convertible Notes in exchange for aggregate cash proceeds of approximately \$20.1 million.

On July 11, 2023, we issued amended and restated the 2022 Convertible Notes to certain of the lenders in replacement of, but not in payment of, certain of the 2022 Convertible Notes. In connection with entering into these amendments, we issued to such lenders warrants to purchase shares of our common stock with par value of \$0.00001 per share.

On September 7, 2023, we entered into a credit agreement with certain lenders, whereby Symbiotic Capital EO Holding, L.P. and Catalio Structured Opportunities AIV I LP were granted warrants in connection with the credit agreement to purchase shares of our common stock with par value of \$0.00001 per share.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. The recipients of securities in the transactions described above represented that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time and appropriate legends were affixed to the instruments representing such securities issued in such transactions.

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(b) Stock Option Grants, Restricted Stock Unit Grants and Option Exercises

Since January 1, 2021 through the date of this prospectus, we granted under the 2011 Plan (i) options to purchase up to 4,892,947 shares, at a weighted average exercise price of \$8.85 per share, to certain of our employees, officers, directors, consultants and advisors, 1,240,900 of which were cancelled, expired without being exercised or were otherwise forfeited, and (ii) 604,509 RSUs to certain of our officers and directors, none of which were cancelled or expired, or otherwise forfeited.

No underwriters were involved in the foregoing issuances of securities. The issuances of stock options described in this paragraph (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors, consultants and advisors, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

Item 16. Exhibits and Financial Statements.

Exhibit No.	Description of Exhibit
1.1	Form of Underwriting Agreement.
3.1	Amended and Restated Certificate of Incorporation of the Registrant (as amended and currently in effect).
3.2*	Bylaws of the Registrant (currently in effect).
3.3	Form of Amended and Restated Certificate of Incorporation of the Registrant (to be in effect upon the consummation of this offering).
3.4	Form of Amended and Restated Bylaws of the Registrant (to be in effect upon the consummation of this offering).
4.1*	Specimen Stock Certificate evidencing the shares of common stock.
4.2*	Fifth Amended and Restated Investors' Rights Agreement, dated June 9, 2021, by and among the Registrant and certain of its stockholders.
5.1	Opinion of Latham & Watkins LLP.
10.1#*	Credit Agreement and Guaranty, dated September 7, 2023, by and among the Registrant, Symbiotic Capital Opportunities Holding, L.P. and Catalio Structured Opportunities AIV LLP.
10.2*	First Amendment to Credit Agreement and Guaranty, dated October 16, 2023, by and among the Registrant, Symbiotic Capital Opportunities Holding, L.P. and Symbiotic Capital Agency LLC.
10.3*	Second Amendment to Credit Agreement and Guaranty, dated December 9, 2023, by and among the Registrant, Symbiotic Capital Opportunities Holding, L.P. and Symbiotic Capital Agency LLC.
10.4†*	Fractyl Health, Inc. Amended and Restated 2011 Stock Incentive Plan and forms of award agreements thereunder.
10.5†	Employment Letter Agreement, dated January 26, 2024, by and between the Registrant and Harith Rajagopalan, M.D., Ph.D.
10.6†	Employment Letter Agreement, dated January 26, 2024, by and between the Registrant and Lisa A. Davidson.
10.7†	Employment Letter Agreement, dated January 26, 2024, by and between the Registrant and Jay D. Caplan.

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<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.8†	Employment Letter Agreement, dated January 26, 2024, by and between the Registrant and Sarah Toomey.
10.9†	Offer Letter, dated September 12, 2023, by and between the Registrant and Timothy Kieffer, Ph.D.
10.10†	First Amendment to Offer Letter, by and between the Registrant and Timothy Kieffer, Ph.D. (to be in effect upon the effectiveness of this registration statement).
10.11†	Severance Agreement and Change in Control Agreement, dated September 12, 2023, by and between the Registrant and Timothy Kieffer, Ph.D.
10.12†	First Amendment to Severance Agreement and Change in Control Agreement, by and between the Registrant and Timothy Kieffer, Ph.D. (to be in effect upon the effectiveness of this registration statement).
10.13*	Lease Agreement, dated November 17, 2015, by and between the Registrant (f/k/a Fractyl Laboratories, Inc.) and BP 17 Hartwell LLC.
10.14*	Lease Agreement, dated August 10, 2022, by and between the Registrant (f/k/a Fractyl Laboratories, Inc.) and BP 17 Hartwell LLC.
10.15†	Fractyl Health, Inc. 2024 Incentive Award Plan and forms of award agreements thereunder.
10.16†	Fractyl Health, Inc. 2024 Employee Stock Purchase Plan.
10.17†	Fractyl Health, Inc. Non-Employee Director Compensation Program.
10.18†*	Form of Indemnification Agreement by and among the Registrant and its directors and officers.
21.1*	List of Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.
23.2	Consent of Latham & Watkins LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page).
107	Filing Fee Table.

* Previously filed.

† Indicates a management contract or compensatory plan or arrangement.

Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets (“[***]”) because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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The undersigned hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Lexington, Commonwealth of Massachusetts, on this 29th day of January, 2024.

FRACTYL HEALTH, INC.

By: /s/ Harith Rajagopalan
Harith Rajagopalan, M.D., Ph.D.
Co-Founder, Chief Executive Officer and Director

We, the undersigned officers and directors of Fractyl Health, Inc., hereby severally constitute and appoint Harith Rajagopalan and Lisa A. Davidson, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Harith Rajagopalan</u> Harith Rajagopalan, M.D., Ph.D.	Co-Founder, Chief Executive Officer and Director (Principal Executive Officer)	January 29, 2024
<u>/s/ Lisa A. Davidson</u> Lisa A. Davidson	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	January 29, 2024
<u>*</u> Kelly Barnes	Director	January 29, 2024
<u>*</u> William W. Bradley	Director	January 29, 2024
<u>/s/ Samuel Conaway</u> Samuel Conaway	Director	January 29, 2024
<u>*</u> Marc Elia	Director	January 29, 2024
<u>*</u> Clive Meanwell, M.B., Ch.B., M.D.	Director	January 29, 2024

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
* <u>Ajay Royan</u>	Director	January 29, 2024
* <u>Amy W. Schulman</u>	Director	January 29, 2024
* <u>Allan R. Will</u>	Chairman	January 29, 2024
*By: /s/ Harith Rajagopalan <u>Attorney-in-fact</u>		

FRACTYL HEALTH, INC.

(a Delaware corporation)

[●] Shares of Common Stock

UNDERWRITING AGREEMENT

Dated: [●], 2024

FRACTYL HEALTH, INC.

(a Delaware corporation)

[●] Shares of Common Stock

UNDERWRITING AGREEMENT

[●], 2024

BofA Securities, Inc.
Morgan Stanley & Co. LLC
Evercore Group L.L.C.
as Representatives of the several Underwriters

c/o BofA Securities, Inc.
One Bryant Park
New York, New York 10036

c/o Morgan Stanley & Co. LLC
1585 Broadway
New York, New York 10036

c/o Evercore Group L.L.C.
55 East 52nd Street
New York, New York 10055

Ladies and Gentlemen:

Fractyl Health, Inc., a Delaware corporation (the “Company”), confirms its agreement with each of BofA Securities, Inc., Morgan Stanley & Co. LLC and Evercore Group L.L.C. (together, the “Representatives”) and each of the other Underwriters named in Schedule A hereto (collectively, the “Underwriters,” which term shall also include any underwriter substituted as hereinafter provided in Section 10 hereof) for whom the Representatives are acting as representatives, with respect to (i) the sale by the Company and the purchase by the Underwriters, acting severally and not jointly, of the respective numbers of shares of Common Stock, par value \$0.00001 per share, of the Company (“Common Stock”) set forth in Schedule A hereto and (ii) the grant by the Company to the Underwriters, acting severally and not jointly, of the option described in Section 2(b) hereof to purchase all or any part of [●] additional shares of Common Stock. The aforesaid [●] shares of Common Stock (the “Initial Securities”) to be purchased by the Underwriters and all or any part of the [●] shares of Common Stock subject to the option described in Section 2(b) hereof (the “Option Securities”) are herein called, collectively, the “Securities.”

The Company understands that the Underwriters propose to make a public offering of the Securities as soon as the Representatives deem advisable after this underwriting agreement (this “Agreement”) has been executed and delivered.

The Company has filed with the Securities and Exchange Commission (the “Commission”) a registration statement on Form S-1 (No. 333-276046), including the related preliminary prospectus or prospectuses, covering the registration of the sale of the Securities under the Securities Act of 1933, as

amended (the “1933 Act”). Promptly after execution and delivery of this Agreement, the Company will prepare and file a prospectus in accordance with the provisions of Rule 430A (“Rule 430A”) of the rules and regulations of the Commission under the 1933 Act (the “1933 Act Regulations”) and Rule 424(b) (“Rule 424(b)”) of the 1933 Act Regulations. The information included in such prospectus that was omitted from such registration statement at the time it became effective but that is deemed to be part of such registration statement at the time it became effective pursuant to Rule 430A(b) is herein called the “Rule 430A Information.” Such registration statement, including the amendments thereto, the exhibits thereto and any schedules thereto, at the time it became effective, and including the Rule 430A Information, is herein called the “Registration Statement.” Any registration statement filed pursuant to Rule 462(b) of the 1933 Act Regulations is herein called the “Rule 462(b) Registration Statement” and, after such filing, the term “Registration Statement” shall include the Rule 462(b) Registration Statement. Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a “preliminary prospectus.” The final prospectus, in the form first furnished to the Underwriters for use in connection with the offering of the Securities, is herein called the “Prospectus.” For purposes of this Agreement, all references to the Registration Statement, any preliminary prospectus, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval system or any successor system (“EDGAR”).

As used in this Agreement:

“Applicable Time” means [●]:00 [P.]/[A.]M., New York City time, on [●], 2024 or such other time as agreed by the Company and the Representatives.

“General Disclosure Package” means any Issuer General Use Free Writing Prospectuses issued at or prior to the Applicable Time, the most recent preliminary prospectus that is distributed to investors prior to the Applicable Time and the information included on Schedule B-1 hereto, all considered together.

“Issuer Free Writing Prospectus” means any “issuer free writing prospectus,” as defined in Rule 433 of the 1933 Act Regulations (“Rule 433”), including without limitation any “free writing prospectus” (as defined in Rule 405 of the 1933 Act Regulations (“Rule 405”)) relating to the Securities that is (i) required to be filed with the Commission by the Company, (ii) a “road show that is a written communication” within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Securities or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g).

“Issuer General Use Free Writing Prospectus” means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a “*bona fide* electronic road show,” as defined in Rule 433 (the “Bona Fide Electronic Road Show”)), as evidenced by its being specified in Schedule B-2 hereto.

“Issuer Limited Use Free Writing Prospectus” means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

“Testing-the-Waters Communication” means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the 1933 Act.

“Written Testing-the-Waters Communication” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the 1933 Act.

SECTION 1. Representations and Warranties.

(a) *Representations and Warranties by the Company.* The Company represents and warrants to each Underwriter as of the date hereof, the Applicable Time, the Closing Time (as defined below) and any Date of Delivery (as defined below), and agrees with each Underwriter, as follows:

(i) Registration Statement and Prospectuses. Each of the Registration Statement and any amendment thereto has become effective under the 1933 Act. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company’s knowledge, contemplated by the Commission. The Company has complied with each request (if any) from the Commission for additional information.

Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, the Applicable Time, the Closing Time and any Date of Delivery, complied and will comply in all material respects with the applicable requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus, the Prospectus and any amendment or supplement thereto, at the time each was filed with the Commission, and, in each case, at the Applicable Time, the Closing Time and any Date of Delivery complied and will comply in all material respects with the applicable requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus delivered to the Underwriters for use in connection with this offering of the Securities and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(ii) Accurate Disclosure. Neither the Registration Statement nor any post-effective amendment thereto, when considered together with the Registration Statement, at its effective time, on the date hereof, at the Closing Time or at any Date of Delivery, contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. At the Applicable Time and any Date of Delivery, none of (A) the General Disclosure Package, (B) any individual Issuer Limited Use Free Writing Prospectus, when considered together with the General Disclosure Package and (C) any individual Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. Neither the Prospectus nor any amendment or supplement thereto, as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Time or at any Date of Delivery, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

The representations and warranties in this subsection shall not apply to statements in or omissions from the Registration Statement (or any amendment thereto), the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) made in reliance upon and in conformity with written information furnished to the Company by any Underwriter through the

Representatives expressly for use therein. For purposes of this Agreement, the only information so furnished shall be the information in the first paragraph under the heading “Underwriting–Commissions and Discounts,” the information in the second paragraph, solely with respect to the actions which may be taken by the Underwriters, and the information in the third and fourth paragraphs under the heading “Underwriting–Price Stabilization, Short Positions and Penalty Bids” and the information under the heading “Underwriting–Electronic Distribution” in each case contained in the Prospectus (collectively, the “Underwriter Information”).

(iii) Issuer Free Writing Prospectuses. No Issuer Free Writing Prospectus conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, and any preliminary or other prospectus deemed to be a part thereof that has not been superseded or modified. The representations and warranties in this subsection shall not apply to statements in or omissions from any Issuer Free Writing Prospectus made in reliance upon and in conformity with the Underwriter Information. The Company has made available a Bona Fide Electronic Road Show in compliance with Rule 433(d)(8)(ii) such that no filing of any “road show” (as defined in Rule 433(h)) is required in connection with the offering of the Securities.

(iv) Testing-the-Waters Materials. The Company (A) has not engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are reasonably believed to be qualified institutional buyers within the meaning of Rule 144A under the 1933 Act or institutions that are accredited investors within the meaning of Rule 501 under the 1933 Act and (B) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule B-2 hereto.

(v) Company Not Ineligible Issuer. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or another offering participant made a *bona fide* offer (within the meaning of Rule 164(h)(2) of the 1933 Act Regulations) of the Securities and at the date hereof, the Company was not and is not an “ineligible issuer,” as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

(vi) Emerging Growth Company Status. From the time of the initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any individual or entity (“Person”) authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an “emerging growth company,” as defined in Section 2(a) of the 1933 Act (an “Emerging Growth Company”).

(vii) Independent Accountants. The accountants who certified the financial statements and supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus are independent public accountants with respect to the Company as required by the 1933 Act, the 1933 Act Regulations and the Public Company Accounting Oversight Board.

(viii) Financial Statements. The financial statements included in the Registration Statement, the General Disclosure Package and the Prospectus, together with the related schedules and notes, present fairly, in all material respects, the financial position of the Company and its consolidated subsidiaries at the dates indicated and the statement of operations, stockholders’

equity and cash flows of the Company and its consolidated subsidiaries for the periods specified; said financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”) applied on a consistent basis throughout the periods involved. The supporting schedules, if any, present fairly, in all material respects, in accordance with GAAP the information required to be stated therein. The selected financial data and the summary financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly, in all material respects, the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included or incorporated by reference in the Registration Statement, the General Disclosure Package or the Prospectus under the 1933 Act or the 1933 Act Regulations.

(ix) No Material Adverse Change in Business. Except as otherwise stated therein, since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, (A) there has been no material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business (a “Material Adverse Effect”), (B) there have been no transactions entered into by the Company or any of its subsidiaries, other than those in the ordinary course of business, which are material with respect to the Company and its subsidiaries considered as one enterprise, and (C) there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of its capital stock.

(x) Good Standing of the Company. The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware and has corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and to enter into and perform its obligations under this Agreement; and the Company is duly qualified as a foreign corporation to transact business and is in good standing in each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure so to qualify or to be in good standing would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect.

(xi) Good Standing of Subsidiaries. Each of Fractyl Laboratories LTD. and Fractyl Securities Corporation (each, a “Subsidiary” and, collectively, the “Subsidiaries”) has been duly organized and is validly existing in good standing under the laws of the jurisdiction of its incorporation or organization, has corporate or similar power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or to be in good standing would not reasonably be expected to result in a Material Adverse Effect. Except as otherwise disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, all of the issued and outstanding capital stock of each Subsidiary has been duly authorized and validly issued, is fully paid and non-assessable and is owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance, claim or equity. None of the outstanding shares of capital stock of any Subsidiary were issued in violation of the preemptive or similar rights of any securityholder of such Subsidiary. The only subsidiaries of the Company are (A) the subsidiaries listed on Exhibit 21 to the Registration Statement and (B) certain other subsidiaries which, considered in the aggregate as a single subsidiary, do not constitute a “significant subsidiary” as defined in Rule 1-02 of Regulation S-X.

(xii) Capitalization. The authorized, issued and outstanding shares of capital stock of the Company are as set forth in the Registration Statement, the General Disclosure Package and the Prospectus in the column entitled “Actual” under the caption “Capitalization” (except for subsequent issuances, if any, pursuant to this Agreement, pursuant to reservations, agreements or employee benefit plans referred to in the Registration Statement, the General Disclosure Package and the Prospectus or pursuant to the exercise of convertible securities or options referred to in the Registration Statement, the General Disclosure Package and the Prospectus or pursuant to the automatic conversions of preferred stock of the Company into shares of Common Stock as a result of the public offering contemplated hereby as described in the Registration Statement, the General Disclosure Package and the Prospectus). The outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable. None of the outstanding shares of capital stock of the Company were issued in violation of the preemptive or other similar rights of any securityholder of the Company, except as have been duly and validly waived.

(xiii) Authorization of Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(xiv) Authorization and Description of Securities. The Securities to be purchased by the Underwriters from the Company have been duly authorized by the Company for issuance and sale to the Underwriters pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement against payment of the consideration set forth herein, will be validly issued and fully paid and non-assessable; and the issuance of the Securities is not subject to the preemptive or other similar rights of any securityholder of the Company, except as have been duly and validly waived. The Common Stock conforms in all material respects to all statements relating thereto contained in the Registration Statement, the General Disclosure Package and the Prospectus and such description conforms in all material respects to the rights set forth in the instruments defining the same. No holder of Securities will be subject to personal liability solely by reason of being such a holder.

(xv) Registration Rights. There are no persons with registration rights or other similar rights to have any securities registered for sale pursuant to the Registration Statement or otherwise registered for sale or sold by the Company under the 1933 Act pursuant to this Agreement, other than those rights that have been disclosed in the Registration Statement, the General Disclosure Package and the Prospectus and have been waived.

(xvi) Absence of Violations, Defaults and Conflicts. Neither the Company nor any of its subsidiaries is (A) in violation of its charter, by-laws or similar organizational document, (B) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound or to which any of the properties or assets of the Company or any subsidiary is subject (collectively, “Agreements and Instruments”), except for such defaults that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, or (C) in violation of any law, statute, rule, regulation, judgment, order, writ or decree of any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency having jurisdiction over the Company or any of its subsidiaries or any of their respective properties, assets or operations (each, a “Governmental Entity”), except for such

violations that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the General Disclosure Package and the Prospectus (including the issuance and sale of the Securities and the use of the proceeds from the sale of the Securities as described therein under the caption "Use of Proceeds") and compliance by the Company with its obligations hereunder have been duly authorized by all necessary corporate action and do not and will not, whether with or without the giving of notice or passage of time or both, conflict with or constitute a breach of, or default or Repayment Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or any subsidiary pursuant to, the Agreements and Instruments (except for such conflicts, breaches, defaults or Repayment Events or liens, charges or encumbrances that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect), nor will such action result in any violation of the (i) provisions of the charter, by-laws or similar organizational document of the Company or any of its subsidiaries or (ii) any law, statute, rule, regulation, judgment, order, writ or decree of any Governmental Entity except, in the case of clause (ii) above, for such violation that would not, singly or in the aggregate, reasonably be expected to result in an Material Adverse Effect. As used herein, a "Repayment Event" means any event or condition which gives the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(xvii) Absence of Labor Dispute. Except as would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, (a) no labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is imminent, and (b) there is no existing or, to the Company's knowledge, imminent labor disturbance by the employees of any of its or any subsidiary's principal suppliers, manufacturers, customers or contractors.

(xviii) Absence of Proceedings. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, there is no action, suit, proceeding, inquiry or investigation before or brought by any Governmental Entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, or which would reasonably be expected to, singly or in the aggregate, materially and adversely affect their respective properties or assets or the consummation of the transactions contemplated in this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject which are not described in the Registration Statement, the General Disclosure Package and the Prospectus, including ordinary routine litigation incidental to the business, would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect.

(xix) Accuracy of Exhibits. There are no contracts or documents which are required to be described in the Registration Statement, the General Disclosure Package or the Prospectus or to be filed as exhibits to the Registration Statement which have not been so described and filed as required.

(xx) Absence of Further Requirements. No filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any Governmental Entity is necessary or required for the performance by the Company of its obligations hereunder, in connection with the offering, issuance or sale of the Securities hereunder or the consummation of the transactions contemplated by this Agreement, except such as have been already obtained or as may be required under the 1933 Act, the 1933 Act Regulations, the rules of the Nasdaq Global Market, state securities laws or the rules of the Financial Industry Regulatory Authority (“FINRA”).

(xxi) Title to Property. The Company and its subsidiaries have good and marketable title to all real property owned by them and good title to all other properties owned by them, in each case, free and clear of all mortgages, pledges, liens, security interests, claims, restrictions or encumbrances of any kind except such as (A) are described in the Registration Statement, the General Disclosure Package and the Prospectus or (B) do not, singly or in the aggregate, materially adversely affect the value of such property and do not adversely interfere with the use made and proposed to be made of such property by the Company or any of its subsidiaries; and all of the leases and subleases material to the business of the Company and its subsidiaries, considered as one enterprise, and under which the Company or any of its subsidiaries holds properties described in the Registration Statement, the General Disclosure Package or the Prospectus, are in full force and effect, and neither the Company nor any such subsidiary has any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any subsidiary under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or such subsidiary to the continued possession of the leased or subleased premises under any such lease or sublease.

(xxii) Regulatory Compliance. Except as would not singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, the Company and its subsidiaries and its and their respective directors, officers and employees, and to the Company’s knowledge, its and their respective agents, affiliates and representatives, are, and have been, in compliance with all Health Care Laws (defined herein). For purposes of this Agreement, “Health Care Laws” shall mean the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the criminal False Claims Act (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. §§ 286, 287, 1347 and 1349, and the health care fraud criminal provisions under the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §§ 1320d et seq.) (“HIPAA”), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), or similar laws, rules and regulations of any national, supranational, federal, state or local governmental or regulatory body or authority (collectively, the “Regulatory Authority”). Except as would not singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect: the Company and its subsidiaries have filed, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission). Neither the Company nor any of its subsidiaries is a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order or similar agreement imposed by any Regulatory Authority with respect to any Health Care Law. Except as would not singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect: neither the Company nor any of its subsidiaries has received any written notification or correspondence, or any other written communication, including, without limitation, any U.S. Food and Drug Administration (“FDA”) Form 483, notice of adverse finding,

warning letter, untitled letter or other correspondence or notice from the FDA or any similar Regulatory Authority, or any notification of any pending or threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action, from any arbitrator or Regulatory Authority or third party alleging potential or actual non-compliance by, or liability of, the Company or its subsidiaries under any Health Care Laws.

(xxiii) License Compliance. Except as would not singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect: (i) each of the Company and its subsidiaries possesses, and is in material compliance with the terms of, all applications, certificates, approvals, clearances, registrations, exemptions, franchises, licenses, permits, consents and other authorizations necessary to conduct their respective businesses as currently conducted (collectively, "Licenses"), issued by Regulatory Authorities, including, without limitation, all Licenses required by the FDA, or any component thereof, and/or by any other Regulatory Authority; (ii) all such Licenses are in full force and effect and neither the Company nor any of its subsidiaries is in violation of any term or conditions of any such License; (iii) each of the Company and its subsidiaries has fulfilled and performed all of its respective obligations with respect to such Licenses; and (iv) neither the Company nor any of its subsidiaries has received any written notice of proceedings relating to the revocation or modification of any such Licenses and no Regulatory Authority has taken any action to limit, suspend or revoke any such License possessed by the Company.

(xxiv) Pre-Clinical Studies and Clinical Studies. The pre-clinical studies and clinical studies, if any, conducted by or on behalf of the Company or its subsidiaries were and, if still pending, are being, conducted in all material respects in accordance with all applicable laws and regulations; the descriptions of the pre-clinical studies and clinical studies, if any, conducted by or, to the Company's knowledge, on behalf of the Company or its subsidiaries, and the results thereof, contained in the Registration Statement, preliminary prospectus and the Prospectus are accurate in all material respects; the Company is not aware of any other pre-clinical studies or clinical studies, the results of which reasonably call into question the results described in the Registration Statement, preliminary prospectus and the Prospectus; and except as disclosed in the Registration Statement, preliminary prospectus and the Prospectus, neither the Company nor any of its subsidiaries have received any written notices or correspondence from the FDA, or any other Regulatory Authority exercising comparable authority or any Institutional Review Board requiring the termination, suspension, material modification or clinical hold of any pre-clinical studies or clinical studies conducted by or on behalf of the Company or its subsidiaries.

(xxv) Company Personnel. Neither the Company nor its subsidiaries, nor any of its or their respective officers, employees or directors, nor any of its or their respective agents or clinical investigators have made an untrue statement of a material fact or fraudulent statement to any Regulatory Authority, including the FDA, failed to disclose a material fact required to be disclosed to any Regulatory Authority, or committed an act, made a material statement or failed to make a material statement, that, including at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in the FDA's Compliance Policy Guide, Section 120.100 (CPG 7150.09), or another Regulatory Authority to invoke a similar policy. Neither the Company nor its subsidiaries, nor any of its or their respective officers, employees or directors, nor any of its or their respective agents or clinical investigators, has been excluded, suspended, disqualified or debarred from participation in any U.S. federal health care program or human clinical research or is subject to a governmental inquiry, investigation, proceeding, or other similar action that would reasonably be expected to result in debarment, disqualification, suspension, or exclusion, or convicted of any crime or engaged in any conduct that would reasonably be expected to result in debarment under 21 U.S.C. § 335a or comparable foreign law.

(xxvi) Possession of Intellectual Property. The Company owns or has valid, binding and enforceable licenses or other rights or can acquire rights (whether by ownership or license) on reasonable terms to practice and use all patents and patent applications, copyrights, trademarks, trademark registrations, service marks, service mark registrations, trade names, service names and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) and all other technology and intellectual property rights necessary for, or material to the conduct, or the proposed conduct, of the business of the Company in the manner described in the preliminary prospectus and the Prospectus (collectively, the “Company Intellectual Property”), and, to the Company’s knowledge, the conduct of its and its subsidiaries’ respective businesses (including the development and commercialization of the product candidates described in preliminary prospectus and the Prospectus) does not and will not infringe or misappropriate any intellectual property rights of others in any material respect; there are, to the knowledge of the Company, no rights of third parties to any of the Company Intellectual Property owned by the Company, and such intellectual property is owned by the Company free and clear of all material liens, security interests, or encumbrances; to the knowledge of the Company, the patents, trademarks and copyrights held or licensed by the Company included within the Company Intellectual Property are valid, enforceable and subsisting; to the Company’s knowledge, there is no infringement by third parties of any of the Company Intellectual Property; other than as disclosed in preliminary prospectus and the Prospectus, (i) neither the Company nor its subsidiaries is obligated to pay a material royalty, grant a license, or provide other material consideration to any third party in connection with the Company Intellectual Property, (ii) no action, suit, claim or other proceeding is pending or, to the knowledge of the Company, is threatened, alleging that the Company or its subsidiaries is infringing, misappropriating, diluting or otherwise violating any rights of others with respect to any of the Company’s product candidates, processes or intellectual property, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim, (iii) no action, suit, claim or other proceeding is pending or, to the knowledge of the Company, is threatened, challenging the validity, enforceability, scope, registration, ownership or use of any of the Company’s Intellectual Property, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim, (iv) no action, suit, claim or other proceeding is pending or, to the knowledge of the Company, is threatened, challenging the Company’s rights in or to any Company Intellectual Property, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim, (v) the Company has not received written notice of any claim of infringement, misappropriation or conflict with any asserted rights of others with respect to any of the Company’s products, proposed products, processes or Company Intellectual Property, (vi) (vii) to the knowledge of the Company, no consultant or independent contractor of the Company or any of its subsidiaries is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement nondisclosure agreement or any restrictive covenant to or with a former employer or independent contractor where the basis of such violation relates to such independent contractor’s engagement with the Company or actions undertaken while employed or engaged with the Company, (ix) the Company has taken reasonable measures to protect its confidential information and trade secrets and to maintain and safeguard the Company’s Intellectual Property, including the execution of appropriate nondisclosure and confidentiality agreements, and to the Company’s knowledge, no employee of the Company is in or has been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement, or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee’s employment with the Company, and (x) the Company has complied in all material respects with the terms of each agreement pursuant to which the Company’s Intellectual Property has been licensed to the Company, and all such agreements are in full force and effect.

(xxvii) Patents and Patent Applications. All patents and patent applications owned by or licensed to the Company or under which the Company has rights have, to the knowledge of the Company, been duly and properly filed and maintained; to the knowledge of the Company, there are no material defects in any of the patents or patent applications disclosed in the Registration Statement and the Prospectus as being owned by the Company and its Subsidiaries; to the knowledge of the Company, the parties prosecuting such applications have complied with their duty of candor and disclosure to the United States Patent and Trademark Office (the “USPTO”) in connection with such applications; and the Company is not aware of any facts required to be disclosed to the USPTO that were not disclosed to the USPTO and which would preclude the grant of a patent in connection with any such application or could form the basis of a finding of invalidity with respect to any patents that have issued with respect to such applications.

(xxviii) Environmental Laws. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus or would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (A) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mold (collectively, “Hazardous Materials”) or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, “Environmental Laws”), (B) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (C) there are no pending or, to the knowledge of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigations or proceedings relating to any Environmental Law against the Company or any of its subsidiaries and (D) to the knowledge of the Company, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or Governmental Entity, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(xxix) Accounting Controls. The Company and each of its subsidiaries maintain effective internal control over financial reporting (as defined under Rules 13-a15 and 15d-15 under the rules and regulations of the Commission under the Securities Exchange Act of 1934, as amended (the “1934 Act,” and such rules and regulations, the “1934 Act Regulations”)) and a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management’s general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management’s general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as described in the Registration Statement, the General

Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (1) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) no change in the Company's internal control over financial reporting that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting.

(xxx) Compliance with the Sarbanes-Oxley Act. The Company has taken all necessary actions to ensure that, upon the effectiveness of the Registration Statement, it will be in compliance with all provisions of the Sarbanes-Oxley Act of 2002 and all rules and regulations promulgated thereunder or implementing the provisions thereof (the "Sarbanes-Oxley Act") that are then in effect and with which the Company is required to comply as of the effectiveness of the Registration Statement, and is taking reasonable steps to enable it to be in compliance with other provisions of the Sarbanes-Oxley Act not currently in effect, upon the effectiveness of such provisions, or which will become applicable to the Company at all times after the effectiveness of the Registration Statement.

(xxxi) Payment of Taxes. All United States federal income tax returns of the Company and its subsidiaries required by law to be filed have been filed as of the date hereof (after giving effect to any extensions provided by law that have been requested) and all taxes shown by such returns or otherwise assessed, which are due and payable, have been paid, except assessments against which appeals have been or will be promptly taken in good faith by the Company and as to which adequate reserves have been provided in accordance with GAAP by the Company or which would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. The Company and its subsidiaries have filed all other tax returns that are required to have been filed by them pursuant to applicable foreign, state, local or other law except insofar as the failure to file such returns would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect, and has paid all taxes due pursuant to such returns or pursuant to any assessment received by the Company and its subsidiaries, except for such taxes, if any, as are being contested in good faith and as to which adequate reserves have been established by the Company. The charges, accruals and reserves on the books of the Company in respect of any income and corporation tax liability for any years not finally determined are adequate to meet any assessments or re-assessments for additional income tax for any years not finally determined, except to the extent of any inadequacy that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect.

(xxxii) Insurance. The Company and its subsidiaries carry or are entitled to the benefits of insurance, with financially sound and reputable insurers, in such amounts and covering such risks as is generally maintained by similarly sized companies of established repute engaged in the same or similar business and at the same or similar stage of development, and all such insurance is in full force and effect. The Company has no reason to believe that it or any of its subsidiaries will not be able (A) to renew its existing insurance coverage as and when such policies expire or (B) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to, singly or in the aggregate, result in a Material Adverse Effect. Neither of the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(xxxiii) Investment Company Act. The Company is not required, and upon the issuance and sale of the Securities as herein contemplated and the application of the net proceeds therefrom as described in the Registration Statement, the General Disclosure Package and the Prospectus will not be required, to register as an "investment company" under the Investment Company Act of 1940, as amended (the "1940 Act").

(xxxiv) Absence of Manipulation. Neither the Company nor, to the knowledge of the Company, any affiliate of the Company has taken, nor will the Company or any affiliate take, directly or indirectly, any action which is designed, or would reasonably be expected, to cause or result in, or which constitutes, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities or to result in a violation of Regulation M under the 1934 Act.

(xxxv) Foreign Corrupt Practices Act and Other Applicable Anti-Corruption Laws. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of or has taken any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, the rules and regulations thereunder (the “FCPA”), and any applicable anti-corruption laws, including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any “foreign official” (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA and any applicable anti-corruption laws, and the Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and any applicable anti-corruption laws and have instituted and maintained and will continue to maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(xxxvi) Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the “Money Laundering Laws”); and no action, suit or proceeding by or before any Governmental Entity involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xxxvii) OFAC. None of the Company, any of its subsidiaries, any director, officer or employee, or, to the knowledge of the Company, any agent, affiliate or representative of the Company or any of its subsidiaries is a Person currently the subject or target of any sanctions administered or enforced by the United States Government, including, without limitation, the U.S. Department of the Treasury’s Office of Foreign Assets Control, the United Nations Security Council, the European Union, His Majesty’s Treasury, or other relevant sanctions authority (collectively, “Sanctions”), nor is the Company located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, the Crimea Region and the non-government controlled areas of the Zaporizhzhia and Kherson Regions of Ukraine, the so-called Donetsk People’s Republic, the so-called Luhansk People’s Republic, Russia, Cuba, Iran, North Korea and Syria); and the Company will not directly or indirectly use the proceeds of the sale of the Securities, or lend, contribute or otherwise make available such proceeds to any subsidiaries, joint venture partners or other Person, to fund or facilitate any activities of or business with any Person, or in any country or territory, that, at the time of such funding or facilitation, is the subject of Sanctions or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions.

(xxxviii) Lending Relationship. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of any Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Securities to repay any outstanding debt owed to any affiliate of any Underwriter.

(xxxix) Statistical and Market-Related Data. Any statistical and market-related data included in the Registration Statement, the General Disclosure Package or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate in all material respects and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

(xl) Cybersecurity. Except as would not reasonably be expected to result in a Material Adverse Effect, (A) to the knowledge of the Company, there has been no security breach or incident, unauthorized access or disclosure, or other compromise of or relating to the Company or its subsidiaries information technology and computer systems, networks, hardware, software, data and databases (including the data and information of their respective customers, employees, suppliers, vendors and any third party data maintained, processed or stored by the Company and its subsidiaries, and any such data processed or stored by third parties on behalf of the Company and its subsidiaries), equipment or technology (collectively, "IT Systems and Data"); (B) neither the Company nor its subsidiaries have been notified of, and each of them have no knowledge of any event or condition that could result in, any security breach or incident, unauthorized access or disclosure or other compromise to their IT Systems and Data and (C) the Company and its subsidiaries have implemented commercially reasonable controls, policies, procedures, and technological safeguards designed to maintain and protect the integrity, availability, privacy and security of their IT Systems and Data reasonably consistent with industry standards and practices, or as required by applicable regulatory standards. The Company and its subsidiaries are presently in material compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification.

(b) *Officer's Certificates*. Any certificate signed by any officer of the Company or any of its subsidiaries delivered to the Representatives or to counsel for the Underwriters shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

SECTION 2. Sale and Delivery to Underwriters; Closing.

(a) *Initial Securities*. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company agrees to sell to each Underwriter, severally and not jointly, and each Underwriter, severally and not jointly, agrees to purchase from the Company, at the price per share set forth in Schedule A, that number of Initial Securities set forth in Schedule A opposite the name of such Underwriter, plus any additional number of Initial Securities which such Underwriter may become obligated to purchase pursuant to the provisions of Section 10 hereof, subject, in each case, to such adjustments among the Underwriters as the Representatives in their sole discretion shall make to eliminate any sales or purchases of fractional shares.

(b) *Option Securities*. In addition, on the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company hereby grants an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock,

at the price per share set forth in Schedule A, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities. The option hereby granted may be exercised for 30 days after the date hereof and may be exercised in whole or in part at any time from time to time upon notice by the Representatives to the Company setting forth the number of Option Securities as to which the several Underwriters are then exercising the option and the time and date of payment and delivery for such Option Securities. Any such time and date of delivery (a "Date of Delivery") shall be determined by the Representatives, but shall not be later than seven full business days after the exercise of said option, nor in any event prior to the Closing Time. If the option is exercised as to all or any portion of the Option Securities, each of the Underwriters, acting severally and not jointly, will purchase that proportion of the total number of Option Securities then being purchased which the number of Initial Securities set forth in Schedule A opposite the name of such Underwriter bears to the total number of Initial Securities, subject, in each case, to such adjustments as the Representatives in their sole discretion shall make to eliminate any sales or purchases of fractional shares.

(c) *Payment.* Payment of the purchase price for, and delivery of certificates or security entitlements for, the Initial Securities shall be made at the offices of Goodwin Procter LLP, The New York Times Building, 620 Eighth Avenue, New York, New York 10018, or at such other place as shall be agreed upon by the Representatives and the Company, at 9:00 A.M. (New York City time) on the second (third, if the pricing occurs after 4:30 P.M. (New York City time) on any given day) business day after the date hereof (unless postponed in accordance with the provisions of Section 10 hereof), or such other time not later than ten business days after such date as shall be agreed upon by the Representatives and the Company (such time and date of payment and delivery being herein called "Closing Time").

In addition, in the event that any or all of the Option Securities are purchased by the Underwriters, payment of the purchase price for, and delivery of certificates or security entitlements for, such Option Securities shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representatives and the Company, on each Date of Delivery as specified in the notice from the Representatives to the Company.

Payment shall be made to the Company by wire transfer of immediately available funds to a bank account designated by the Company against delivery to the Representatives for the respective accounts of the Underwriters of certificates or security entitlements for the Securities to be purchased by them. It is understood that each Underwriter has authorized the Representatives, for its account, to accept delivery of, receipt for, and make payment of the purchase price for, the Initial Securities and the Option Securities, if any, which it has agreed to purchase. Each of the Representatives, individually and not as representative of the Underwriters, may (but shall not be obligated to) make payment of the purchase price for the Initial Securities or the Option Securities, if any, to be purchased by any Underwriter whose funds have not been received by the Closing Time or the relevant Date of Delivery, as the case may be, but such payment shall not relieve such Underwriter from its obligations hereunder.

SECTION 3. Covenants of the Company. The Company covenants with each Underwriter as follows:

(a) *Compliance with Securities Regulations and Commission Requests.* The Company, subject to Section 3(b), will comply with the requirements of Rule 430A, and will notify the Representatives promptly, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed, (ii) of the receipt of any comments from the Commission, (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or for additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or

suspending the use of any preliminary prospectus or the Prospectus, or of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the 1933 Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the 1933 Act in connection with the offering of the Securities. The Company will effect all filings required under Rule 424(b), in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and will take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company will use commercially reasonable efforts to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof as soon as practicable.

(b) *Continued Compliance with Securities Laws.* The Company will comply with the 1933 Act and the 1933 Act Regulations so as to permit the completion of the distribution of the Securities as contemplated in this Agreement and in the Registration Statement, the General Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172 of the 1933 Act Regulations (“Rule 172”), would be) required by the 1933 Act to be delivered in connection with sales of the Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) amend or supplement the General Disclosure Package or the Prospectus in order that the General Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the General Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the 1933 Act or the 1933 Act Regulations, the Company will promptly (A) give the Representatives notice of such event, (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the General Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representatives with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representatives or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request.

(c) *Delivery of Registration Statements.* The Company has furnished or will deliver to the Representatives and counsel for the Underwriters, without charge, conformed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and conformed copies of all consents and certificates of experts. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(d) *Delivery of Prospectuses.* The Company has delivered to each Underwriter, without charge, as many copies of each preliminary prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the 1933 Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(e) *Blue Sky Qualifications.* The Company will use its reasonable best efforts, in cooperation with the Underwriters, to qualify the Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representatives may reasonably designate and to maintain such qualifications in effect so long as required to complete the distribution of the Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

(f) *Rule 158.* The Company will timely file (which filing may be satisfied via EDGAR) such reports pursuant to the 1934 Act, as are necessary in order to make generally available to its securityholders as soon as practicable an earnings statement for the purposes of, and to provide to the Underwriters the benefits contemplated by, the last paragraph of Section 11(a) of the 1933 Act.

(g) *Use of Proceeds.* The Company will use the net proceeds received by it from the sale of the Securities in the manner specified in the Registration Statement, the General Disclosure Package and the Prospectus under “Use of Proceeds.”

(h) *Listing.* The Company will use its reasonable best efforts to effect and maintain the listing of the Common Stock (including the Securities) on the Nasdaq Global Market.

(i) *Restriction on Sale of Securities.* During a period of 180 days from the date of the Prospectus, the Company will not, without the prior written consent of the Representatives, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or file or confidentially submit any registration statement under the 1933 Act with respect to any of the foregoing or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock, whether any such swap or transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise. The foregoing sentence shall not apply to (A) the Securities to be sold hereunder, (B) any shares of Common Stock issued by the Company upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (C) any shares of Common Stock issued or options to purchase Common Stock or other equity awards covering Common Stock granted, in each case, pursuant to existing employee benefit plans of the Company referred to in the Registration Statement, the General Disclosure Package and the Prospectus or (D) any shares of Common Stock issued pursuant to any non-employee director compensation plan or program or dividend reinvestment plan referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (E) the filing by the Company of a registration statement with the Commission on Form S-8 in respect of any shares or other equity instruments issued pursuant to any plans or programs described in (C) or (D) above, or (F) the sale or issuance of or entry into an agreement to sell or issue shares of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock in connection with any (1) mergers, (2) acquisition of securities, businesses, property or other assets, (3) joint ventures or (4) strategic alliances or relationships; provided, that the aggregate number of shares of Common Stock or securities convertible into or exercisable for Common Stock (on an as-converted or as-exercised basis, as the case may be) that the Company may sell or issue or agree to sell or issue pursuant to this clause (F) shall

not exceed 5% of the total number of shares of the Company's Common Stock issued and outstanding immediately following the completion of the transactions contemplated by this Agreement; and provided further, that each recipient of shares of Common Stock or securities convertible into or exercisable for Common Stock pursuant to this clause (F) shall execute a lock-up agreement substantially in the form of Exhibit A hereto.

(j) *Waiver of Lock-Up Agreement.* If the Representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up agreement described in Section 5(j) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two business days before the effective date of the release or waiver or such other manner in satisfaction of FINRA Rule 5131(d)(2).

(k) *Reporting Requirements.* The Company, during the period when a Prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, will file all documents required to be filed with the Commission pursuant to the 1934 Act within the time periods required by the 1934 Act and 1934 Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Securities as may be required under Rule 463 under the 1933 Act.

(l) *Issuer Free Writing Prospectuses.* The Company agrees that, unless it obtains the prior written consent of the Representatives, it will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus," or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Representatives will be deemed to have consented to the Issuer Free Writing Prospectuses listed on Schedule B-2 hereto and any "road show that is a written communication" within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representatives. The Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented to, by the Representatives as an "issuer free writing prospectus," as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement which has not been superseded or modified, any preliminary prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(m) *Certification Regarding Beneficial Owners.* The Company will deliver to the Representatives, on the date of execution of this Agreement, a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers, together with copies of identifying documentation, and the Company undertakes to provide such additional supporting documentation as the Representatives may reasonably request in connection with the verification of the foregoing certification.

(n) *Testing-the-Waters Materials.* If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(o) Emerging Growth Company Status. The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Securities within the meaning of the 1933 Act and (ii) completion of the 180-day restricted period referred to in Section 3(i) hereof.

SECTION 4. Payment of Expenses.

(a) *Expenses*. The Company will pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, printing and filing of the Registration Statement (including financial statements and exhibits) as originally filed and each amendment thereto, (ii) the preparation, printing and delivery to the Underwriters of copies of each preliminary prospectus, each Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto and any reasonable costs associated with electronic delivery of any of the foregoing by the Underwriters to investors, (iii) the preparation, issuance and delivery of the certificates or security entitlements for the Securities to the Underwriters, including any stock or other transfer taxes and any stamp or other duties payable upon the sale, issuance or delivery of the Securities to the Underwriters, (iv) the fees and disbursements of the Company's counsel, accountants and other advisors engaged by the Company, (v) subject to the limitation set forth in clause (viii) below, the qualification of the Securities under securities laws in accordance with the provisions of Section 3(e) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters in connection therewith and in connection with the preparation of the Blue Sky Survey and any supplement thereto, (vi) the fees and expenses of any transfer agent or registrar for the Securities, (vii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the Securities, including without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged with the Company's consent in connection with the road show presentations, travel and lodging expenses of the representatives and officers of the Company and any such consultants customarily paid by the Company, and 50% of the cost of aircraft and other transportation chartered in connection with the road show, (viii) the filing fees incident to, and the reasonable fees and disbursements of counsel to the Underwriters in connection with, the review by FINRA of the terms of the sale of the Securities, (ix) the fees and expenses incurred in connection with the listing of the Securities on the Nasdaq Global Market and (x) the costs and expenses (including, without limitation, any damages or other amounts payable in connection with legal or contractual liability) associated with the reforming of any contracts for sale of the Securities made by the Underwriters caused by a breach of the representation contained in the third sentence of Section 1(a)(ii). For the avoidance of doubt, the Company shall not be responsible for any expense of the Representatives and Underwriters except as set forth in Section 4 and Section 6 hereof and any counsel fee in connection with the foregoing clauses (v) and (viii) shall be limited to \$30,000 in the aggregate.

(b) *Termination of Agreement*. If this Agreement is terminated by the Representatives in accordance with the provisions of Section 5, Section 9(a) (i) or (iii) or Section 10 hereof, the Company shall reimburse the non-defaulting Underwriters for all of their reasonably incurred and documented out of pocket expenses, including the reasonable and documented fees and disbursements of counsel for the Underwriters.

SECTION 5. Conditions of Underwriters' Obligations. The obligations of the several Underwriters hereunder are subject to the accuracy of the representations and warranties of the Company contained herein or in certificates of any officer of the Company or any of its subsidiaries delivered pursuant to the provisions hereof, to the performance by the Company of its covenants and other obligations hereunder, and to the following further conditions:

(a) *Effectiveness of Registration Statement; Rule 430A Information.* The Registration Statement, including any Rule 462(b) Registration Statement, has become effective and, at the Closing Time, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated; and the Company has complied with each request (if any) from the Commission for additional information. A prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) without reliance on Rule 424(b)(8) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

(b) *Downgrading of any Rated Securities.* Neither the Company nor any of its subsidiaries has any securities rated by any "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Exchange Act

(c) *Opinion of Counsel for Company.* At the Closing Time, the Representatives shall have received the favorable opinion and negative assurance letter, each dated the Closing Time, of Latham & Watkins LLP, counsel for the Company, in form and substance reasonably satisfactory to counsel for the Underwriters, together with signed or reproduced copies of such letters for each of the other Underwriters.

(d) *Opinions of Intellectual Property Counsel for Company.* At the Closing Time, the Representatives shall have received the favorable opinion and negative assurance letter, dated the Closing Time, from each of Wilson Sonsini Goodrich & Rosati PC and Wolf, Greenfield & Sacks, P.C., respectively, intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, together with signed or reproduced copies of such letters for each of the other Underwriters.

(e) *Opinion of Counsel for Underwriters.* At the Closing Time, the Representatives shall have received the favorable opinion and negative assurance letter, dated the Closing Time, of Goodwin Procter LLP, counsel for the Underwriters, in form and substance reasonably satisfactory to the Representatives, together with signed or reproduced copies of such letter for each of the other Underwriters with respect to such matters the Representatives may require.

(f) *Officers' Certificate.* At the Closing Time, there shall not have been, since the date hereof or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, and the Representatives shall have received a certificate of the Chief Executive Officer or the President of the Company and of the chief financial or chief accounting officer of the Company, dated the Closing Time, to the effect that (i) there has been no such material adverse change, (ii) the representations and warranties of the Company in this Agreement are true and correct with the same force and effect as though expressly made at and as of the Closing Time, (iii) the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied at or prior to the Closing Time, and (iv) no stop order suspending the effectiveness of the Registration Statement under the 1933 Act has been issued, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to their knowledge, contemplated by the Commission.

(g) *Accountant's Comfort Letter.* At the time of the execution of this Agreement, the Representatives shall have received from Ernst & Young LLP a letter, dated such date, in form and substance reasonably satisfactory to the Representatives, together with signed or reproduced copies of such letter for each of the other Underwriters containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the General Disclosure Package and the Prospectus.

(h) *Bring-down Comfort Letter.* At the Closing Time, the Representatives shall have received from Ernst & Young LLP a letter, dated as of the Closing Time, to the effect that they reaffirm the statements made in the letter furnished pursuant to subsection (e) of this Section, except that the specified date referred to shall be a date not more than three business days prior to the Closing Time.

(i) *Approval of Listing.* At the Closing Time, the Securities shall have been approved for listing on the Nasdaq Global Market, subject only to official notice of issuance.

(j) *No Objection.* FINRA shall have confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Securities.

(k) *Lock-up Agreements.* At the date of this Agreement, the Representatives shall have received an agreement substantially in the form of Exhibit A hereto signed by substantially all security holders of the Company and each of the Company's directors and officers.

(l) *Conditions to Purchase of Option Securities.* In the event that the Underwriters exercise their option provided in Section 2(b) hereof to purchase all or any portion of the Option Securities, the representations and warranties of the Company contained herein and the statements in any certificates furnished by the Company and any of its subsidiaries hereunder shall be true and correct as of each Date of Delivery and, at the relevant Date of Delivery, the Representatives shall have received:

(i) Officers' Certificate. A certificate, dated such Date of Delivery, of the Chief Executive Officer of the Company and of the chief financial or chief accounting officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(e) hereof remains true and correct as of such Date of Delivery.

(ii) Opinion of Counsel for Company. The favorable opinion and negative assurance letter of Latham & Watkins LLP, counsel for the Company, in form and substance reasonably satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(b) hereof.

(iii) Opinions of Intellectual Property Counsel for Company. The favorable opinion and negative assurance letter from each of Wilson Sonsini Goodrich & Rosati PC and Wolf, Greenfield & Sacks, P.C., respectively, intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(c) hereof.

(iv) Opinion of Counsel for Underwriters. The favorable opinion and negative assurance letter of Goodwin Procter LLP, counsel for the Underwriters, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(d) hereof.

(v) Bring-down Comfort Letter. A letter from Ernst & Young LLP, in form and substance reasonably satisfactory to the Representatives and dated such Date of Delivery, substantially in the same form and substance as the letter furnished to the Representatives pursuant to Section 5(f) hereof, except that the “specified date” in the letter furnished pursuant to this paragraph shall be a date not more than three business days prior to such Date of Delivery.

(m) Additional Documents. At the Closing Time and at each Date of Delivery (if any) counsel for the Underwriters shall have been furnished with such customary documents as they may reasonably require for the purpose of enabling them to pass upon the issuance and sale of the Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters.

(n) Termination of Agreement. If any condition specified in this Section shall not have been fulfilled when and as required to be fulfilled, this Agreement, or, in the case of any condition to the purchase of Option Securities on a Date of Delivery which is after the Closing Time, the obligations of the several Underwriters to purchase the relevant Option Securities, may be terminated by the Representatives by notice to the Company at any time at or prior to Closing Time or such Date of Delivery, as the case may be, and such termination shall be without liability of any party to any other party except as provided in Section 4 and except that Sections 1, 6, 7, 8, 14, 15, 16 and 17 shall survive any such termination and remain in full force and effect.

SECTION 6. Indemnification.

(a) Indemnification of Underwriters. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates (as such term is defined in Rule 501(b) under the 1933 Act (each, an “Affiliate”)), its selling agents and each person, if any, who controls any Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, arising out of any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including the Rule 430A Information, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or arising out of any untrue statement or alleged untrue statement of a material fact included (A) in any preliminary prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto), or (B) in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities (“Marketing Materials”), including any roadshow or investor presentations made to investors by the Company (whether in person or electronically), or the omission or alleged omission in any preliminary prospectus, Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, Prospectus or in any Marketing Materials of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 6(d) hereof) any such settlement is effected with the written consent of the Company;

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel chosen by the Representatives), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above;

provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package, or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(b) *Indemnification of Company, Directors and Officers.* Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its directors, each of its officers who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act, against any and all loss, liability, claim, damage and expense described in the indemnity contained in subsection (a) of this Section, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendment thereto), including the Rule 430A Information, the General Disclosure Package, any preliminary prospectus or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(c) *Actions against Parties; Notification.* Each indemnified party shall give notice as promptly as reasonably practicable to each indemnifying party of any action commenced against it in respect of which indemnity may be sought hereunder, but failure to so notify an indemnifying party shall not relieve such indemnifying party from any liability hereunder to the extent it is not materially prejudiced as a result thereof and in any event shall not relieve it from any liability which it may have otherwise than on account of this indemnity agreement. In the case of parties indemnified pursuant to Section 6(a) hereof, counsel to the indemnified parties shall be selected by the Representatives, and, in the case of parties indemnified pursuant to Section 6(b) hereof, counsel to the indemnified parties shall be selected by the Company. An indemnifying party may participate at its own expense in the defense of any such action; provided, however, that counsel to the indemnifying party shall not (except with the consent of the indemnified party) also be counsel to the indemnified party. In no event shall the indemnifying parties be liable for fees and expenses of more than one counsel (in addition to any local counsel) separate from their own counsel for all indemnified parties in connection with any one action or separate but similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification or contribution could be sought under this Section 6 or Section 7 hereof (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) *Settlement without Consent if Failure to Reimburse.* If at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a)(ii) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

SECTION 7. Contribution. If the indemnification provided for in Section 6 hereof is for any reason unavailable to or insufficient to hold harmless an indemnified party in respect of any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount of such losses, liabilities, claims, damages and expenses reasonably incurred by such indemnified party, as incurred, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Securities pursuant to this Agreement or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and of the Underwriters, on the other hand, in connection with the statements or omissions, which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations.

The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Securities pursuant to this Agreement shall be deemed to be in the same respective proportions as the total net proceeds from the offering of the Securities pursuant to this Agreement (after deducting underwriting discount and commission and before deducting expenses) received by the Company, on the one hand, and the total underwriting discount received by the Underwriters, on the other hand, in each case as set forth on the cover of the Prospectus, bear to the aggregate initial public offering price of the Securities as set forth on the cover of the Prospectus.

The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 7 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 7. The aggregate amount of losses, liabilities, claims, damages and expenses reasonably incurred by an indemnified party and referred to above in this Section 7 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission.

Notwithstanding the provisions of this Section 7, no Underwriter shall be required to contribute any amount in excess of the underwriting commissions received by such Underwriter in connection with the Securities underwritten by it and distributed to the public.

No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

For purposes of this Section 7, each person, if any, who controls an Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act and each Underwriter's Affiliates and selling agents shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act shall have the same rights to contribution as the Company. The Underwriters' respective obligations to contribute pursuant to this Section 7 are several in proportion to the number of Initial Securities set forth opposite their respective names in Schedule A hereto and not joint.

SECTION 8. Representations, Warranties and Agreements to Survive. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company or any of its subsidiaries submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company and (ii) delivery of and payment for the Securities.

SECTION 9. Termination of Agreement.

(a) *Termination.* The Representatives may terminate this Agreement, by notice to the Company, at any time at or prior to the Closing Time (i) if there has been, in the judgment of the Representatives, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, or (ii) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the completion of the offering or to enforce contracts for the sale of the Securities, or (iii) if trading in any securities of the Company has been suspended or materially limited by the Commission or the Nasdaq Global Market, or (iv) if trading generally on the NYSE MKT or the New York Stock Exchange or in the Nasdaq Global Market has been suspended or materially limited, or minimum or maximum prices for trading have been fixed, or maximum ranges for prices have been required, by any of said exchanges or by order of the Commission, FINRA or any other governmental authority, or (v) a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States or with respect to Clearstream or Euroclear systems in Europe, or (vi) if a banking moratorium has been declared by either Federal or New York authorities.

(b) *Liabilities.* If this Agreement is terminated pursuant to this Section, such termination shall be without liability of any party to any other party except as provided in Section 4 hereof, and provided further that Sections 1, 6, 7, 8, 14, 15, 16 and 17 hereof shall survive such termination and remain in full force and effect.

SECTION 10. Default by One or More of the Underwriters. If one or more of the Underwriters shall fail at the Closing Time or a Date of Delivery to purchase the Securities which it or they are obligated to purchase under this Agreement (the “Defaulted Securities”), the Representatives shall have the right, within 24 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other underwriters, to purchase all, but not less than all, of the Defaulted Securities in such amounts as may be agreed upon and upon the terms herein set forth; if, however, the Representatives shall not have completed such arrangements within such 24-hour period, then:

(i) if the number of Defaulted Securities does not exceed 10% of the number of Securities to be purchased on such date, each of the non-defaulting Underwriters shall be obligated, severally and not jointly, to purchase the full amount thereof in the proportions that their respective underwriting obligations hereunder bear to the underwriting obligations of all non-defaulting Underwriters, or

(ii) if the number of Defaulted Securities exceeds 10% of the number of Securities to be purchased on such date, this Agreement or, with respect to any Date of Delivery which occurs after the Closing Time, the obligation of the Underwriters to purchase, and the Company to sell, the Option Securities to be purchased and sold on such Date of Delivery shall terminate without liability on the part of any non-defaulting Underwriter.

No action taken pursuant to this Section shall relieve any defaulting Underwriter from liability in respect of its default.

In the event of any such default which does not result in a termination of this Agreement or, in the case of a Date of Delivery which is after the Closing Time, which does not result in a termination of the obligation of the Underwriters to purchase and the Company to sell the relevant Option Securities, as the case may be, either the (i) Representatives or (ii) the Company shall have the right to postpone Closing Time or the relevant Date of Delivery, as the case may be, for a period not exceeding seven days in order to effect any required changes in the Registration Statement, the General Disclosure Package or the Prospectus or in any other documents or arrangements. As used herein, the term “Underwriter” includes any person substituted for an Underwriter under this Section 10.

SECTION 11. Notices. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted by any standard form of telecommunication. Notices to the Underwriters shall be directed to BofA at One Bryant Park, New York, New York 10036, attention of Syndicate Department (email: dg.ecm_execution_services@bofa.com), with a copy to ECM Legal (email: dg.ecm_legal@bofa.com); Morgan Stanley & Co. LLC at 1585 Broadway, New York, New York 10036 Attention: Equity Syndicate Desk, with a copy to the Legal Department; Evercore Group L.L.C. 55 East 52nd Street, 35th Floor, New York, New York 10055, attention of ECM General Counsel; with a copy to Goodwin Procter LLP, The New York Times Building, 620 Eighth Avenue, New York, New York 10018, attention to Edwin O’Connor; and notices to the Company shall be directed to it at 17 Hartwell Avenue, Lexington, Massachusetts 02421, attention of Harith Rajagopalan, MD, Ph.D; with a copy to Latham & Watkins LLP at 1271 Avenue of the Americas, New York, New York 10020, attention of Nathan Ajiashvili.

SECTION 12. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Securities pursuant to this Agreement, including the determination of the initial public offering price of the Securities and any related discounts and commissions, is an arm’s-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering of the Securities and the process leading thereto, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, any of its subsidiaries or their respective stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Securities or the process leading thereto (irrespective of whether such

Underwriter has advised or is currently advising the Company or any of its subsidiaries on other matters) and no Underwriter has any obligation to the Company with respect to the offering of the Securities except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering of the Securities and the Company has consulted its own respective legal, accounting, regulatory and tax advisors to the extent it deemed appropriate and (f) none of the activities of the Underwriters in connection with the transactions contemplated herein constitutes a recommendation, investment advice, or solicitation of any action by the Underwriters with respect to any entity or natural person.

SECTION 13. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Section 13, a “BHC Act Affiliate” has the meaning assigned to the term “affiliate” in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). “Covered Entity” means any of the following: (i) a “covered entity” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a “covered bank” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a “covered FSI” as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). “Default Right” has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable. “U.S. Special Resolution Regime” means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

SECTION 14. Parties. This Agreement shall each inure to the benefit of and be binding upon the Underwriters and the Company and their respective successors. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, firm or corporation, other than the Underwriters and the Company and their respective successors and the controlling persons and officers and directors referred to in Sections 6 and 7 hereof, as applicable, and their heirs and legal representatives, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the Underwriters and the Company and their respective successors, and said controlling persons and officers and directors and their heirs and legal representatives, as applicable, and for the benefit of no other person, firm or corporation. No purchaser of Securities from any Underwriter shall be deemed to be a successor by reason merely of such purchase.

SECTION 15. Trial by Jury. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

SECTION 16. GOVERNING LAW. THIS AGREEMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK WITHOUT REGARD TO ITS CHOICE OF LAW PROVISIONS.

SECTION 17. Consent to Jurisdiction. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby shall be instituted in (i) the federal courts of the United States of America located in the City and County of New York, Borough of Manhattan or (ii) the courts of the State of New York located in the City and County of New York, Borough of Manhattan (collectively, the "Specified Courts"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

SECTION 18. TIME. TIME SHALL BE OF THE ESSENCE OF THIS AGREEMENT. EXCEPT AS OTHERWISE SET FORTH HEREIN, SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME.

SECTION 19. Counterparts and Electronic Signatures. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement. Electronic signatures complying with the New York Electronic Signatures and Records Act (N.Y. State Tech. §§ 301-309), as amended from time to time, or other applicable law will be deemed original signatures for purposes of this Agreement. Transmission by telecopy, electronic mail or other transmission method of an executed counterpart of this Agreement will constitute due and sufficient delivery of such counterpart.

SECTION 20. Effect of Headings. The Section headings herein are for convenience only and shall not affect the construction hereof.

This Underwriting Agreement may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docuSign.com or www.echosign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement among the Underwriters and the Company in accordance with its terms.

Very truly yours,

FRACTYL HEALTH, INC.

By _____
Title:

CONFIRMED AND ACCEPTED,
as of the date first above written:

BOFA SECURITIES, INC.
MORGAN STANLEY & CO. LLC
EVERCORE GROUP L.L.C.

By: BOFA SECURITIES, INC.

By _____
Authorized Signatory

By: MORGAN STANLEY & CO. LLC

By _____
Authorized Signatory

By: EVERCORE GROUP L.L.C.

By _____
Authorized Signatory

For themselves and as Representatives of the other Underwriters named in Schedule A hereto.

[Signature Page to Underwriting Agreement]

SCHEDULE A

The initial public offering price per share for the Securities shall be \$[●].

The purchase price per share for the Securities to be paid by the several Underwriters shall be \$[●], being an amount equal to the initial public offering price set forth above less \$[●] per share, subject to adjustment in accordance with Section 2(b) for dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities.

Name of Underwriter	Number of Initial Securities
BofA Securities, Inc.	
Morgan Stanley & Co. LLC	
Evercore Group L.L.C.	
Total	<u> </u> [●]

SCHEDULE B-1

Pricing Terms

1. The Company is selling [●] shares of Common Stock.
2. The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock.
3. The initial public offering price per share for the Securities shall be \$[●].

Sch B-1

SCHEDULE B-2
Free Writing Prospectuses

[None.]

Sch B-2

FORM OF LOCK-UP FROM DIRECTORS, OFFICERS AND OTHER STOCKHOLDERS PURSUANT TO SECTION 5(j)

_____, 2023

BofA Securities, Inc.
Morgan Stanley & Co. LLC
Evercore Group L.L.C.

as Representatives of the several
Underwriters to be named in the
within-mentioned Underwriting Agreement

c/o BofA Securities, Inc.
One Bryant Park
New York, New York 10036

c/o Morgan Stanley & Co. LLC
1585 Broadway
New York, New York 10036

c/o Evercore Group L.L.C.
55 East 52nd Street
New York, New York 10055

Re: Proposed Public Offering by Fractyl Health, Inc.

Dear Sir/Madam:

The undersigned, a stockholder and/or a stock option holder and/or an officer and/or a director, as applicable, of Fractyl Health, Inc., a Delaware corporation (the "Company"), understands that BofA Securities, Inc. ("BofA"), Morgan Stanley & Co. LLC ("Morgan Stanley") and Evercore Group L.L.C. ("Evercore," and together with BofA and Morgan Stanley, the "Representatives") and the other Underwriters party thereto propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Company providing for the public offering (the "Public Offering") of shares of the Company's common stock, par value \$0.00001 per share (the "Common Stock"). In recognition of the benefit that the Public Offering will confer upon the undersigned as a stockholder and/or a stock option holder and/or an officer and/or a director, as applicable, of the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each Underwriter to be named in the Underwriting Agreement that, during the period beginning on the date hereof and ending on the date that is 180 days from the date of the Underwriting Agreement (the "Lock-Up Period"), the undersigned will not, without the prior written consent of the Representatives, on behalf of the Underwriters, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of the Company's Common Stock or any securities convertible into or exercisable or exchangeable for shares of Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition

Exh. A

(collectively, the “Lock-Up Securities”), or exercise any right with respect to the registration of any of the Lock-Up Securities, or file, cause to be filed or cause to be confidentially submitted any registration statement in connection therewith, under the Securities Act of 1933, as amended, or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Lock-Up Securities, whether any such swap or transaction is to be settled by delivery of Common Stock or other securities, in cash or otherwise. If the undersigned is an officer or director of the Company (whether as of the date hereof or at the time of receiving any shares of Common Stock), the undersigned further agrees that the foregoing provisions shall be equally applicable to any issuer-directed shares of Common Stock the undersigned may purchase in the Public Offering.

If the undersigned is an officer or director of the Company, (1) the Representatives agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, the Representatives will notify the Company of the impending release or waiver, and (2) the Company has agreed, or will agree, in the Underwriting Agreement to announce the impending release or waiver by a press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (i) the release or waiver is effected solely to permit a transfer not for consideration or to an immediate family member as defined in FINRA Rule 5130(i)(5) and (ii) the transferee has agreed in writing to be bound by the same terms described in this lock-up agreement to the extent and for the duration that such terms remain in effect at the time of the transfer.

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may, without the prior written consent of the Representatives:

- a) transfer Lock-Up Securities; provided that (1) the Representatives receive a signed lock-up agreement for the balance of the Lock-Up Period from each donee, trustee, distributee, or transferee, as the case may be, (2) any such transfer shall not involve a disposition for value, (3) in the case of clauses (ii) through (iv) below, such transfers are not required to be reported during the Lock-Up Period with the Securities and Exchange Commission (the “SEC”) on Form 4 in accordance with Section 16 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and in the case of clause (i) below, if the undersigned is required to file a report under Section 16 of the Exchange Act during the Lock-Up Period, the undersigned shall include a statement in such report to the effect that such report relates to a bona fide gift or gifts, and (4) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers during the Lock-Up Period:
- (i) as a *bona fide* gift or gifts;
 - (ii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this lock-up agreement, “immediate family” shall mean any relationship by blood, marriage or adoption, not more remote than first cousin);
 - (iii) as a distribution to limited partners, members, stockholders or other equity holders of the undersigned;
 - (iv) to the undersigned’s affiliates or to any investment fund or other entity that directly, or indirectly, controls or manages, is controlled or managed by, or is under common control or management with, the undersigned;

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- (v) by will or intestate succession upon the death of the undersigned, provided that, any required filing under Section 16 of the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described above; or
 - (vi) pursuant to a court order, a qualified domestic order or in connection with a divorce settlement provided that, any required filing under Section 16 of the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described above.
- b) exercise any rights to purchase, exchange or convert any stock options granted to the undersigned pursuant to the Company's equity incentive plans described to in the prospectus relating to the Public Offering, or any warrants or other securities convertible into or exercisable or exchangeable for shares of Common Stock, which warrants or other securities are described in the prospectus relating to the Public Offering, provided that (1) the underlying shares of Common Stock continue to be subject to the restrictions on transfer set forth in this lock-up agreement, (2) any required filing under Section 16 of the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described above and (B) the underlying shares of Common Stock continue to be subject to the restrictions on transfer set forth in this lock-up agreement and (3) the undersigned does not otherwise voluntarily effect any other public filings or reports regarding such exercise during the Lock-Up Period;
- c) sell or otherwise transfer Lock-Up Securities to the Company pursuant to a repurchase right arising in connection with the termination of the undersigned's employment or other service with the Company, provided that any filing under Section 16 of the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described in this clause and no public filing, report or announcement shall be voluntarily made; provided further, that no other public announcement shall be voluntarily made in connection with such transfer;
- d) transfer Lock-Up Securities pursuant to a bona fide third-party tender offer, or in connection with a merger, consolidation or other similar transaction, that is approved by the Board of Directors of the Company, made to all holders of the Company's capital stock involving a change of control of the Company; provided that, in the event that such tender offer, merger, consolidation or other transaction is not completed, such securities shall remain subject to the restrictions on transfer set forth in this lock-up agreement; provided further that any shares of Common Stock not transferred in such third-party tender offer, merger, consolidation, or other similar transaction shall remain subject to the provisions of this lock-up agreement (for purposes hereof, "change of control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of capital stock of the Company if, after such transaction or transactions, such person or group of affiliated persons would hold more than 50% of the outstanding voting securities of the Company (or the surviving entity));
- e) convert shares of preferred stock of the Company into shares of Common Stock in connection with the consummation of the Public Offering, as described in the prospectus relating to the Public Offering, provided that any shares of Common Stock received upon such conversion shall be subject to the terms of this lock-up agreement; provided further that if required, any public report or filing under Section 16 of the Exchange Act shall clearly indicate in the footnotes thereto that such transfer is being made pursuant to the circumstances described in this clause (e); and

Exh. A

- f) transfer Lock-Up Securities to the Company upon (i) a vesting event of any equity award granted under any equity incentive plan or stock purchase plan of the Company described in the prospectus relating to the Public Offering, or (ii) upon the exercise by the undersigned of options or warrants in accordance with clause (b) above, in each case, on a “net” or “cashless” exercise basis, and/or to cover tax withholding obligations of the undersigned in connection therewith, provided, in each case, that (1) any filing under Section 16 of the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described above, as applicable, (2) no Lock-Up Securities were sold by the reporting person other than such transfers to the Company as described above and (3) the undersigned does not otherwise voluntarily effect any other public filings or reports regarding such transfers during the Lock-Up Period.

Notwithstanding anything herein to the contrary, nothing in this lock-up agreement shall prevent the undersigned from establishing a 10b5-1 trading plan that complies with Rule 10b5-1 under the Exchange Act (“10b5-1 Trading Plan”) or from amending an existing 10b5-1 Trading Plan so long as there are no sales of Lock-Up Securities under such plan during the Lock-Up Period; and provided that, the establishment of a 10b5-1 Trading Plan or the amendment of a 10b5-1 Trading Plan, in either case, providing for sales of Lock-Up Securities shall only be permitted if the undersigned does not voluntarily effect any public filing or report regarding the establishment or amendment of such plan during the Lock-Up Period.

In the event that a director, officer or stockholder of the Company that beneficially owns (as such term is used in Rule 13d-3 of the Exchange Act) one percent (1.0%) or more of the then outstanding Common Stock (measured as of the date of the prospectus on an as-converted basis) (collectively, the “Restricted Parties”) is released from its obligations under such lock-up restrictions contained in a lock-up agreement (a “Discretionary Release”), then the same percentage of the total number of outstanding securities of the Company held by the undersigned as the percentage of the total number of outstanding securities of the Company held by such Restricted Party that are the subject of such Discretionary Release shall be automatically immediately and fully released on the same terms from the applicable prohibition(s) set forth herein. The provisions of this paragraph will not apply (1) if (x) the Discretionary Release is effected solely to permit a transfer not involving a disposition for value and (y) the transferee agrees in writing to be bound by the same terms described in this lock-up agreement to the extent and for the duration that such terms remain in effect at the time of transfer or (2) to the extent all such Discretionary Releases granted to all Restricted Parties constitute, in the aggregate, an amount less than one percent (1.0%) of the Company’s total outstanding shares of Common Stock (determined as of the date of the prospectus on an as-converted basis). The Representatives shall use commercially reasonable efforts to notify the Company, and the Company shall notify the undersigned, of any such Discretionary Release described in this paragraph within three business days before the effective date of any such Discretionary Release (provided that the failure by the Representatives to provide such notice shall not give rise to any claim or liability against the Representatives or the Underwriters), which notifications shall state the percentage of shares held by such person or entity to be released and the effective date of such release. The undersigned acknowledges that the Representatives are under no obligation to inquire into whether, or to ensure that, the Company notifies the undersigned of the delivery by the Representatives on behalf of the Underwriters of any such notice, which is a matter between the undersigned and the Company. The foregoing shall not apply to any release granted to a holder of Common Stock in the case of a secondary underwritten public offering of shares of Common Stock (including a secondary underwritten public offering with a primary component) (a “Follow-on Offering”), provided that the undersigned shall be offered the opportunity to participate on a pro rata basis in such Follow-on Offering and on pricing terms that are no less favorable than the terms of the Follow-on Offering.

Exh. A

Furthermore, the undersigned may sell shares of Common Stock of the Company purchased by the undersigned from the Underwriters in the Public Offering (other than any issuer-directed shares of Common Stock purchased in the Public Offering by any officer or director of the Company) or on the open market following the effectiveness of the registration statement for the Public Offering if and only if (i) such sales are not required to be reported during the Lock-Up Period in any public report or filing with the SEC, or otherwise and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales during the Lock-Up Period.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the Lock-Up Securities except in compliance with the foregoing restrictions.

The undersigned acknowledges and agrees that the foregoing precludes the undersigned from engaging in any hedging or other transaction designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition of any shares of Common Stock, or any securities convertible into or exercisable or exchangeable for Common Stock, even if any such sale or disposition transaction or transactions would be made or executed by or on behalf of someone other than the undersigned.

The undersigned acknowledges and agrees that the Underwriters have not provided any recommendation or investment advice nor have the Underwriters solicited any action from the undersigned with respect to the Public Offering of the Shares and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate. The undersigned further acknowledges and agrees that, although the Underwriters may provide certain Regulation Best Interest and Form CRS disclosures or other related documentation to you in connection with the Public Offering, the Underwriters are not making a recommendation to you to participate in the Public Offering or sell any Shares at the price determined in the Public Offering, and nothing set forth in such disclosures or documentation is intended to suggest that any Underwriter is making such a recommendation. The undersigned further acknowledges and agrees that none of the Underwriters has made any recommendation or provided any investment or other advice to the undersigned with respect to this Lock-Up Agreement or the subject matter hereof, and the undersigned has consulted its own legal, accounting, financial, regulatory, tax and other advisors with respect to this Lock-Up Agreement and the subject matter hereof to the extent the undersigned has deemed appropriate.

The undersigned understands that, if (1) the execution of the Underwriting Agreement in connection with the Public Offering shall not have occurred on or before December 29, 2023; provided, however, the Company may, by written notice to the undersigned prior to such date, extend such date for a period of up to three additional months, (2) the date that the Company withdraws the registration statement relating to the Public Offering, (3) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Stock to be sold thereunder, or (4) the Representatives, on behalf of the Underwriters, advise the Company, or the Company advises the Representatives, in each case in writing, prior to the execution of the Underwriting Agreement, that they have determined not to proceed with the Public Offering, the undersigned shall be released from all obligations under this lock-up agreement.

This lock-up agreement may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com or www.echosign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

This lock-up agreement shall be governed by and construed in accordance with the laws of the State of New York.

[Signature Page Follows]

Exh. A

Very truly yours,

[If signatory is an individual]

Signature: _____

Name: _____

[If signatory is an entity]

Entity: _____

Signature: _____

Name: _____

Exh. A

FORM OF PRESS RELEASE
TO BE ISSUED PURSUANT TO SECTION 3(j)

FRACTYL HEALTH, INC.
[Date]

FRACTYL HEALTH, INC. (the "Company") announced today that BofA Securities, Inc., Morgan Stanley & Co. LLC and Evercore Group L.L.C., the lead book-running managers in the Company's recent public sale of [●] shares of common stock, are [waiving] [releasing] a lock-up restriction with respect to [●] shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on [●], 20 [●], and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

Exh. B

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
FRACTYL LABORATORIES INC.

(Pursuant to Sections 242 and 245 of the
General Corporation Law of the State of Delaware)

Fractyl Laboratories Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the “**General Corporation Law**”),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Fractyl Laboratories Inc., and that this corporation was originally incorporated under the name MedCatalyst, Inc. pursuant to the General Corporation Law on August 30, 2010.

2. That the Board of Directors duly adopted resolutions proposing to amend and restate the Certificate of Incorporation of this corporation, declaring said amendment and restatement to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

RESOLVED, that the Certificate of Incorporation of this corporation be amended and restated in its entirety to read as follows:

FIRST: The name of this corporation is Fractyl Health, Inc. (the “**Corporation**”).

SECOND: The address of the registered office of the Corporation in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle 19801. The name of its registered agent at such address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 107,000,000 shares of common stock, par value \$0.00001 per share (“**Common Stock**”), and (ii) 78,112,639 shares of preferred stock, par value \$0.00001 per share (“**Preferred Stock**”).

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. Voting. The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings). There shall be no cumulative voting. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by (in addition to any vote of the holders of one or more series of Preferred Stock that may be required by the terms of this Certificate of Incorporation) the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law.

B. PREFERRED STOCK

Preferred Stock may be issued from time to time in one or more series, each such series to consist of such number of shares and to have such terms, rights, powers and preferences, and the qualifications and limitations with respect thereto, as stated or expressed herein.

C. SERIES A PREFERRED STOCK, SERIES B PREFERRED STOCK, SERIES C-1 PREFERRED STOCK, SERIES C-2 PREFERRED STOCK, SERIES D PREFERRED STOCK, SERIES E PREFERRED STOCK AND SERIES F PREFERRED STOCK

Of the 78,112,639 shares of Preferred Stock, (i) 5,500,000 shares of the authorized Preferred Stock of the Corporation are hereby designated Series A Preferred Stock (the “**Series A Preferred Stock**”); (ii) 11,451,453 shares of the authorized Preferred Stock of the Corporation are hereby designated Series B Preferred Stock (the “**Series B Preferred Stock**”); (iii) 9,064,640 shares of the authorized Preferred Stock of the Corporation are hereby designated Series C-1 Preferred Stock (the “**Series C-1 Preferred Stock**”); (iv) 15,336,464 shares of the authorized Preferred Stock of the Corporation are hereby designated Series C-2 Preferred Stock (the “**Series C-2 Preferred Stock**”); (v) 11,994,461 shares of the authorized Preferred Stock of the Corporation are hereby designated Series D Preferred Stock (the “**Series D Preferred Stock**”); (vi) 12,838,573 shares of the authorized Preferred Stock of the Corporation are hereby designated Series E Preferred Stock (the “**Series E Preferred Stock**”); and (vii) 11,927,048 shares of the authorized Preferred Stock of the Corporation are hereby designated Series F Preferred Stock (the “**Series F Preferred Stock**”), with each series having the following rights, preferences, powers, privileges and restrictions, qualifications and limitations. Unless otherwise indicated, references to “Sections” or “Subsections” in this Part C of this Article Fourth refer to sections and subsections of Part C of this Article FOURTH.

1. Dividends.

1.1 From and after the date of the issuance of any shares of Series A Preferred Stock, dividends at the rate per annum of six percent of the Series A Original Issue Price (as defined below) per share shall accrue on such shares of Series A Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock) (the “**Series A Accruing Dividends**”).

1.2 From and after the date of the issuance of any shares of Series B Preferred Stock, dividends at the rate per annum of six percent of the Series B Original Issue Price (as defined below) per share shall accrue on such shares of Series B Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock) (the “**Series B Accruing Dividends**”).

1.3 From and after the date of the issuance of any shares of Series C-1 Preferred Stock, dividends at the rate per annum of six percent of the Series C-1 Original Issue Price (as defined below) per share shall accrue on such shares of Series C-1 Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C-1 Preferred Stock) (the “**Series C-1 Accruing Dividends**”).

1.4 From and after the date of the issuance of any shares of Series C-2 Preferred Stock, dividends at the rate per annum of six percent of the Series C-2 Original Issue Price (as defined below) per share shall accrue on such shares of Series C-2 Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C-2 Preferred Stock) (the “**Series C-2 Accruing Dividends**”).

1.5 From and after the date of the issuance of any shares of Series D Preferred Stock, dividends at the rate per annum of six percent of the Series D Original Issue Price (as defined below) per share shall accrue on such shares of Series D Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series D Preferred Stock) (the “**Series D Accruing Dividends**”).

1.6 From and after the date of the issuance of any shares of Series E Preferred Stock, dividends at the rate per annum of six percent of the Series E Original Issue Price (as defined below) per share shall accrue on such shares of Series E Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series E Preferred Stock) (the “**Series E Accruing Dividends**”).

1.7 From and after the date of the issuance of any shares of Series F Preferred Stock, dividends at the rate per annum of six percent of the Series F Original Issue Price (as defined below) per share shall accrue on such shares of Series F Preferred Stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series F Preferred Stock) (the “**Series F Accruing Dividends**”) and, together with the Series A Accruing Dividends, the Series B Accruing Dividends, the Series C-1 Accruing Dividends, the Series C-2 Accruing Dividends, the Series D Accruing Dividends and the Series E Accruing Dividends, the “**Accruing Dividends**”).

1.8 Accruing Dividends shall accrue from day to day, whether or not declared, and shall be cumulative; provided however, that except as set forth in the following sentence of this Subsection 1.8 or in Subsection 2.1, such Accruing Dividends shall be payable only when, as, and if declared by the Board of Directors of the Corporation (the “**Board of Directors**”) and the Corporation shall be under no obligation to pay such Accruing Dividends. The Corporation shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Corporation (other than dividends on shares of Common Stock payable in shares of Common Stock) unless (in addition to the obtaining of any consents required elsewhere in the Certificate of Incorporation) the holders of each series of Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to the greater of (i) the amount of the aggregate Accruing Dividends then accrued on such share of Preferred Stock and not previously paid and (ii) (A) in the case of a dividend on Common Stock or any class or series that is convertible into Common Stock, that dividend per share of Preferred Stock as would equal the product of (1) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into Common Stock and (2) the number of shares of Common Stock issuable upon conversion of a share of the applicable series of Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (B) in the case of a dividend on any class or series that is not convertible into Common Stock, at a rate per share of such series of Preferred Stock determined by (1) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (2) multiplying such fraction by an amount equal to the Original Issue Price (as defined below) applicable to such series of Preferred Stock; provided that, if the Corporation declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of capital stock of the Corporation, the dividend payable to the holders of a series of Preferred Stock pursuant to this Section 1 shall be calculated based upon the dividend on the class or series of capital stock that would result in the highest Preferred Stock dividend for such series. The “**Series A Original Issue Price**” shall mean \$1.00 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock. The “**Series B Original Issue Price**” shall mean \$1.266 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series B Preferred Stock. The “**Series C-1 Original Issue Price**” shall mean \$2.2356 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C-1 Preferred Stock. The “**Series C-2 Original Issue Price**” shall mean \$3.0756 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series C-2 Preferred Stock. The “**Series D Original Issue Price**” shall mean \$3.6667 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series D Preferred Stock. The “**Series E Original Issue Price**” shall mean \$4.2893 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series E Preferred Stock. The “**Series F Original Issue Price**” shall mean \$8.3843 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series F Preferred Stock. Each of the Series A Original Issue Price, the Series B Original Issue Price, the Series C-1 Original Issue Price, the Series C-2 Original Issue Price, the Series D Original Issue Price, the Series E Original Issue Price and the Series F Original Issue Price is sometimes referred to herein as an “**Original Issue Price**.”

2. Liquidation, Dissolution or Winding Up; Certain Mergers, Consolidations and Asset Sales.

2.1 Payments to Holders of Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation (including a Deemed Liquidation Event, as defined below), the holders of shares of each series of Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Corporation available for distribution to the Corporation's stockholders, before any payment shall be made to the holders of Common Stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Original Issue Price applicable to such series, plus any Accruing Dividends accrued but unpaid thereon, whether or not declared, together with any other dividends declared but unpaid thereon, and (ii) such amount per share as would have been payable had all shares of such series of Preferred Stock been converted into Common Stock pursuant to Section 4 immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (the amount payable pursuant to this sentence, as applicable to each series of Preferred Stock, the "**Preferred Liquidation Amount**"). If upon any such liquidation, dissolution or winding up of the Corporation, the assets of the Corporation available for distribution to the Corporation's stockholders shall be insufficient to pay the holders of shares of Preferred Stock the full amount to which they shall be entitled under this Subsection 2.1, the holders of shares of Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

2.2 Payments to Holders of Common Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Corporation (including a Deemed Liquidation Event), after the payment of all preferential amounts required to be paid to the holders of shares of Preferred Stock, the remaining assets of the Corporation available for distribution to the Corporation's stockholders shall be distributed among the holders of shares of Common Stock, pro rata based on the number of shares held by each such holder.

2.3 Deemed Liquidation Events.

2.3.1 Definition. Each of the following events shall be deemed to be a liquidation of the Corporation for purposes of this Section 2 (a "**Deemed Liquidation Event**") unless the holders of at least 60% of the then outstanding shares of Preferred Stock (voting as a single class and on an as-converted basis) (the "**Requisite Investors**") elect otherwise by written notice given to the Corporation at least 10 days prior to the effective date of any such event:

- (a) a merger or consolidation in which
 - (i) the Corporation is a constituent party or
 - (ii) a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation,

except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation (provided that, for the purpose of this Subsection 2.3.1, all shares of Common Stock issuable upon exercise of Options (as defined below) outstanding immediately prior to such merger or consolidation or upon conversion of Convertible Securities (as defined below) outstanding immediately prior to such merger or consolidation shall be deemed to be outstanding immediately prior to such merger or consolidation and, if applicable, converted or exchanged in such merger or consolidation on the same terms as the actual outstanding shares of Common Stock are converted or exchanged);

(b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets or intellectual property of the Corporation and its subsidiaries taken as a whole, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation; or

(c) the acquisition by any person or group of related persons in one or a series of related transactions of shares of capital stock of the Corporation that represent, immediately following any such transaction, at least a majority, by voting power, of the Corporation's capital stock; provided, however, that any such transaction involving the Corporation, the principal purpose of which is to raise capital for the Corporation, shall not constitute a "Deemed Liquidation Event."

Notwithstanding the foregoing, a Qualified SPAC Transaction (as defined below) shall not be a Deemed Liquidation Event. A "**Qualified SPAC Transaction**" means a business combination involving the Corporation (or any of its subsidiaries) and a newly incorporated blank check company that is a publicly traded special purpose acquisition company or its affiliate formed solely for the purpose of effecting such a business combination with one or more business, which, for the avoidance of doubt, is deemed to be a "blank check" company under the applicable U.S. securities laws (a "**SPAC**" and any such transaction a "**SPAC Transaction**"), whether by merger, consolidation, reorganization, recapitalization, capital stock exchange, stock sale, asset sale or other similar transaction or business combination (or series of related transactions or related business combinations) in which the shares of common stock of such SPAC ("**SPAC Shares**") to be received by the holders of Preferred Stock in respect of each share of Preferred Stock (including, for the avoidance of doubt, any Common Stock that may be issuable upon conversion of Preferred Stock) in connection therewith at the closing on the date of consummation of such SPAC Transaction (A) are common stock of the SPAC, (B) are listed on the New York Stock Exchange, the Nasdaq Global Market or the Nasdaq Global Select Market (each, an "**Approved Exchange**") and (C) are registered pursuant to a registration statement on Form S-4.

2.3.2 Effecting a Deemed Liquidation Event.

(a) The Corporation shall not have the power to effect a Deemed Liquidation Event referred to in Subsection 2.3.1(a)(i) unless the agreement or plan of merger or consolidation for such transaction (the “**Merger Agreement**”) provides that the consideration payable to the stockholders of the Corporation shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2.

(b) In the event of a Deemed Liquidation Event referred to in Subsection 2.3.1(a)(ii) or 2.3.1(b), if the Corporation does not effect a dissolution of the Corporation under the General Corporation Law within 90 days after such Deemed Liquidation Event, then (i) the Corporation shall send a written notice to each holder of Preferred Stock no later than the 90th day after the Deemed Liquidation Event advising such holders of their right (and the requirements to be met to secure such right) pursuant to the terms of the following clause (ii) to require the redemption of such shares of Preferred Stock, and (ii) if the Requisite Investors so request in a written instrument delivered to the Corporation not later than 120 days after such Deemed Liquidation Event, the Corporation shall use the consideration received by the Corporation for such Deemed Liquidation Event (net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the Board of Directors), together with any other assets of the Corporation available for distribution to its stockholders, all to the extent permitted by Delaware law governing distributions to stockholders (the “**Available Proceeds**”), on the 150th day after such Deemed Liquidation Event, to redeem all outstanding shares of Preferred Stock at a price per share for each series equal to the Preferred Liquidation Amount applicable to such series. Notwithstanding the foregoing, in the event of a redemption pursuant to the preceding sentence, if the Available Proceeds are not sufficient to redeem all outstanding shares of Preferred Stock, the Corporation shall redeem a pro rata portion of each holder’s shares of Preferred Stock to the fullest extent of such Available Proceeds, based on the respective amounts which would otherwise be payable in respect of the shares to be redeemed if the Available Proceeds were sufficient to redeem all such shares, and shall redeem the remaining shares to have been redeemed as soon as practicable after the Corporation has funds legally available therefor.

(c) To effect such a redemption, the Corporation shall send written notice of the redemption (the “**Redemption Notice**”) to each holder of record of Preferred Stock not less than 20 days prior to each redemption date. Each Redemption Notice shall state:

- (i) the number of shares of each series of Preferred Stock held by the holder that the Corporation shall redeem on the redemption date specified in the Redemption Notice;
- (ii) the redemption date and the applicable redemption price at which each share shall be redeemed;
- (iii) the date upon which the holder’s right to convert such shares terminates (as determined in accordance with Subsection 4.1); and

- (iv) that the holder is to surrender to the Corporation, in the manner and at the place designated, his, her or its certificate or certificates representing the shares of Preferred Stock to be redeemed.

(d) On or before the applicable redemption date, each holder of shares of Preferred Stock to be redeemed on such redemption date, unless such holder has exercised his, her or its right to convert such shares as provided in Section 4, shall deliver to the Corporation, in the manner and at the place designated in the Redemption Notice, the certificate or certificates representing the shares of Preferred Stock so redeemed, duly endorsed or signed in blank or to the Corporation (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) and thereupon the redemption price for such shares shall be payable to the order of the person whose name appears on such certificate or certificates as the owner thereof. In the event less than all of the shares of Preferred Stock represented by a certificate are redeemed, a new certificate representing the unredeemed shares of Preferred Stock shall promptly be issued to such holder.

(e) If the Redemption Notice shall have been duly given, and if on the applicable redemption date the redemption price payable upon redemption of the shares of Preferred Stock to be redeemed on such redemption date is paid or tendered for payment or deposited with an independent payment agent so as to be available therefor in a timely manner, then notwithstanding that the certificates evidencing any of the shares of Preferred Stock so called for redemption shall not have been surrendered, dividends with respect to such shares of Preferred Stock shall cease to accrue after such redemption date and all rights with respect to such shares shall forthwith after the redemption date terminate, except only the right of the holders to receive the redemption price without interest upon surrender of their certificate or certificates therefor.

(f) Prior to the distribution or redemption provided for in Subsection 2.3.2(b), the Corporation shall not expend or dissipate the consideration received for such Deemed Liquidation Event, except to discharge expenses incurred in connection with such Deemed Liquidation Event or in the ordinary course of business.

2.3.3 Amount Deemed Paid or Distributed. The amount deemed paid or distributed to the holders of capital stock of the Corporation upon any such voluntary or involuntary liquidation, dissolution or winding up of the Corporation, Deemed Liquidation Event or redemption pursuant to Subsection 2.3.2(b) shall be the cash or the value of the property, rights or securities paid or distributed to such holders by the Corporation or the acquiring person, firm or other entity. The value of such property, rights or securities shall be determined in good faith by the Board of Directors.

2.3.4 Allocation of Escrow. In the event of a Deemed Liquidation Event pursuant to Subsection 2.3.1(a)(i), if any portion of the consideration payable to the stockholders of the Corporation is placed into escrow and/or is payable to the stockholders of the Corporation subject to contingencies, the Merger Agreement shall provide that (a) the portion of such consideration that is not placed in escrow and not subject to any contingencies (the “**Initial Consideration**”) shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2 as if the Initial Consideration were the only consideration payable in connection with such Deemed Liquidation Event and (b) any additional consideration which becomes payable to the stockholders of the Corporation upon release from escrow or satisfaction of contingencies shall be allocated among the holders of capital stock of the Corporation in accordance with Subsections 2.1 and 2.2 after taking into account the previous payment of the Initial Consideration as part of the same transaction.

3. Voting.

3.1 General. On any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of this Certificate of Incorporation, holders of Preferred Stock shall vote together with the holders of Common Stock as a single class.

3.2 Board of Directors. The holders of record of the shares of Preferred Stock, exclusively and as a separate class, shall be entitled to elect four directors of the Corporation (the “**Preferred Directors**”). Any director elected as provided in the preceding sentence may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class or series of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. If the holders of shares of Preferred Stock fail to elect a sufficient number of directors to fill all directorships for which they are entitled to elect directors, voting exclusively and as a separate class, pursuant to the first sentence of this Subsection 3.2, then any directorship not so filled shall remain vacant until such time as the holders of the Preferred Stock elect a person to fill such directorship by vote or written consent in lieu of a meeting; and no such directorship may be filled by stockholders of the Corporation other than by the stockholders of the Corporation that are entitled to elect a person to fill such directorship, voting exclusively and as a separate class. The holders of record of the shares of Common Stock and of any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Corporation. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. Except as otherwise provided in this Subsection 3.2, a vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this Subsection 3.2.

3.3 Preferred Stock Protective Provisions. At any time when shares of Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do (or permit any subsidiary to do) any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of the Requisite Investors, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect:

(a) liquidate, dissolve or wind-up the business and affairs of the Corporation or effect any Deemed Liquidation Event, or consent to any of the foregoing, except in the case of a Qualified SPAC Transaction;

(b) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Corporation.

(c) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series D Preferred Stock, Series E Preferred Stock and Series F Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series D Preferred Stock, Series E Preferred Stock or Series F Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock unless the same ranks junior to the Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series D Preferred Stock, Series E Preferred Stock and Series F Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends and rights of redemption;

(d) (i) reclassify, alter or amend any existing security of the Corporation that is *pari passu* with the Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series D Preferred Stock, Series E Preferred Stock or Series F Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series D Preferred Stock, Series E Preferred Stock or Series F Preferred Stock in respect of any such right, preference or privilege, or (ii) reclassify, alter or amend any existing security of the Corporation that is junior to the Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series D Preferred Stock, Series E Preferred Stock or Series F Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Corporation, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or *pari passu* with the Series A Preferred Stock, Series B Preferred Stock, Series C-1 Preferred Stock, Series C-2 Preferred Stock, Series D Preferred Stock, Series E Preferred Stock or Series F Preferred Stock in respect of any such right, preference or privilege;

(e) purchase, retire, or redeem, directly or indirectly, including by permitting any subsidiary of the Corporation to purchase, retire, or redeem, any shares of capital stock of the Corporation or otherwise, other than (i) redemptions of the Preferred Stock as expressly authorized herein, and (ii) repurchases of stock from former employees, officers, directors, consultants or other persons who performed services for the Corporation or any subsidiary in connection with the cessation of such employment or service at the lower of the original purchase price or the then-current fair market value thereof;

(f) create, or authorize the creation of, or issue, or authorize the issuance of any debt security, or incur indebtedness for borrowed money, or permit any subsidiary to take any such action with respect to any debt security or indebtedness for borrowed money, if (i) the aggregate indebtedness of the Corporation and its subsidiaries for borrowed money following such action would exceed \$500,000, or (ii) the debt security or indebtedness is participating or has any equity features;

(g) create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Corporation, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Corporation, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary;

(h) pay or declare any dividend or make any distribution on any shares of capital stock of the Corporation other than the Preferred Stock, except for dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock;

(i) acquire all or substantially all of the properties, assets or stock of any other person or entity;

(j) effect a significant change in the business of the Corporation and its subsidiaries as conducted at the time of the effectiveness of the filing of this Certificate of Incorporation;

(k) exclusively license all or substantially all of the assets or intellectual property of the Corporation or any subsidiary of the Corporation;

(l) permit any subsidiary of the Corporation to issue such subsidiary's equity securities other than to the Corporation or as approved by the Board of Directors, including the approval of at least the total number of Preferred Directors then in office less one (the "**Preferred Director Consent**");

(m) make any loan or advance to, or acquire any stock or other securities of, any entity unless it is wholly owned by the Corporation;

(n) make any loan or advance to any person or entity (other than a wholly owned subsidiary of the Corporation), including, without limitation, any employee or director of the Corporation or any subsidiary of the Corporation, other than advances and similar expenditures in the ordinary course of business or under the terms of an equity plan approved by the Board of Directors, including the Preferred Director Consent;

(o) guarantee directly or indirectly any indebtedness or obligations other than trade accounts of any subsidiary of the Corporation arising in the ordinary course of business;

(p) without the approval of the Board of Directors, including the Preferred Director Consent, amend, modify or adopt any employee equity plan or any transfer, vesting or repurchase provisions with respect to any restricted stock or option with any employee, or any new equity-based agreements that contain more favorable provisions with respect to vesting, repurchase or transfer; or

(q) change the authorized number of directors constituting the Board of Directors to a number other than nine.

3.4 Series E Preferred Stock Protective Provisions. At any time when shares of Series E Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do (or permit any subsidiary to do) any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of a majority of the Series E Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect:

(a) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Corporation in a manner that disproportionately (as compared with shares of any other series of Preferred Stock) and adversely affects any of the powers, preferences, privileges or rights of the Series E Preferred Stock; or

(b) increase or decrease the authorized number of shares of Series E Preferred Stock.

3.5 Series F Preferred Stock Protective Provisions. At any time when shares of Series F Preferred Stock are outstanding, the Corporation shall not, either directly or indirectly by amendment, merger, consolidation or otherwise, do (or permit any subsidiary to do) any of the following without (in addition to any other vote required by law or the Certificate of Incorporation) the written consent or affirmative vote of a majority of the Series F Preferred Stock, given in writing or by vote at a meeting, consenting or voting (as the case may be) separately as a class, and any such act or transaction entered into without such consent or vote shall be null and void *ab initio*, and of no force or effect:

(a) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Corporation in a manner that disproportionately (as compared with shares of any other series of Preferred Stock) and adversely affects any of the powers, preferences, privileges or rights of the Series F Preferred Stock; or

(b) increase or decrease the authorized number of shares of Series F Preferred Stock.

4. Optional Conversion.

The holders of the Preferred Stock shall have conversion rights as follows (the “**Conversion Rights**”):

4.1 Right to Convert.

4.1.1 Conversion Ratio. Each share of Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and nonassessable shares of Common Stock as is determined by dividing the Original Issue Price applicable to such series of Preferred Stock by the applicable Conversion Price (as defined below) in effect at the time of conversion. The “**Series A Conversion Price**” shall initially be equal to \$1.00. The “**Series B Conversion Price**” shall initially be equal to \$1.266. The “**Series C-1 Conversion Price**” shall initially be equal to \$2.2356. The “**Series C-2 Conversion Price**” shall initially be equal to \$3.0756. The “**Series D Conversion Price**” shall initially be equal to \$3.6667. The “**Series E Conversion Price**” shall initially be equal to \$4.2893. The “**Series F Conversion Price**” shall initially be equal to \$ 8.3843. Each of the Series A Conversion Price, the Series B Conversion Price, the Series C-1 Conversion Price, the Series C-2 Conversion Price, the Series D Conversion Price, the Series E Conversion Price and the Series F Conversion Price is sometimes referred to herein as a “**Conversion Price**,” and they are sometimes collectively referred to herein as the “**Conversion Prices**.” Each such initial Conversion Price, and the rates at which shares of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustment as provided below.

4.1.2 Termination of Conversion Rights. In the event of a liquidation, dissolution or winding up of the Corporation or a Deemed Liquidation Event, the Conversion Rights shall terminate at the close of business on the last full day preceding the date fixed for the payment of any such amounts distributable on such event to the holders of Preferred Stock.

4.2 Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of the Preferred Stock. In lieu of any fractional shares of Common Stock to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

4.3 Mechanics of Conversion.

4.3.1 Notice of Conversion. In order for a holder of Preferred Stock to voluntarily convert shares of Preferred Stock into shares of Common Stock, such holder shall surrender the certificate or certificates for such shares of Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent), together with written notice that such holder elects to convert all or any number of the shares of the Preferred Stock represented by such certificate or certificates and, if applicable, any event on which such conversion is contingent. Such notice shall state such holder's name or the names of the nominees in which such holder wishes the certificate or certificates for shares of Common Stock to be issued. If required by the Corporation, certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such certificates (or lost certificate affidavit and agreement) and notice shall be the time of conversion (the "**Conversion Time**"), and the shares of Common Stock issuable upon conversion of the shares represented by such certificate shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time, (i) issue and deliver to such holder of Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable upon such conversion in accordance with the provisions hereof and a certificate for the number (if any) of the shares of Preferred Stock represented by the surrendered certificate that were not converted into Common Stock, (ii) pay in cash such amount as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and (iii) pay all declared but unpaid dividends on the shares of Preferred Stock converted.

4.3.2 Reservation of Shares. The Corporation shall at all times when Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Preferred Stock, such number of its duly authorized shares of Common Stock as shall from time to time be sufficient to effect the conversion of all outstanding Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock shall not be sufficient to effect the conversion of all then outstanding shares of the Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to this Certificate of Incorporation. Before taking any action which would cause an adjustment reducing the Conversion Price applicable to a series of Preferred Stock below the then par value of the shares of Common Stock issuable upon conversion of such series of Preferred Stock, the Corporation will take any corporate action which may, in the opinion of its counsel, be necessary in order that the Corporation may validly and legally issue fully paid and nonassessable shares of Common Stock at such adjusted Conversion Price.

4.3.3 Effect of Conversion. All shares of Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares, including the rights, if any, to receive notices and vote, shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock in exchange therefor, to receive payment in lieu of any fraction of a share otherwise issuable upon such conversion as provided in Subsection 4.2 and to receive payment of any dividends declared but unpaid thereon. Any shares of Preferred Stock so converted shall be retired and cancelled and shall not be reissued as shares of such series, and the Corporation (without the need for stockholder action) may thereafter take such appropriate action as may be necessary to reduce the authorized number of shares of Preferred Stock accordingly.

4.3.4 No Further Adjustment. Upon any such conversion, no adjustment to the Conversion Price applicable to a series of Preferred Stock shall be made for any declared but unpaid dividends on the Preferred Stock surrendered for conversion or on the Common Stock delivered upon conversion.

4.3.5 Taxes. The Corporation shall pay any and all issue and other similar taxes that may be payable in respect of any issuance or delivery of shares of Common Stock upon conversion of shares of Preferred Stock pursuant to this Section 4. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of shares of Common Stock in a name other than that in which the shares of Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid.

4.4 Adjustments to Conversion Price for Diluting Issues.

4.4.1 Special Definitions. For purposes of this Certificate of Incorporation, the following definitions shall apply:

(a) “**Option**” shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire Common Stock or Convertible Securities.

(b) “**Series F Original Issue Date**” shall mean the date on which the first share of Series F Preferred Stock was issued.

(c) “**Convertible Securities**” shall mean any evidences of indebtedness, shares or other securities directly or indirectly convertible into or exchangeable for Common Stock, but excluding Options.

(d) “**Additional Shares of Common Stock**” shall mean all shares of Common Stock issued (or, pursuant to Subsection 4.4.3 below, deemed to be issued) by the Corporation after the Series F Original Issue Date, other than (1) the following shares of Common Stock and (2) shares of Common Stock deemed issued pursuant to the following Options and Convertible Securities (clauses (1) and (2), collectively, “**Exempted Securities**”):

- (i) shares of Common Stock, Options or Convertible Securities issued as a dividend or distribution on all series of Preferred Stock on a pro rata basis;
- (ii) shares of Common Stock, Options or Convertible Securities issued by reason of a dividend, stock split, split-up or other distribution on shares of Common Stock that is covered by Subsection 4.5, 4.6, 4.7 or 4.8;
- (iii) shares of Common Stock or Options issued to employees or directors of, or consultants or advisors to, the Corporation or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors, including the Preferred Director Consent;

- (iv) shares of Common Stock or Convertible Securities actually issued upon the exercise of Options or shares of Common Stock actually issued upon the conversion or exchange of Convertible Securities, in each case provided such issuance is pursuant to the terms of such Option or Convertible Security;
- (v) shares of Common Stock, Options or Convertible Securities issued to banks, equipment lessors or other financial institutions, or to real property lessors, pursuant to a debt financing, equipment leasing or real property leasing transaction approved by the Board of Directors, including the Preferred Director Consent;
- (vi) shares of Common Stock, Options or Convertible Securities issued to suppliers or third party service providers in connection with the provision of goods or services pursuant to transactions approved by the Board of Directors, including the Preferred Director Consent; or
- (vii) shares of Common Stock, Options or Convertible Securities issued in connection with sponsored research, collaboration, technology license, development, OEM, marketing or other similar agreements or strategic partnerships approved by the Board of Directors, including the Preferred Director Consent.

4.4.2 No Adjustment of Conversion Prices. No adjustment in the Conversion Prices shall be made as the result of the issuance or deemed issuance of Additional Shares of Common Stock if the Corporation receives written notice from the Requisite Investors agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of such Additional Shares of Common Stock.

4.4.3 Deemed Issue of Additional Shares of Common Stock.

(a) If the Corporation at any time or from time to time after the Series F Original Issue Date shall issue any Options or Convertible Securities (excluding Options or Convertible Securities which are themselves Exempted Securities) or shall fix a record date for the determination of holders of any class of securities entitled to receive any such Options or Convertible Securities, then the maximum number of shares of Common Stock (as set forth in the instrument relating thereto, assuming the satisfaction of any conditions to exercisability, convertibility or exchangeability but without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or, in the case of Convertible Securities and Options therefor, the conversion or exchange of such Convertible Securities, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue or, in case such a record date shall have been fixed, as of the close of business on such record date.

(b) If the terms of any Option or Convertible Security, the issuance of which resulted in an adjustment to the Conversion Price applicable to a series of Preferred Stock pursuant to the terms of Subsection 4.4.4, are revised as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase or decrease in the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any such Option or Convertible Security or (2) any increase or decrease in the consideration payable to the Corporation upon such exercise, conversion and/or exchange, then, effective upon such increase or decrease becoming effective, the applicable Conversion Price computed upon the original issue of such Option or Convertible Security (or upon the occurrence of a record date with respect thereto) shall be readjusted to such Conversion Price as would have obtained had such revised terms been in effect upon the original date of issuance of such Option or Convertible Security. Notwithstanding the foregoing, no readjustment pursuant to this clause (b) shall have the effect of increasing the Conversion Price applicable to a series of Preferred Stock to an amount which exceeds the lower of (i) the applicable Conversion Price in effect immediately prior to the original adjustment made as a result of the issuance of such Option or Convertible Security, or (ii) the applicable Conversion Price that would have resulted from any issuances of Additional Shares of Common Stock (other than deemed issuances of Additional Shares of Common Stock as a result of the issuance of such Option or Convertible Security) between the original adjustment date and such readjustment date.

(c) If the terms of any Option or Convertible Security (excluding Options or Convertible Securities which are themselves Exempted Securities), the issuance of which did not result in an adjustment to the Conversion Price applicable to a series of Preferred Stock pursuant to the terms of Subsection 4.4.4 (either because the consideration per share (determined pursuant to Subsection 4.4.5) of the Additional Shares of Common Stock subject thereto was equal to or greater than the applicable Conversion Price then in effect, or because such Option or Convertible Security was issued before the Series F Original Issue Date), are revised after the Series F Original Issue Date as a result of an amendment to such terms or any other adjustment pursuant to the provisions of such Option or Convertible Security (but excluding automatic adjustments to such terms pursuant to anti-dilution or similar provisions of such Option or Convertible Security) to provide for either (1) any increase in the number of shares of Common Stock issuable upon the exercise, conversion or exchange of any such Option or Convertible Security or (2) any decrease in the consideration payable to the Corporation upon such exercise, conversion or exchange, then such Option or Convertible Security, as so amended or adjusted, and the Additional Shares of Common Stock subject thereto (determined in the manner provided in Subsection 4.4.3(a)) shall be deemed to have been issued effective upon such increase or decrease becoming effective.

(d) Upon the expiration or termination of any unexercised Option or unconverted or unexchanged Convertible Security (or portion thereof) which resulted (either upon its original issuance or upon a revision of its terms) in an adjustment to the Conversion Price applicable to a series of Preferred Stock pursuant to the terms of Subsection 4.4.4, such Conversion Price shall be readjusted to the Conversion Price as would have obtained had such Option or Convertible Security (or portion thereof) never been issued.

(e) If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, is calculable at the time such Option or Convertible Security is issued or amended but is subject to adjustment based upon subsequent events, any adjustment to the Conversion Price applicable to a series of Preferred Stock provided for in this Subsection 4.4.3 shall be effected at the time of such issuance or amendment based on such number of shares or amount of consideration without regard to any provisions for subsequent adjustments (and any subsequent adjustments shall be treated as provided in clauses (b) and (c) of this Subsection 4.4.3). If the number of shares of Common Stock issuable upon the exercise, conversion and/or exchange of any Option or Convertible Security, or the consideration payable to the Corporation upon such exercise, conversion and/or exchange, cannot be calculated at the time such Option or Convertible Security is issued or amended, any adjustment to the applicable Conversion Price that would result under the terms of this Subsection 4.4.3 at the time of such issuance or amendment shall instead be effected at the time such number of shares and/or amount of consideration is first calculable (even if subject to subsequent adjustments), assuming for purposes of calculating such adjustment to the applicable Conversion Price that such issuance or amendment took place at the time such calculation can first be made.

4.4.4 Adjustment of Conversion Prices Upon Issuance of Additional Shares of Common Stock. In the event the Corporation shall at any time after the Series F Original Issue Date issue Additional Shares of Common Stock (including Additional Shares of Common Stock deemed to be issued pursuant to Subsection 4.4.3), without consideration or for a consideration per share less than the Conversion Price applicable to a series of Preferred Stock in effect immediately prior to such issue, then such Conversion Price shall be reduced, concurrently with such issue, to a price (calculated to the nearest one-hundredth of a cent) determined in accordance with the following formula:

$$CP_2 = CP_1 \times (A + B) \div (A + C)$$

For purposes of the foregoing formula, the following definitions shall apply:

(a) “**CP₂**” shall mean the Conversion Price with respect to the particular series of Preferred Stock in effect immediately after such issue of Additional Shares of Common Stock

(b) “**CP₁**” shall mean the Conversion Price with respect to the particular series of Preferred Stock in effect immediately prior to such issue of Additional Shares of Common Stock;

(c) “A” shall mean the number of shares of Common Stock outstanding and deemed outstanding immediately prior to such issue of Additional Shares of Common Stock (treating for this purpose as outstanding all shares of Common Stock issuable upon exercise of Options outstanding immediately prior to such issue or upon conversion or exchange of Convertible Securities (including the Preferred Stock) outstanding (assuming exercise of any outstanding Options therefor) immediately prior to such issue);

(d) “B” shall mean the number of shares of Common Stock that would have been issued if such Additional Shares of Common Stock had been issued at a price per share equal to CP_1 (determined by dividing the aggregate consideration received by the Corporation in respect of such issue by CP_1); and

(e) “C” shall mean the number of such Additional Shares of Common Stock issued in such transaction.

4.4.5 Determination of Consideration. For purposes of this Subsection 4.4, the consideration received by the Corporation for the issue of any Additional Shares of Common Stock shall be computed as follows:

(a) Cash and Property: Such consideration shall:

- (i) insofar as it consists of cash, be computed at the aggregate amount of cash received by the Corporation, excluding amounts paid or payable for accrued interest;
- (ii) insofar as it consists of property other than cash, be computed at the fair market value thereof at the time of such issue, as determined in good faith by the Board of Directors; and
- (iii) in the event Additional Shares of Common Stock are issued together with other shares or securities or other assets of the Corporation for consideration which covers both, be the proportion of such consideration so received, computed as provided in clauses (i) and (ii) above, as determined in good faith by the Board of Directors.

(b) Options and Convertible Securities. The consideration per share received by the Corporation for Additional Shares of Common Stock deemed to have been issued pursuant to Subsection 4.4.3, relating to Options and Convertible Securities, shall be determined by dividing

- (i) the total amount, if any, received or receivable by the Corporation as consideration for the issue of such Options or Convertible Securities, plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Corporation upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities, by
- (ii) the maximum number of shares of Common Stock (as set forth in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such Options or the conversion or exchange of such Convertible Securities, or in the case of Options for Convertible Securities, the exercise of such Options for Convertible Securities and the conversion or exchange of such Convertible Securities.

4.4.6 Multiple Closing Dates. In the event the Corporation shall issue on more than one date Additional Shares of Common Stock that are a part of one transaction or a series of related transactions and that would result in an adjustment to the Conversion Price applicable to a series of Preferred Stock pursuant to the terms of Subsection 4.4.4, and such issuance dates occur within a period of no more than 90 days from the first such issuance to the final such issuance, then, upon the final such issuance, such Conversion Price shall be readjusted to give effect to all such issuances as if they occurred on the date of the first such issuance (and without giving effect to any additional adjustments as a result of any such subsequent issuances within such period).

4.5 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the Series F Original Issue Date effect a subdivision of the outstanding Common Stock, each Conversion Price in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock issuable on conversion of each share of Preferred Stock shall be increased in proportion to such increase in the aggregate number of shares of Common Stock outstanding. If the Corporation shall at any time or from time to time after the Series F Original Issue Date combine the outstanding shares of Common Stock, each Conversion Price in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock issuable on conversion of each share of Preferred Stock shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock outstanding. Any adjustment under this subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

4.6 Adjustment for Certain Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series F Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable on the Common Stock in additional shares of Common Stock, then and in each such event the Conversion Price applicable to each series of Preferred Stock in effect immediately before such event shall be decreased as of the time of such issuance or, in the event such a record date shall have been fixed, as of the close of business on such record date, by multiplying such Conversion Price then in effect by a fraction:

- (1) the numerator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date, and
- (2) the denominator of which shall be the total number of shares of Common Stock issued and outstanding immediately prior to the time of such issuance or the close of business on such record date plus the number of shares of Common Stock issuable in payment of such dividend or distribution.

Notwithstanding the foregoing, (a) if such record date shall have been fixed and such dividend is not fully paid or if such distribution is not fully made on the date fixed therefor, each Conversion Price shall be recomputed accordingly as of the close of business on such record date and thereafter such Conversion Price shall be adjusted pursuant to this subsection as of the time of actual payment of such dividends or distributions and (b) no such adjustment shall be made if the holders of Preferred Stock simultaneously receive a dividend or other distribution of shares of Common Stock in a number equal to the number of shares of Common Stock as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.7 Adjustments for Other Dividends and Distributions. In the event the Corporation at any time or from time to time after the Series F Original Issue Date shall make or issue, or fix a record date for the determination of holders of Common Stock entitled to receive, a dividend or other distribution payable in securities of the Corporation (other than a distribution of shares of Common Stock in respect of outstanding shares of Common Stock) or in other property and the provisions of Section 1 do not apply to such dividend or distribution, then and in each such event the holders of Preferred Stock shall receive, simultaneously with the distribution to the holders of Common Stock, a dividend or other distribution of such securities or other property in an amount equal to the amount of such securities or other property as they would have received if all outstanding shares of Preferred Stock had been converted into Common Stock on the date of such event.

4.8 Adjustment for Merger or Reorganization, etc. Subject to the provisions of Subsection 2.3, if there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Subsections 4.4, 4.6 or 4.7), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of such series of Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of such series of Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors) shall be made in the application of the provisions in this Section 4 with respect to the rights and interests thereafter of the holders of such series of Preferred Stock, to the end that the provisions set forth in this Section 4 (including provisions with respect to changes in and other adjustments of the Conversion Price applicable to such series of Preferred Stock) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of such series of Preferred Stock.

4.9 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of any Conversion Price pursuant to this Section 4, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than 15 days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of the series of Preferred Stock affected a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which such series of Preferred Stock is convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Preferred Stock (but in any event not later than 15 days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the Conversion Price then applicable to such series of Preferred Stock, and (ii) the number of shares of Common Stock and the amount, if any, of other securities, cash or property which then would be received upon the conversion of such Preferred Stock.

4.10 Notice of Record Date. In the event:

(a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of any series of Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or

(b) of any capital reorganization of the Corporation, any reclassification of the Common Stock of the Corporation, or any Deemed Liquidation Event; or

(c) of the voluntary or involuntary dissolution, liquidation or winding-up of the Corporation,

then, and in each such case, the Corporation will send or cause to be sent to the holders of Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of such series of Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, transfer, dissolution, liquidation or winding-up, and the amount per share and character of such exchange applicable to such series of Preferred Stock and the Common Stock. Such notice shall be sent at least 15 days prior to the record date or effective date for the event specified in such notice.

5. Mandatory Conversion.

5.1 Trigger Events. Upon either (a) the closing of the sale of shares of Common Stock to the public in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$60,000,000 of gross proceeds to the Corporation (a “**Qualified Public Offering**”), (b) the consummation of a Qualified SPAC Transaction, or (c) the date and time, or the occurrence of an event, specified by vote or written consent of the Requisite Investors (the time of such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the “**Mandatory Conversion Time**”), (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rates and (ii) such shares may not be reissued by the Corporation. For the avoidance of doubt, upon automatic conversion of all outstanding shares of Preferred Stock into shares of Common Stock immediately prior to a Qualified SPAC Transaction pursuant to the preceding sentence, all rights of the Preferred Stock under Section 2 with respect to preferential payments (or any other payments that may otherwise differ from distributions to Common Stock) will terminate.

5.2 Procedural Requirements. All holders of record of shares of Preferred Stock shall be sent written notice of the Mandatory Conversion Time and the place designated for mandatory conversion of all such shares of Preferred Stock pursuant to this Section 5. Such notice need not be sent in advance of the occurrence of the Mandatory Conversion Time. Upon receipt of such notice, each holder of shares of Preferred Stock shall surrender his, her or its certificate or certificates for all such shares (or, if such holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate) to the Corporation at the place designated in such notice. If so required by the Corporation, certificates surrendered for conversion shall be endorsed or accompanied by written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or by his, her or its attorney duly authorized in writing. All rights with respect to the Preferred Stock converted pursuant to Subsection 5.1, including the rights, if any, to receive notices and vote (other than as a holder of Common Stock), will terminate at the Mandatory Conversion Time (notwithstanding the failure of the holder or holders thereof to surrender the certificates at or prior to such time), except only the rights of the holders thereof, upon surrender of their certificate or certificates (or lost certificate affidavit and agreement) therefor, to receive the items provided for in the next sentence of this Subsection 5.2. As soon as practicable after the Mandatory Conversion Time and the surrender of the certificate or certificates (or lost certificate affidavit and agreement) for Preferred Stock, the Corporation shall issue and deliver to such holder, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock issuable on such conversion in accordance with the provisions hereof, together with cash as provided in Subsection 4.2 in lieu of any fraction of a share of Common Stock otherwise issuable upon such conversion and the payment of any declared but unpaid dividends on the shares of Preferred Stock converted. Such converted Preferred Stock shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of such shares of Preferred Stock accordingly.

6. Redemption. The Preferred Stock shall not have any rights to redemption except as explicitly set forth in Subsection 2.3.2.

7. Redeemed or Otherwise Acquired Shares. Any shares of Preferred Stock that are redeemed or otherwise acquired by the Corporation or any of its subsidiaries shall be automatically and immediately cancelled and retired and shall not be reissued, sold or transferred. Neither the Corporation nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Preferred Stock following redemption.

8. Waiver. Any of the rights, powers, preferences and other terms of a series of Preferred Stock set forth herein may be waived on behalf of all holders of such series of Preferred Stock by the affirmative written consent or vote of the Requisite Investors, except as otherwise specified in this Certificate of Incorporation. Notwithstanding the foregoing, (a) any of the rights, powers, preferences and other terms of the Series E Preferred Stock with respect to the protective provisions set forth in Article IV(C) 3.4 herein may only be waived by the affirmative written consent or vote of the a majority of the holders of Series E Preferred Stock and (b) any of the rights, powers, preferences and other terms of the Series F Preferred Stock with respect to the protective provisions set forth in Article IV(C) 3.5 herein may only be waived by the affirmative written consent or vote of the a majority of the holders of Series F Preferred Stock.

9. Notices. Any notice required or permitted by the provisions of this Article FOURTH to be given to a holder of shares of Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the General Corporation Law, and shall be deemed sent upon such mailing or electronic transmission.

FIFTH: Subject to any additional vote required by this Certificate of Incorporation or By-Laws of the Corporation, in furtherance of and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to make, repeal, alter, amend and rescind any or all of the By-Laws of the Corporation.

SIXTH: Subject to any additional vote required by this Certificate of Incorporation, the number of directors of the Corporation shall be determined in the manner set forth in the By-Laws of the Corporation.

SEVENTH: Elections of directors need not be by written ballot unless the By-Laws of the Corporation shall so provide.

EIGHTH: Meetings of stockholders may be held within or without the State of Delaware, as the By-Laws of the Corporation may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the By-Laws of the Corporation.

NINTH: To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article NINTH to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article NINTH by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

TENTH: The following indemnification provisions shall apply to the persons enumerated below.

1. Right to Indemnification of Directors and Officers. The Corporation shall indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any person (an “**Indemnified Person**”) who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a “**Proceeding**”), by reason of the fact that such person, or a person for whom such person is the legal representative, is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys’ fees) reasonably incurred by such Indemnified Person in such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 3 of this Article TENTH, the Corporation shall be required to indemnify an Indemnified Person in connection with a Proceeding (or part thereof) commenced by such Indemnified Person only if the commencement of such Proceeding (or part thereof) by the Indemnified Person was authorized in advance by the Board of Directors.

2. Prepayment of Expenses of Directors and Officers. The Corporation shall pay the expenses (including attorneys’ fees) incurred by an Indemnified Person in defending any Proceeding in advance of its final disposition, provided, however, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the Indemnified Person to repay all amounts advanced if it should be ultimately determined that the Indemnified Person is not entitled to be indemnified under this Article TENTH or otherwise.

3. Claims by Directors and Officers. If a claim for indemnification or advancement of expenses under this Article TENTH is not paid in full within 30 days after a written claim therefor by the Indemnified Person has been received by the Corporation, the Indemnified Person may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim. In any such action the Corporation shall have the burden of proving that the Indemnified Person is not entitled to the requested indemnification or advancement of expenses under applicable law.

4. Indemnification of Employees and Agents. The Corporation may indemnify and advance expenses to any person who was or is made or is threatened to be made or is otherwise involved in any Proceeding by reason of the fact that such person, or a person for whom such person is the legal representative, is or was an employee or agent of the Corporation or, while an employee or agent of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorney's fees) reasonably incurred by such person in connection with such Proceeding. The ultimate determination of entitlement to indemnification of persons who are non-director or officer employees or agents shall be made in such manner as is determined by the Board of Directors in its sole discretion. Notwithstanding the foregoing sentence, the Corporation shall not be required to indemnify a person in connection with a Proceeding initiated by such person if the Proceeding was not authorized in advance by the Board of Directors.

5. Advancement of Expenses of Employees and Agents. The Corporation may pay the expenses (including attorney's fees) incurred by an employee or agent in defending any Proceeding in advance of its final disposition on such terms and conditions as may be determined by the Board of Directors.

6. Non-Exclusivity of Rights. The rights conferred on any person by this Article TENTH shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, the By-Laws of the Corporation, agreement, vote of stockholders or disinterested directors or otherwise.

7. Other Indemnification. The Corporation's obligation, if any, to indemnify any person who was or is serving at its request as a director, officer or employee of another corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise shall be reduced by any amount such person has actually collected as indemnification from such other corporation, partnership, limited liability company, joint venture, trust, organization or other enterprise.

8. Insurance. The Board of Directors may, to the full extent permitted by applicable law as it presently exists, or may hereafter be amended from time to time, authorize an appropriate officer or officers to purchase and maintain at the Corporation's expense insurance: (a) to indemnify the Corporation for any obligation which it incurs as a result of the indemnification of directors, officers and employees under the provisions of this Article TENTH; and (b) to indemnify or insure directors, officers and employees against liability in instances in which they may not otherwise be indemnified by the Corporation under the provisions of this Article TENTH.

Amendment or Repeal. Any repeal or modification of the foregoing provisions of this Article TENTH shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification. The rights provided hereunder shall inure to the benefit of any Indemnified Person and such person's heirs, executors and administrators.

ELEVENTH: The Corporation renounces any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An “**Excluded Opportunity**” is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, (i) any director of the Corporation who is not an employee of or consultant to the Corporation or any of its subsidiaries, or (ii) any holder of Preferred Stock or any partner, member, director, stockholder, employee or agent of any such holder, other than someone who is an employee of or consultant to the Corporation or any of its subsidiaries (collectively, “**Covered Persons**”), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person’s capacity as a director of the Corporation.

* * *

3. That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of this Corporation in accordance with Section 228 of the General Corporation Law.

4. That this Amended and Restated Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation’s Certificate of Incorporation, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law.

[signature page follows]

IN WITNESS WHEREOF, this Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this Corporation on this 9th day of June, 2021.

By: /s/ Harith Rajagopalan
Harith Rajagopalan
Chief Executive Officer

**CERTIFICATE OF AMENDMENT TO
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
FRACTYL HEALTH, INC.**

Fractyl Health, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "Corporation"), DOES HEREBY CERTIFY:

FIRST: That the Board of Directors of the Corporation duly adopted resolutions by written consent recommending and declaring advisable that the Amended and Restated Certificate of Incorporation of the Corporation be amended and that such amendment be submitted to the stockholders of the Corporation for their consideration, as follows:

RESOLVED, that the following is hereby inserted into Article FOURTH of the Amended and Restated Certificate of Incorporation of the Corporation immediately before the first sentence therein:

“Effective upon the filing of this Certificate of Amendment of the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the “**Effective Time**”), every 2.146 shares of Common Stock then issued and outstanding or held in the treasury of the Corporation immediately prior to the Effective Time shall automatically be combined into one (1) share of Common Stock, without any further action by the holders of such shares (the “**Stock Split**”). The Stock Split will be effected on a holder-by-holder basis, and any fractional shares resulting from such combination shall be rounded down to the nearest whole share on a holder-by-holder basis. No fractional shares shall be issued in connection with the Stock Split. In lieu of any fractional shares to which a holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Corporation’s Board of Directors. The Stock Split shall occur automatically without any further action by the holders of the shares of Common Stock and Preferred Stock affected thereby. All rights, preferences and privileges of the Common Stock and the Preferred Stock shall be appropriately adjusted to reflect the Stock Split in accordance with this Amended and Restated Certificate of Incorporation.”

SECOND: That in lieu of a meeting and vote of stockholders, the stockholders have given written consent to said amendments in accordance with the provisions of Section 228 of the General Corporation Law of the State of Delaware.

THIRD: That the aforesaid amendments were duly adopted in accordance with the applicable provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by Harith Rajagopalan, M.D., Ph.D., the Chief Executive Officer of the Corporation, this 26th day of January, 2024.

FRACTYL HEALTH, INC.

By: /s/ Harith Rajagopalan, M.D., Ph.D.
Harith Rajagopalan, M.D., Ph.D.
Chief Executive Officer

**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
FRACTYL HEALTH, INC.**

Fractyl Health, Inc. (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "DGCL"), does hereby certify as follows:

1. The name of the Corporation is Fractyl Health, Inc. The Corporation was incorporated under the name MedCatalyst, Inc. by the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware on August 30, 2010.

2. This Amended and Restated Certificate of Incorporation (the "Restated Certificate"), which amends, restates and further integrates the certificate of incorporation of the Corporation as heretofore in effect, has been approved by the Board of Directors of the Corporation (the "Board of Directors") in accordance with Sections 242 and 245 of the DGCL, and has been adopted by the written consent of the stockholders of the Corporation in accordance with Section 228 of the DGCL.

3. The text of the certificate of incorporation of the Corporation, as heretofore amended, is hereby amended and restated by this Restated Certificate to read in its entirety as set forth in EXHIBIT A attached hereto.

IN WITNESS WHEREOF, Fractyl Health, Inc. has caused this Restated Certificate to be signed by a duly authorized office of the Corporation, on _____, 2024.

Fractyl Health, Inc., a Delaware corporation

By: _____
Name: Harith Rajagopalan
Title: Chief Executive Officer

[Signature Page to Certificate of Incorporation]

EXHIBIT A

ARTICLE I

The name of the corporation is Fractyl Health, Inc. (the “Corporation”).

ARTICLE II

The address of the Corporation’s registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, and the name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the “DGCL”) as it now exists or may hereafter be amended and supplemented.

ARTICLE IV

The Corporation is authorized to issue two classes of stock to be designated, respectively, “Common Stock” and “Preferred Stock.” The total number of shares of capital stock which the Corporation shall have authority to issue is 310 million (310,000,000). The total number of shares of Common Stock that the Corporation is authorized to issue is 300 million (300,000,000), having a par value of \$0.00001 per share, and the total number of shares of Preferred Stock that the Corporation is authorized to issue is 10 million (10,000,000), having a par value of \$0.00001 per share.

ARTICLE V

The designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation are as follows:

A. COMMON STOCK.

1. General. The voting, dividend, liquidation, and other rights and powers of the Common Stock are subject to and qualified by the rights, powers and preferences of any series of Preferred Stock as may be designated by the Board of Directors of the Corporation (the “Board of Directors”) and outstanding from time to time.

2. Voting. Except as otherwise provided herein or expressly required by law, each holder of Common Stock, as such, shall be entitled to vote on each matter submitted to a vote of stockholders and shall be entitled to one (1) vote for each share of Common Stock held of record by such holder as of the record date for determining stockholders entitled to vote on such matter. Except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Restated Certificate (including any Certificate of Designation (as defined below)) that relates solely to the rights, powers, preferences (or the qualifications, limitations or restrictions thereof) or other terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Restated Certificate (including any Certificate of Designation) or pursuant to the DGCL.

Subject to the rights of any holders of any outstanding series of Preferred Stock, the number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the DGCL.

3. Dividends. Subject to applicable law and the rights and preferences of any holders of any outstanding series of Preferred Stock, the holders of Common Stock, as such, shall be entitled to the payment of dividends on the Common Stock when, as and if declared by the Board of Directors in accordance with applicable law.

4. Liquidation. Subject to the rights and preferences of any holders of any shares of any outstanding series of Preferred Stock, in the event of any liquidation, dissolution or winding up of the Corporation, whether voluntary or involuntary, the funds and assets of the Corporation that may be legally distributed to the Corporation's stockholders shall be distributed among the holders of the then outstanding Common Stock pro rata in accordance with the number of shares of Common Stock held by each such holder.

B. PREFERRED STOCK

Shares of Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the creation and issuance of such series adopted by the Board of Directors as hereinafter provided.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designation relating thereto in accordance with the DGCL (a "Certificate of Designation"), to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, and to increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series as shall be stated and expressed in such resolutions, all to the fullest extent now or hereafter permitted by the DGCL. Without limiting the generality of the foregoing, the resolution or resolutions providing for the creation and issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law and this Restated Certificate (including any Certificate of Designation). Except as otherwise required by law, holders of any series of Preferred Stock shall be entitled only to such voting rights, if any, as shall expressly be granted thereto by this Restated Certificate (including any Certificate of Designation).

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the DGCL.

ARTICLE VI

For the management of the business and for the conduct of the affairs of the Corporation it is further provided that:

A. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the directors of the Corporation shall be classified with respect to the time for which they severally hold office into three classes, designated as Class I, Class II and Class III. The initial Class I directors shall serve for a term expiring at the first annual meeting of the stockholders following the initial registration of the Corporation's Common Stock pursuant to the Securities Exchange Act of 1934, as amended; the initial Class II directors shall serve for a term expiring at the second annual meeting of the stockholders following such registration; and the initial Class III directors shall serve for a term expiring at the third annual meeting following such registration. At each annual meeting of stockholders of the Corporation beginning with the first annual meeting of stockholders following the Effective Time, subject to any special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual meeting of stockholders held in the third year following the year of their election. Each director shall hold office until his or her successor is duly elected and qualified or until his or her earlier death, resignation, disqualification or removal. No decrease in the number of directors shall shorten the term of any incumbent director. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II and Class III.

B. Except as otherwise expressly provided by the DGCL or this Restated Certificate, the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed exclusively by one or more resolutions adopted from time to time by the Board of Directors.

C. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the Board of Directors or any individual director may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least two-thirds of the voting power of all of the then outstanding shares of voting stock of the Corporation entitled to vote at an election of directors.

D. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, except as otherwise provided by law, any vacancies on the Board of Directors resulting from death, resignation, disqualification, retirement, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall be filled exclusively by the affirmative vote of a majority of the directors then in office, even though less than a quorum, or by a sole remaining director (other than any directors elected by the separate vote of one or more outstanding series of Preferred Stock), and shall not be filled by the stockholders. Any director appointed in accordance with the preceding sentence shall hold office until the expiration of the term of the class to which such director shall have been appointed or until his or her earlier death, resignation, retirement, disqualification, or removal.

E. Whenever the holders of any one or more series of Preferred Stock issued by the Corporation shall have the right, voting separately as a series or separately as a class with one or more such other series, to elect directors at an annual or special meeting of stockholders, the election, term of office, removal and other features of such directorships shall be governed by the terms of this Certificate of Incorporation (including any Certificate of Designation). Notwithstanding anything to the contrary in this Article VI, the number of directors that may be elected by the holders of any such series of Preferred Stock shall be in addition to the number fixed pursuant to paragraph B of this Article VI, and the total number of directors constituting the whole Board of Directors shall be automatically adjusted accordingly. Except as otherwise provided in the Certificate of Designation(s) in respect of one or more series of Preferred Stock, whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to the provisions of such Certificate of Designation(s), the terms of office of all such additional directors elected by the holders of such series of Preferred Stock, or elected to fill any vacancies resulting from the death, resignation, disqualification or removal of such additional directors, shall forthwith terminate (in which case each such director thereupon shall cease to be qualified as, and shall cease to be, a director) and the total authorized number of directors of the Corporation shall automatically be reduced accordingly.

F. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, amend or repeal Bylaws of the Corporation. In addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Certificate of Incorporation (including any Certificate of Designation in respect of one or more series of Preferred Stock) or the Bylaws of the Corporation, the adoption, amendment or repeal of the Bylaws of the Corporation by the stockholders of the Corporation shall require the affirmative vote of the holders of at least two-thirds of the voting power of all of the then outstanding shares of voting stock of the Corporation entitled to vote generally in an election of directors.

G. The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

ARTICLE VII

The Corporation renounces any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An “Excluded Opportunity” is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, any director of the Corporation who is not an employee or officer of the Corporation or any of its subsidiaries (a “Covered Person”), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person’s capacity as a director of the Corporation.

ARTICLE VIII

A. Any action required or permitted to be taken by the stockholders of the Corporation must be effected at an annual or special meeting of the stockholders of the Corporation, and shall not be taken by written consent in lieu of a meeting. Notwithstanding the foregoing, any action required or permitted to be taken by the holders of any series of Preferred Stock, voting separately as a series or separately as a class with one or more other such series, may be taken without a meeting, without prior notice and without a vote, to the extent expressly so provided by the applicable Certificate of Designation relating to such series of Preferred Stock, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding shares of the relevant series of Preferred Stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Corporation in accordance with the applicable provisions of the DGCL.

B. Subject to the special rights of the holders of one or more series of Preferred Stock, special meetings of the stockholders of the Corporation may be called, for any purpose or purposes, at any time only by or at the direction of the Board of Directors, the Chairperson of the Board of Directors, the Chief Executive Officer or President, and shall not be called by any other person or persons.

C. Advance notice of stockholder nominations for the election of directors and of other business proposed to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

ARTICLE IX

No director of the Corporation shall have any personal liability to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL as the same exists or hereafter may be amended. Any amendment, repeal or modification of this Article IX, or the adoption of any provision of the Restated Certificate inconsistent with this Article IX, shall not adversely affect any right or protection of a director of the Corporation with respect to any act or omission occurring prior to such amendment, repeal, modification or adoption. If the DGCL is amended after approval by the stockholders of this Article IX to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL as so amended.

ARTICLE X

The Corporation shall have the power to provide rights to indemnification and advancement of expenses to its current and former officers, directors, employees and agents and to any person who is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise.

ARTICLE XI

Unless the Corporation consents in writing to the selection of an alternative forum, (a) the Court of Chancery (the “Chancery Court”) of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action, suit or proceeding brought on behalf of the Corporation, (ii) any action, suit or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer or stockholder of the Corporation to the Corporation or to the Corporation’s stockholders, (iii) any action, suit or proceeding arising pursuant to any provision of the DGCL or the bylaws of the Corporation or this Restated Certificate (as either may be amended from time to time) or (iv) any action, suit or proceeding asserting a claim against the Corporation governed by the internal affairs doctrine; and (b) subject to the preceding provisions of this Article XI, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act of 1933, as amended, including all causes of action asserted against any defendant to such complaint. If any action the subject matter of which is within the scope of clause (a) of the immediately preceding sentence is filed in a court other than the courts in the State of Delaware (a “Foreign Action”) in the name of any stockholder, such stockholder shall be deemed to have consented to (x) the personal jurisdiction of the state and federal courts in the State of Delaware in connection with any action brought in any such court to enforce the provisions of clause (a) of the immediately preceding sentence and (y) having service of process made upon such stockholder in any such action by service upon such stockholder’s counsel in the Foreign Action as agent for such stockholder.

Any person or entity purchasing or otherwise acquiring any interest in any security of the Corporation shall be deemed to have notice of and consented to this Article XI. Notwithstanding the foregoing, the provisions of this Article XI shall not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts of the United States have exclusive jurisdiction.

If any provision or provisions of this Article XI shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever, (a) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article XI (including, without limitation, each portion of any paragraph of this Article XI containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (b) the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

ARTICLE XII

A. Notwithstanding anything contained in this Restated Certificate to the contrary, in addition to any vote required by applicable law, the following provisions in this Restated Certificate may be amended, altered, repealed or rescinded, in whole or in part, or any provision inconsistent therewith or herewith may be adopted, only by the affirmative vote of the holders of at least 66 2/3% of the total voting power of all the then outstanding shares of stock of the Corporation entitled to vote thereon, voting together as a single class: Part B of Article V, Article VI, Article VII, Article VIII, Article IX, Article X, Article XI and this Article XII.

B. If any provision or provisions of this Restated Certificate shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever: (i) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Restated Certificate (including, without limitation, each portion of any paragraph of this Restated Certificate containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not, to the fullest extent permitted by applicable law, in any way be affected or impaired thereby and (ii) to the fullest extent permitted by applicable law, the provisions of this Restated Certificate (including, without limitation, each such portion of any paragraph of this Restated Certificate containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to permit the Corporation to protect its directors, officers, employees and agents from personal liability in respect of their good faith service to or for the benefit of the Corporation to the fullest extent permitted by law.

Amended and Restated Bylaws of

Fractyl Health, Inc.

(a Delaware corporation)

as of [•], 2024

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**Amended and Restated Bylaws of
Fractyl Health, Inc.**

Article I - Corporate Offices

1.1 Registered Office.

The address of the registered office of Fractyl Health, Inc. (the "Corporation") in the State of Delaware, and the name of its registered agent at such address, shall be as set forth in the Corporation's certificate of incorporation, as the same may be amended and/or restated from time to time (the "Certificate of Incorporation").

1.2 Other Offices.

The Corporation may have additional offices at any place or places, within or outside the State of Delaware, as the Corporation's board of directors (the "Board") may from time to time establish or as the business of the Corporation may require.

Article II - Meetings of Stockholders

2.1 Place of Meetings.

Meetings of stockholders shall be held at any place within or outside the State of Delaware, designated by the Board. The Board may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the General Corporation Law of the State of Delaware (the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Corporation's principal executive office.

2.2 Annual Meeting.

The Board shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and other proper business properly brought before the meeting in accordance with Section 2.4 of these bylaws may be transacted. The Board may postpone, reschedule or cancel any previously scheduled annual meeting of stockholders.

2.3 Special Meeting.

Special meetings of the stockholders may be called at any time by the Board, Chairperson of the Board, Chief Executive Officer or President (in the absence of a Chief Executive Officer) of the Corporation, but such special meetings may not be called by any other person or persons.

No business may be transacted at any special meeting of stockholders other than the business specified in the notice of such meeting. The Board may postpone, reschedule or cancel any previously scheduled special meeting of stockholders. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board may be held.

2.4 Advance Notice of Business to be Brought before a Meeting.

(a) At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (i) specified in a notice of meeting given by or at the direction of the Board of Directors, (ii) if not specified in a notice of meeting, otherwise brought before the meeting by the Board of Directors or the Chairman of the Board or (iii) otherwise properly brought before the meeting by a stockholder present in person who (A) (1) was a record owner of shares of the Corporation both at the time of giving the notice provided for in this Section 2.4 and at the time of the meeting, (2) is entitled to vote at the meeting, and (3) has complied with this Section 2.4 in all applicable respects or (B) properly made such proposal in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (as so amended and inclusive of such rules and regulations, the "Exchange Act"). The foregoing clause (iii) shall be the exclusive means for a stockholder to propose business to be brought before an annual meeting of the stockholders. The only matters that may be brought before a special meeting are the matters specified in the notice of meeting given by or at the direction of the person calling the meeting pursuant to Section 2.3, and stockholders shall not be permitted to propose business to be brought before a special meeting of the stockholders. For purposes of this Section 2.4, "present in person" shall mean that the stockholder proposing that the business be brought before the annual meeting of the Corporation, or a qualified representative of such proposing stockholder, appear at such annual meeting. A "qualified representative" of such proposing stockholder shall be a duly authorized officer, manager or partner of such stockholder or any other person authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders. Stockholders seeking to nominate persons for election to the Board of Directors must comply with Section 2.5 of these bylaws, and this Section 2.4 shall not be applicable to nominations except as expressly provided in Section 2.5 of these bylaws.

(b) Without qualification, for business to be properly brought before an annual meeting by a stockholder, the stockholder must (i) provide Timely Notice (as defined below) thereof in writing and in proper form to the Secretary of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.4. To be timely, a stockholder's notice must be delivered to, or mailed and received at, the principal executive offices of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the one-year anniversary of the preceding year's annual meeting; *provided, however*, that if the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date, notice by the stockholder to be timely must be so delivered, or mailed and received, not later than the ninetieth (90th) day prior to such annual meeting or, if later, the tenth (10th) day following the day on which public disclosure of the date of such annual meeting was first made by the Corporation (such notice within such time periods, "Timely Notice"); *provided, further*, that for the purposes of calculating Timely Notice for the first annual meeting held after the Company's initial public offering of its shares pursuant to a registration statement on Form S-1, the date of the immediately preceding annual meeting shall be deemed to be [•]. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of Timely Notice as described above.

(c) To be in proper form for purposes of this Section 2.4, a stockholder's notice to the Secretary shall set forth:

(i) As to each Proposing Person (as defined below), (A) the name and address of such Proposing Person (including, if applicable, the name and address that appear on the Corporation's books and records); and (B) the class or series and number of shares of the Corporation that are, directly or indirectly, owned of record or beneficially owned (within the meaning of Rule 13d-3 under the Exchange Act) by such Proposing Person, except that such Proposing Person shall in all events be deemed to beneficially own any shares of any class or series of the Corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future (the disclosures to be made pursuant to the foregoing clauses (A) and (B) are referred to as "Stockholder Information");

(ii) As to each Proposing Person, (A) the full notional amount of any securities that, directly or indirectly, underlie any "derivative security" (as such term is defined in Rule 16a-1(c) under the Exchange Act) that constitutes a "call equivalent position" (as such term is defined in Rule 16a-1(b) under the Exchange Act) ("Synthetic Equity Position") and that is, directly or indirectly, held or maintained by such Proposing Person with respect to any shares of any class or series of shares of the Corporation; provided that, for the purposes of the definition of "Synthetic Equity Position," the term "derivative security" shall also include any security or instrument that would not otherwise constitute a "derivative security" as a result of any feature that would make any conversion, exercise or similar right or privilege of such security or instrument becoming determinable only at some future date or upon the happening of a future occurrence, in which case the determination of the amount of securities into which such security or instrument would be convertible or exercisable shall be made assuming that such security or instrument is immediately convertible or exercisable at the time of such determination; and, provided, further, that any Proposing Person satisfying the requirements of Rule 13d-1(b)(1) under the Exchange Act (other than a Proposing Person that so satisfies Rule 13d-1(b)(1) under the Exchange Act solely by reason of Rule 13d-1(b)(1)(ii)(E)) shall not be deemed to hold or maintain the notional amount of any securities that underlie a Synthetic Equity Position held by such Proposing Person as a hedge with respect to a bona fide derivatives trade or position of such Proposing Person arising in the ordinary course of such Proposing Person's business as a derivatives dealer, (B) any rights to dividends on the shares of any class or series of shares of the Corporation owned beneficially by such Proposing Person that are separated or separable from the underlying shares of the Corporation, (C) any material pending or threatened legal proceeding in which such Proposing Person is a party or material participant involving the Corporation or any of its officers or directors, or any affiliate of the Corporation, (D) any other material relationship between such Proposing Person, on the one hand, and the Corporation, any affiliate of the Corporation, on the other hand, (E) any direct or indirect material interest in any material contract or agreement of such Proposing Person with the Corporation or any affiliate of the Corporation (including, in any such case, any employment agreement, collective bargaining agreement or consulting agreement), (F) a representation that such Proposing Person intends or is part of a group which intends to deliver a proxy statement or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to approve or adopt the proposal or otherwise solicit proxies from stockholders in support of such proposal and (G) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act (the disclosures to be made pursuant to the foregoing clauses (A) through (G) are referred to as "Disclosable Interests"); provided, however, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these Bylaws on behalf of a beneficial owner; and

(iii) As to each item of business that the stockholder proposes to bring before the annual meeting, (A) a brief description of the business desired to be brought before the annual meeting, the reasons for conducting such business at the annual meeting and any material interest in such business of each Proposing Person, (B) the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the Bylaws, the language of the proposed amendment), and (C) a reasonably detailed description of all agreements, arrangements and understandings (x) between or among any of the Proposing Persons or (y) between or among any Proposing Person and any other person or entity (including their names) in connection with the proposal of such business by such stockholder; and (D) any other information relating to such item of business that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act; provided, however, that the disclosures required by this paragraph (iii) shall not include any disclosures with respect to any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these Bylaws on behalf of a beneficial owner.

For purposes of this Section 2.4, the term "Proposing Person" shall mean (i) the stockholder providing the notice of business proposed to be brought before an annual meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before the annual meeting is made, and (iii) any participant (as defined in paragraphs (a)(ii)-(vi) of Instruction 3 to Item 4 of Schedule 14A) with such stockholder in such solicitation.

(d) A Proposing Person shall update and supplement its notice to the Corporation of its intent to propose business at an annual meeting, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.4 shall be true and correct as of the record date for stockholders entitled to vote at the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary at the principal executive offices of the Corporation not later than five (5) business days after the record date for stockholders entitled to vote at the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof). For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these Bylaws shall not limit the Corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any proposal or to submit any new proposal, including by changing or adding matters, business or resolutions proposed to be brought before a meeting of the stockholders.

(e) Notwithstanding anything in these Bylaws to the contrary, no business shall be conducted at an annual meeting that is not properly brought before the meeting in accordance with this Section 2.4. The presiding officer of the meeting shall, if the facts warrant, determine that the business was not properly brought before the meeting in accordance with this Section 2.4, and if he or she should so determine, he or she shall so declare to the meeting and any such business not properly brought before the meeting shall not be transacted.

(f) This Section 2.4 is expressly intended to apply to any business proposed to be brought before an annual meeting of stockholders other than any proposal made in accordance with Rule 14a-8 under the Exchange Act and included in the Corporation's proxy statement. In addition to the requirements of this Section 2.4 with respect to any business proposed to be brought before an annual meeting, each Proposing Person shall comply with all applicable requirements of the Exchange Act with respect to any such business. Nothing in this Section 2.4 shall be deemed to affect the rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

(g) For purposes of these Bylaws, "public disclosure" shall mean disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Sections 13, 14 or 15(d) of the Exchange Act.

2.5 Advance Notice of Nominations for Election to the Board of Directors.

(a) Nominations of any person for election to the Board of Directors at an annual meeting or at a special meeting (but only if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting) may be made at such meeting only (i) by or at the direction of the Board of Directors, including by any committee or persons authorized to do so by the Board of Directors or these bylaws, or (ii) by a stockholder present in person (A) who was a record owner of shares of the Corporation both at the time of giving the notice provided for in this Section 2.5 and at the time of the meeting, (B) is entitled to vote at the meeting, and (C) has complied with this Section 2.5 and Section 2.6 as to such notice and nomination. For purposes of this Section 2.5, "present in person" shall mean that the stockholder proposing that the business be brought before the meeting of the Corporation, or a qualified representative of such stockholder, appear at such meeting. A "qualified representative" of such proposing stockholder shall be a duly authorized officer, manager or partner of such stockholder or any other person authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders. The foregoing clause (ii) shall be the exclusive means for a stockholder to make any nomination of a person or persons for election to the Board of Directors at an annual meeting or special meeting.

(b) (i) Without qualification, for a stockholder to make any nomination of a person or persons for election to the Board of Directors at an annual meeting, the stockholder must (1) provide Timely Notice (as defined in Section 2.4) thereof in writing and in proper form to the Secretary of the Corporation, (2) provide the information, agreements and questionnaires with respect to such stockholder and its candidate for nomination as required to be set forth by this Section 2.5 and Section 2.6 and (3) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5 and Section 2.6.

(ii) Without qualification, if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling a special meeting, then for a stockholder to make any nomination of a person or persons for election to the Board of Directors at a special meeting, the stockholder must (i) provide timely notice thereof in writing and in proper form to the Secretary of the Corporation at the principal executive offices of the Corporation, (ii) provide the information with respect to such stockholder and its candidate for nomination as required by this Section 2.5 and Section 2.6 and (iii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. To be timely, a stockholder's notice for nominations to be made at a special meeting must be delivered to, or mailed and received at, the principal executive offices of the Corporation not earlier than the one hundred twentieth (120th) day prior to such special

meeting and not later than the ninetieth (90th) day prior to such special meeting or, if later, the tenth (10th) day following the day on which public disclosure (as defined in Section 2.4) of the date of such special meeting was first made. In no event shall any adjournment or postponement of an annual meeting or special meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described above.

(c) To be in proper form for purposes of this Section 2.5, a stockholder's notice to the Secretary shall set forth:

(i) As to each Nominating Person (as defined below), the Stockholder Information (as defined in Section 2.4(c)(i)), except that for purposes of this Section 2.5 the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(c)(i);

(ii) As to each Nominating Person, any Disclosable Interests (as defined in Section 2.4(c)(ii)), except that for purposes of this Section 2.5 the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(c)(ii) and the disclosure with respect to the business to be brought before the meeting in Section 2.4(c)(ii) shall be made with respect to the election of directors at the meeting); and

(iii) As to each candidate whom a Nominating Person proposes to nominate for election as a director, (A) all information with respect to such candidate for nomination that would be required to be set forth in a stockholder's notice pursuant to this Section 2.5 and Section 2.6 if such candidate for nomination were a Nominating Person, (B) all information relating to such candidate for nomination that is required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14(a) under the Exchange Act (including such candidate's written consent to being named in the proxy statement as a nominee and to serving as a director if elected), (C) a description of any direct or indirect material interest in any material contract or agreement between or among any Nominating Person, on the one hand, and each candidate for nomination or his or her respective associates or any other participants in such solicitation, on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K if such Nominating Person were the "registrant" for purposes of such rule and the candidate for nomination were a director or executive officer of such registrant (the disclosures to be made pursuant to the foregoing clauses (A) through (C) are referred to as "Nominee Information"), and (D) a completed and signed questionnaire, representation and agreement as provided in Section 2.6(a).

For purposes of this Section 2.5, the term "Nominating Person" shall mean (i) the stockholder providing the notice of the nomination proposed to be made at the meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made, and (iii) any other participant in such solicitation.

(d) A stockholder providing notice of any nomination proposed to be made at a meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.5 shall be true and correct as of the record date for stockholders entitled to vote at the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary at the principal executive offices of the Corporation not later than five (5) business days after the record date for stockholders entitled to vote at the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the

date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof). For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these Bylaws shall not limit the Corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any nomination or to submit any new nomination.

(e) In addition to the requirements of this Section 2.5 with respect to any nomination proposed to be made at a meeting, each Nominating Person shall comply with all applicable requirements of the Exchange Act with respect to any such nominations.

2.6 Additional Requirements for Valid Nomination of Candidates to Serve as Director and, if Elected, to be Seated as Directors.

(a) To be eligible to be a candidate for election as a director of the Corporation at an annual or special meeting, a candidate must be nominated in the manner prescribed in Section 2.5 and the candidate for nomination, whether nominated by the Board of Directors or by a stockholder of record, must have previously delivered (in accordance with the time period prescribed for delivery in a notice to such candidate given by or on behalf of the Board of Directors), to the Secretary at the principal executive offices of the Corporation, (i) a completed written questionnaire (in a form provided by the Corporation) with respect to the background, qualifications, stock ownership and independence of such proposed nominee and (ii) a written representation and agreement (in form provided by the Corporation) that such candidate for nomination (A) is not and, if elected as a director during his or her term of office, will not become a party to (1) any agreement, arrangement or understanding with, and has not given and will not give any commitment or assurance to, any person or entity as to how such proposed nominee, if elected as a director of the Corporation, will act or vote on any issue or question (a "Voting Commitment") or (2) any Voting Commitment that could limit or interfere with such proposed nominee's ability to comply, if elected as a director of the Corporation, with such proposed nominee's fiduciary duties under applicable law, (B) is not, and will not become a party to, any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation or reimbursement for service as a director that has not been disclosed to the Corporation, (C) if elected as a director of the Corporation, will comply with all applicable corporate governance, conflict of interest, confidentiality, stock ownership and trading and other policies and guidelines of the Corporation applicable to directors and in effect during such person's term in office as a director (and, if requested by any candidate for nomination, the Secretary of the Corporation shall provide to such candidate for nomination all such policies and guidelines then in effect) and (D) if elected as director of the Corporation, intends to serve the entire term until the next meeting at which such candidate would face re-election.

(b) The Board of Directors may also require any proposed candidate for nomination as a Director to furnish such other information as may reasonably be requested by the Board of Directors in writing prior to the meeting of stockholders at which such candidate's nomination is to be acted upon in order for the Board of Directors to determine the eligibility of such candidate for nomination to be an independent director of the Corporation in accordance with the Corporation's Corporate Governance Guidelines.

(c) A candidate for nomination as a director shall further update and supplement the materials delivered pursuant to this Section 2.6, if necessary, so that the information provided or required to be provided pursuant to this Section 2.6 shall be true and correct as of the record date for stockholders entitled to vote at the

meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary at the principal executive offices of the Corporation (or any other office specified by the Corporation in any public announcement) not later than five (5) business days after the record date for stockholders entitled to vote at the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof). For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these Bylaws shall not limit the Corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any proposal or to submit any new proposal, including by changing or adding nominees, matters, business or resolutions proposed to be brought before a meeting of the stockholders.

(d) No candidate shall be eligible for nomination as a director of the Corporation unless such candidate for nomination and the Nominating Person seeking to place such candidate's name in nomination has complied with Section 2.5 and this Section 2.6, as applicable. The presiding officer at the meeting shall, if the facts warrant, determine that a nomination was not properly made in accordance with Section 2.5 and this Section 2.6, and if he or she should so determine, he or she shall so declare such determination to the meeting, the defective nomination shall be disregarded and any ballots cast for the candidate in question (but in the case of any form of ballot listing other qualified nominees, only the ballots cast for the nominee in question) shall be void and of no force or effect.

(e) Notwithstanding anything in these Bylaws to the contrary, no candidate for nomination shall be eligible to be seated as a director of the Corporation unless nominated and elected in accordance with Section 2.5 and this Section 2.6.

2.7 Notice of Stockholders' Meetings.

Unless otherwise provided by law, the Certificate of Incorporation or these bylaws, the notice of any meeting of stockholders shall be sent or otherwise given in accordance with Section 8.1 of these bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting. The notice shall specify the place, if any, date and time of the meeting, the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

2.8 Quorum.

Unless otherwise provided by law, the Certificate of Incorporation or these bylaws, the holders of a majority in voting power of the stock issued and outstanding and entitled to vote, present in person, or by remote communication, if applicable, or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum. If, however, a quorum is not present or represented at any meeting of the stockholders, then either (i) the person presiding over the meeting or (ii) a majority in voting power of the stockholders entitled to vote at the meeting, present in person, or by remote communication, if

applicable, or represented by proxy, shall have power to recess the meeting or adjourn the meeting from time to time in the manner provided in Section 2.9 of these bylaws until a quorum is present or represented. At any recessed or adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.9 Adjourned Meeting; Notice.

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken or are provided in any other manner permitted by the DGCL. At any adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for determination of stockholders entitled to vote is fixed for the adjourned meeting, the Board shall fix as the record date for determining stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote at the adjourned meeting, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such meeting as of the record date so fixed for notice of such adjourned meeting.

2.10 Conduct of Business.

The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting by the person presiding over the meeting. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting, to prescribe such rules, regulations and procedures (which need not be in writing) and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the person presiding over the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present (including, without limitation, rules and procedures for removal of disruptive persons from the meeting); (iii) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the person presiding over the meeting shall determine; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting (including, without limitation, determinations with respect to the administration and/or interpretation of any of the rules, regulations or procedures of the meeting, whether adopted by the Board or prescribed by the person presiding over the meeting), shall, if the facts warrant, determine and declare to the meeting that a matter of business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

2.11 Voting.

Except as may be otherwise provided in the Certificate of Incorporation, these bylaws or the DGCL, each stockholder shall be entitled to one (1) vote for each share of capital stock held by such stockholder.

Except as otherwise provided by the Certificate of Incorporation, at all duly called or convened meetings of stockholders at which a quorum is present, for the election of directors, a plurality of the votes cast shall be sufficient to elect a director. Except as otherwise provided by the Certificate of Incorporation, these bylaws, the rules or regulations of any stock exchange applicable to the Corporation, or applicable law or pursuant to any regulation applicable to the Corporation or its securities, each other matter presented to the stockholders at a duly called or convened meeting at which a quorum is present shall be decided by the affirmative vote of the holders of a majority in voting power of the votes cast (excluding abstentions and broker non-votes) on such matter.

2.12 Record Date for Stockholder Meetings and Other Purposes.

In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall, unless otherwise required by law, not be more than sixty (60) days nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be the close of business on the next day preceding the day on which notice is first given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting; and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment or any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of capital stock, or for the purposes of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than sixty (60) days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

2.13 Proxies.

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law, including Rule 14a-19 promulgated under the Exchange Act, filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A proxy may be in the form of an electronic transmission which sets forth or is submitted with information from which it can be determined that the transmission was authorized by the stockholder.

Any stockholder directly or indirectly soliciting proxies from other stockholders must use a proxy card color other than white, which shall be reserved for the exclusive use by the Board.

2.14 List of Stockholders Entitled to Vote.

The Corporation shall prepare, no later than the tenth day before each meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (provided, however, that if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of ten (10) days ending on the day before the meeting date: (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the Corporation's principal executive office. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. Such list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them. Except as otherwise provided by law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 2.14 or to vote in person or by proxy at any meeting of stockholders.

2.15 Inspectors of Election.

Before any meeting of stockholders, the Corporation shall appoint an inspector or inspectors of election to act at the meeting or its adjournment and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If any person appointed as inspector or any alternate fails to appear or fails or refuses to act, then the person presiding over the meeting shall appoint a person to fill that vacancy.

Such inspectors shall:

(i) determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting and the validity of any proxies and ballots;

(ii) count all votes or ballots;

(iii) count and tabulate all votes;

(iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspector(s); and

(v) certify its or their determination of the number of shares represented at the meeting and its or their count of all votes and ballots.

Each inspector, before entering upon the discharge of the duties of inspector, shall take and sign an oath faithfully to execute the duties of inspection with strict impartiality and according to the best of such inspector's ability. Any report or certificate made by the inspectors of election is prima facie evidence of the facts stated therein. The inspectors of election may appoint such persons to assist them in performing their duties as they determine.

2.16 Delivery to the Corporation.

Whenever this Article II requires one or more persons (including a record or beneficial owner of stock) to deliver a document or information to the Corporation or any officer, employee or agent thereof (including any notice, request, questionnaire, revocation, representation or other document or agreement), such document or information shall be in writing exclusively (and not in an electronic transmission) and shall be delivered exclusively by hand (including, without limitation, overnight courier service) or by certified or registered mail, return receipt requested, and the Corporation shall not be required to accept delivery of any document not in such written form or so delivered. For the avoidance of doubt, the Corporation expressly opts out of Section 116 of the DGCL with respect to the delivery of information and documents to the Corporation required by this Article II.

Article III - Directors

3.1 Powers.

Except as otherwise provided by the Certificate of Incorporation or the DGCL, the business and affairs of the Corporation shall be managed by or under the direction of the Board.

3.2 Number of Directors.

Subject to the Certificate of Incorporation, the total number of directors constituting the Board shall be determined from time to time by resolution of the Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 Election, Qualification and Term of Office of Directors.

Except as provided in Section 3.4 of these bylaws, and subject to the Certificate of Incorporation, each director, including a director elected to fill a vacancy or newly created directorship, shall hold office until the expiration of the term of the class, if any, for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation, disqualification or removal. Directors need not be stockholders. The Certificate of Incorporation or these bylaws may prescribe qualifications for directors.

3.4 Resignation and Vacancies.

Any director may resign at any time upon notice given in writing or by electronic transmission to the Corporation. The resignation shall take effect at the time specified therein or upon the happening of an event specified therein, and if no time or event is specified, at the time of its receipt. When one or more directors so resigns and the resignation is effective at a future date or upon the happening of an event to occur on a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in Section 3.3.

Unless otherwise provided in the Certificate of Incorporation or these bylaws, vacancies resulting from the death, resignation, disqualification or removal of any director, and newly created directorships resulting from any increase in the authorized number of directors shall be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director.

3.5 Place of Meetings; Meetings by Telephone.

The Board may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the Certificate of Incorporation or these bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting pursuant to this bylaw shall constitute presence in person at the meeting.

3.6 Regular Meetings.

Regular meetings of the Board may be held within or outside the State of Delaware and at such time and at such place as which has been designated by the Board and publicized among all directors, either orally or in writing, by telephone, including a voice-messaging system or other system designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other means of electronic transmission. No further notice shall be required for regular meetings of the Board.

3.7 Special Meetings; Notice.

Special meetings of the Board for any purpose or purposes may be called at any time by the chairperson of the Board, the Chief Executive Officer, the President, the Secretary or a majority of the total number of directors constituting the Board.

Notice of the time and place of special meetings shall be:

- (i) delivered personally by hand, by courier or by telephone;
- (ii) sent by United States first-class mail, postage prepaid;
- (iii) sent by facsimile or electronic mail; or
- (iv) sent by other means of electronic transmission,

directed to each director at that director's address, telephone number, facsimile number or electronic mail address, or other address for electronic transmission, as the case may be, as shown on the Corporation's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile or electronic mail, or (iii) sent by other means of electronic transmission, it shall be delivered or sent at least twenty-four (24) hours before the time of the holding of the meeting. If the notice is sent by U.S. mail, it shall be deposited in the U.S. mail at least four (4) days before the time of the holding of the meeting. The notice need not specify the place of the meeting (if the meeting is to be held at the Corporation's principal executive office) nor the purpose of the meeting.

3.8 Quorum.

At all meetings of the Board, unless otherwise provided by the Certificate of Incorporation, a majority of the total number of directors shall constitute a quorum for the transaction of business. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board, except as may be otherwise specifically provided by statute, the Certificate of Incorporation or these bylaws. If a quorum is not present at any meeting of the Board, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

3.9 Board Action without a Meeting.

Unless otherwise restricted by the Certificate of Incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission. After an action is taken, the consent or consents relating thereto shall be filed with the minutes of the proceedings of the Board, or the committee thereof, in the same paper or electronic form as the minutes are maintained. Such action by written consent or consent by electronic transmission shall have the same force and effect as a unanimous vote of the Board.

3.10 Fees and Compensation of Directors.

Unless otherwise restricted by the Certificate of Incorporation or these bylaws, the Board shall have the authority to fix the compensation, including fees and reimbursement of expenses, of directors for services to the Corporation in any capacity.

3.11 Removal of Directors.

Subject to the rights of the holders of the shares of any series of preferred stock of the Corporation, the Board or any individual director may be removed from office only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon.

Article IV - Committees

4.1 Committees of Directors.

The Board may designate one (1) or more committees, each committee to consist, of one (1) or more of the directors of the Corporation. The Board may designate one (1) or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board or in these

bylaws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the Corporation.

4.2 Committee Minutes.

Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

4.3 Meetings and Actions of Committees.

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

- (i) Section 3.5 (place of meetings; meetings by telephone);
- (ii) Section 3.6 (regular meetings);
- (iii) Section 3.7 (special meetings; notice);
- (iv) Section 3.9 (board action without a meeting); and
- (v) Section 7.13 (waiver of notice),

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the Board and its members. *However:*

- (i) the time of regular meetings of committees may be determined either by resolution of the Board or by resolution of the committee;
- (ii) special meetings of committees may also be called by resolution of the Board or the chairperson of the applicable committee; and
- (iii) the Board may adopt rules for the governance of any committee to override the provisions that would otherwise apply to the committee pursuant to this Section 4.3, provided that such rules do not violate the provisions of the Certificate of Incorporation or applicable law.

4.4 Subcommittees.

Unless otherwise provided in the Certificate of Incorporation, these bylaws or the resolutions of the Board designating the committee, a committee may create one (1) or more subcommittees, each subcommittee to consist of one (1) or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

Article V - Officers

5.1 Officers.

The officers of the Corporation shall include a Chief Executive Officer, a President and a Secretary. The Corporation may also have, at the discretion of the Board, a Chairperson of the Board, a Vice Chairperson of the Board, a Chief Financial Officer, a Treasurer, one (1) or more Vice Presidents, one (1) or more Assistant Vice Presidents, one (1) or more Assistant Treasurers, one (1) or more Assistant Secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person. No officer need be a stockholder or director of the Corporation.

5.2 Appointment of Officers.

The Board shall appoint the officers of the Corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws.

5.3 Subordinate Officers.

The Board may appoint, or empower the Chief Executive Officer or, in the absence of a Chief Executive Officer, the President, to appoint, such other officers and agents as the business of the Corporation may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the Board may from time to time determine.

5.4 Removal and Resignation of Officers.

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the Board or, except in the case of an officer chosen by the Board, by any officer upon whom such power of removal may be conferred by the Board.

Any officer may resign at any time by giving written notice to the Corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party.

5.5 Vacancies in Offices.

Any vacancy occurring in any office of the Corporation shall be filled by the Board or as provided in Section 5.2.

5.6 Representation of Shares of Other Corporations.

The Chairperson of the Board, the Chief Executive Officer, or the President of this Corporation, or any other person authorized by the Board, the Chief Executive Officer or the President, is authorized to vote, represent and exercise on behalf of this Corporation all rights incident to any and all shares or voting securities of any other corporation or other person standing in the name of this Corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 Authority and Duties of Officers.

All officers of the Corporation shall respectively have such authority and perform such duties in the management of the business of the Corporation as may be provided herein or designated from time to time by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

5.8 Compensation.

The compensation of the officers of the Corporation for their services as such shall be fixed from time to time by or at the direction of the Board. An officer of the Corporation shall not be prevented from receiving compensation by reason of the fact that he or she is also a director of the Corporation.

Article VI - Records

A stock ledger consisting of one or more records in which the names of all of the Corporation's stockholders of record, the address and number of shares registered in the name of each such stockholder, and all issuances and transfers of stock of the corporation are recorded in accordance with Section 224 of the DGCL shall be administered by or on behalf of the Corporation. Any records administered by or on behalf of the Corporation in the regular course of its business, including its stock ledger, books of account, and minute books, may be kept on, or by means of, or be in the form of, any information storage device, or method, or one or more electronic networks or databases (including one or more distributed electronic networks or databases), provided that the records so kept can be converted into clearly legible paper form within a reasonable time and, with respect to the stock ledger, that the records so kept (i) can be used to prepare the list of stockholders specified in Sections 219 and 220 of the DGCL, (ii) record the information specified in Sections 156, 159, 217(a) and 218 of the DGCL, and (iii) record transfers of stock as governed by Article 8 of the Uniform Commercial Code as adopted in the State of Delaware.

Article VII - General Matters

7.1 Execution of Corporate Contracts and Instruments.

The Board, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the Corporation; such authority may be general or confined to specific instances.

7.2 Stock Certificates.

The shares of the Corporation shall be represented by certificates, provided that the Board by resolution may provide that some or all of the shares of any class or series of stock of the Corporation shall be uncertificated. Certificates for the shares of stock, if any, shall be in such form as is consistent with the Certificate of Incorporation and applicable law. Every holder of stock represented by a certificate shall be entitled to have a certificate signed by, or in the name of the Corporation by, any two officers authorized to sign stock certificates representing the number of shares registered in certificate form. The Chairperson or Vice Chairperson of the Board, Chief Executive Officer, the President, Vice President, the Treasurer, any Assistant Treasurer, the Secretary or any Assistant Secretary of the Corporation shall be specifically authorized to sign

stock certificates. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he or she were such officer, transfer agent or registrar at the date of issue.

The Corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, or upon the books and records of the Corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

7.3 Special Designation of Certificates.

If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or on the back of the certificate that the Corporation shall issue to represent such class or series of stock (or, in the case of uncertificated shares, set forth in a notice provided pursuant to Section 151 of the DGCL); provided, however, that except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock (or, in the case of any uncertificated shares, included in the aforementioned notice) a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

7.4 Lost Certificates.

Except as provided in this Section 7.4, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Corporation and cancelled at the same time. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

7.5 Shares Without Certificates

The Corporation may adopt a system of issuance, recordation and transfer of its shares of stock by electronic or other means not involving the issuance of certificates, provided the use of such system by the Corporation is permitted in accordance with applicable law.

7.6 Construction; Definitions.

Unless the context requires otherwise, the general provisions, rules of construction and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural and the plural number includes the singular.

7.7 Dividends.

The Board, subject to any restrictions contained in either (i) the DGCL or (ii) the Certificate of Incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property or in shares of the Corporation's capital stock.

The Board may set apart out of any of the funds of the Corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the Corporation, and meeting contingencies.

7.8 Fiscal Year.

The fiscal year of the Corporation shall be fixed by resolution of the Board and may be changed by the Board.

7.9 Seal.

The Corporation may adopt a corporate seal, which shall be adopted and which may be altered by the Board. The Corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

7.10 Transfer of Stock.

Shares of the Corporation shall be transferable in the manner prescribed by law and in these bylaws. Shares of stock of the Corporation shall be transferred on the books of the Corporation only by the holder of record thereof or by such holder's attorney duly authorized in writing, upon surrender to the Corporation of the certificate or certificates representing such shares endorsed by the appropriate person or persons (or by delivery of duly executed instructions with respect to uncertificated shares), with such evidence of the authenticity of such endorsement or execution, transfer, authorization and other matters as the Corporation may reasonably require, and accompanied by all necessary stock transfer stamps. No transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing the names of the persons from and to whom it was transferred.

7.11 Stock Transfer Agreements.

The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes or series of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

7.12 Registered Stockholders.

The Corporation:

(i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner; and

(ii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of the State of Delaware.

7.13 Waiver of Notice.

Whenever notice is required to be given under any provision of the DGCL, the Certificate of Incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the Certificate of Incorporation or these bylaws.

Article VIII - Notice

8.1 Delivery of Notice; Notice by Electronic Transmission.

Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provisions of the DGCL, the Certificate of Incorporation, or these bylaws may be given in writing directed to the stockholder's mailing address (or by electronic transmission directed to the stockholder's electronic mail address, as applicable) as it appears on the records of the Corporation and shall be given (1) if mailed, when the notice is deposited in the U.S. mail, postage prepaid, (2) if delivered by courier service, the earlier of when the notice is received or left at such stockholder's address or (3) if given by electronic mail, when directed to such stockholder's electronic mail address unless the stockholder has notified the Corporation in writing or by electronic transmission of an objection to receiving notice by electronic mail. A notice by electronic mail must include a prominent legend that the communication is an important notice regarding the Corporation.

Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provision of the DGCL, the Certificate of Incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice or electronic transmission to the Corporation. Notwithstanding the provisions of this paragraph, the Corporation may give a notice by electronic mail in accordance with the first paragraph of this section without obtaining the consent required by this paragraph.

Any notice given pursuant to the preceding paragraph shall be deemed given:

- (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;
- (ii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and
- (iii) if by any other form of electronic transmission, when directed to the stockholder.

Notwithstanding the foregoing, a notice may not be given by an electronic transmission from and after the time that (1) the Corporation is unable to deliver by such electronic transmission two (2) consecutive notices given by the Corporation and (2) such inability becomes known to the Secretary or an Assistant Secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice, provided, however, the inadvertent failure to discover such inability shall not invalidate any meeting or other action.

An affidavit of the Secretary or an Assistant Secretary or of the transfer agent or other agent of the Corporation that the notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Article IX - Indemnification

9.1 Indemnification of Directors and Officers.

The Corporation shall indemnify and hold harmless, to the fullest extent permitted by the DGCL as it presently exists or may hereafter be amended, any director or officer of the Corporation who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding") by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Corporation or, while serving as a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership (a "covered person"), joint venture, trust, enterprise or non-profit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees, judgments, fines ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred by such person in connection with any such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 9.4, the Corporation shall be required to indemnify a person in connection with a Proceeding initiated by such person only if the Proceeding was authorized in the specific case by the Board.

9.2 Indemnification of Others.

The Corporation shall have the power to indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any employee or agent of the Corporation who was or is made or is threatened to be made a party or is otherwise involved in any Proceeding by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was an employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or non-profit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses reasonably incurred by such person in connection with any such Proceeding.

9.3 Prepayment of Expenses.

The Corporation shall to the fullest extent not prohibited by applicable law pay the expenses (including attorneys' fees) incurred by any covered person, and may pay the expenses incurred by any employee or agent of the Corporation, in defending any Proceeding in advance of its final disposition; *provided, however,* that such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the person to repay all amounts advanced if it should be ultimately determined that the person is not entitled to be indemnified under this Article IX or otherwise.

9.4 Determination; Claim.

If a claim for indemnification (following the final disposition of such Proceeding) under this Article IX is not paid in full within sixty (60) days, or a claim for advancement of expenses under this Article IX is not paid in full within thirty (30) days, after a written claim therefor has been received by the Corporation the claimant may thereafter (but not before) file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim to the fullest extent permitted by law. In any such action the Corporation shall have the burden of proving that the claimant was not entitled to the requested indemnification or payment of expenses under applicable law.

9.5 Non-Exclusivity of Rights.

The rights conferred on any person by this Article IX shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, these bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

9.6 Insurance.

The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust enterprise or non-profit entity against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify him or her against such liability under the provisions of the DGCL.

9.7 Other Indemnification.

The Corporation's obligation, if any, to indemnify or advance expenses to any person who was or is serving at its request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, enterprise or non-profit entity shall be reduced by any amount such person may collect as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, enterprise or non-profit enterprise.

9.8 Continuation of Indemnification.

The rights to indemnification and to prepayment of expenses provided by, or granted pursuant to, this Article IX shall continue notwithstanding that the person has ceased to be a director or officer of the Corporation and shall inure to the benefit of the estate, heirs, executors, administrators, legatees and distributees of such person.

9.9 Amendment or Repeal; Interpretation.

The provisions of this Article IX shall constitute a contract between the Corporation, on the one hand, and, on the other hand, each individual who serves or has served as a director or officer of the Corporation (whether before or after the adoption of these bylaws), in consideration of such person's performance of such services, and pursuant to this Article IX the Corporation intends to be legally bound to each such current or former director or officer of the Corporation. With respect to current and former directors and officers of the Corporation, the rights conferred under this Article IX are present contractual rights and such rights are fully vested, and shall be deemed to have vested fully, immediately upon adoption of these bylaws. With respect to any directors or officers of the Corporation who commence service following adoption of these bylaws, the rights conferred under this provision shall be present contractual rights and such rights shall fully vest, and be deemed to have vested fully, immediately upon such director or officer commencing service as a director or officer of the Corporation. Any repeal or modification of the foregoing provisions of this Article IX shall not adversely affect any right or protection (i) hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification or (ii) under any agreement providing for indemnification or advancement of expenses to an officer or director of the Corporation in effect prior to the time of such repeal or modification.

Any reference to an officer of the Corporation in this Article IX shall be deemed to refer exclusively to the Chief Executive Officer, President, and Secretary, or other officer of the Corporation appointed by (x) the Board pursuant to Article V of these bylaws or (y) an officer to whom the Board has delegated the power to appoint officers pursuant to Article V of these bylaws, and any reference to an officer of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be deemed to refer exclusively to an officer appointed by the board of directors (or equivalent governing body) of such other entity pursuant to the certificate of incorporation and bylaws (or equivalent organizational documents) of such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise. The fact that any person who is or was an employee of the Corporation or an employee of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise has been given or has used the title of "Vice President" or any other title that could be construed to suggest or imply that such person is or may be an officer of the Corporation or of such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall not result in such person being constituted as, or being deemed to be, an officer of the Corporation or of such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise for purposes of this Article IX.

Article X - Amendments

The Board is expressly empowered to adopt, amend or repeal the bylaws of the Corporation. The stockholders also shall have power to adopt, amend or repeal the bylaws of the Corporation; *provided, however*, that such action by stockholders shall require, in addition to any other vote required by the Certificate of Incorporation or applicable law, the affirmative vote of the holders of at least two-thirds of the voting power of all the then-outstanding shares of voting stock of the Corporation with the power to vote generally in an election of directors, voting together as a single class.

Article XI - Definitions

As used in these bylaws, unless the context otherwise requires, the following terms shall have the following meanings:

An “electronic transmission” means any form of communication, not directly involving the physical transmission of paper, including the use of, or participation in, one or more electronic networks or databases (including one or more distributed electronic networks or databases), that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

An “electronic mail” means an electronic transmission directed to a unique electronic mail address (which electronic mail shall be deemed to include any files attached thereto and any information hyperlinked to a website if such electronic mail includes the contact information of an officer or agent of the Corporation who is available to assist with accessing such files and information).

An “electronic mail address” means a destination, commonly expressed as a string of characters, consisting of a unique user name or mailbox (commonly referred to as the “local part” of the address) and a reference to an internet domain (commonly referred to as the “domain part” of the address), whether or not displayed, to which electronic mail can be sent or delivered.

The term “person” means any individual, general partnership, limited partnership, limited liability company, corporation, trust, business trust, joint stock company, joint venture, unincorporated association, cooperative or association or any other legal entity or organization of whatever nature, and shall include any successor (by merger or otherwise) of such entity.

Fractyl Health, Inc.

Certificate of Amendment and Restatement of Bylaws

The undersigned hereby certifies that she is the duly elected, qualified, and acting Secretary of Fractyl Health, Inc., a Delaware corporation (the "Corporation"), and that the foregoing bylaws were approved on _____, 2024, effective as of _____, 2024 by the Corporation's board of directors.

IN WITNESS WHEREOF, the undersigned has hereunto set her hand this ___ day of _____, 2024.

Sarah Toomey
General Counsel and Secretary



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January 29, 2024

Fractyl Health, Inc.
 17 Hartwell Avenue
 Lexington, Massachusetts 02421

Re: Registration Statement No. 333-276046
Up to 8,433,332 shares of common stock, par value \$0.00001 per share

To the addressee set forth above:

We have acted as special counsel to Fractyl Health, Inc., a Delaware corporation (the “*Company*”), in connection with the proposed issuance of up to 8,433,332 shares of common stock, \$0.00001 par value per share, which are being offered by the Company (the “*Shares*”). The Shares are included in a registration statement on Form S-1 under the Securities Act of 1933, as amended (the “*Act*”), initially filed with the Securities and Exchange Commission (the “*Commission*”) on December 14, 2023 (Registration No. 333-276046, as amended, the “*Registration Statement*”). The term “*Shares*” shall include any additional shares of common stock registered by the Company pursuant to Rule 462(b) under the Act in connection with the offering contemplated by the Registration Statement. This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or related Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

As such counsel, we have examined such matters of fact and questions of law as we have considered appropriate for purposes of this letter. With your consent, we have relied upon certificates and other assurances of officers of the Company and others as to factual matters without having independently verified such factual matters. We are opining herein as to General Corporation Law of the State of Delaware, and we express no opinion with respect to any other laws.



Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, when the Shares shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers and have been issued by the Company against payment therefor (not less than par value) in the circumstances contemplated by the form of underwriting agreement most recently filed as an exhibit to the Registration Statement, the issue and sale of the Shares will have been duly authorized by all necessary corporate action of the Company, and the Shares will be validly issued, fully paid and nonassessable. In rendering the foregoing opinion, we have assumed that the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the General Corporation Law of the State of Delaware.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Registration Statement and to the reference to our firm in the Prospectus under the heading "Legal Matters." We further consent to the incorporation by reference of this letter and consent into any registration statement filed pursuant to Rule 462(b) with respect to the Shares. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Sincerely,

/s/ Latham & Watkins LLP

Employment Agreement

This Employment Agreement (this “Agreement”), dated as of January 26, 2024, is made by and between Fractyl Health, Inc. a Delaware corporation (together with any successor thereto, the “Company”), and Harith Rajagopalan (“Executive”) (collectively referred to herein as the “Parties” or individually referred to as a “Party”), and will become effective, if at all, upon the date of the Company’s initial public offering of stock (“IPO”) pursuant to an effective registration statement filed under the Securities Act of 1933, as amended (the “Effective Date”).

RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement.
- B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1. Employment.

(a) General. Effective on the Effective Date, the Company shall employ Executive, and Executive shall be employed by the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided; provided, however, that this Agreement is expressly conditioned upon the IPO closing before June 30, 2024, and will be null and void if this condition is not satisfied.

(b) At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law, and that Executive’s employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This “at-will” nature of Executive’s employment shall remain unchanged during Executive’s tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive’s employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the “Term”) shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as Chief Executive Officer of the Company, with such responsibilities, duties and authority normally associated with such position and as may from time to time be assigned to Executive by the Board of Directors of the Company or an authorized committee thereof (in either case, the “Board”). Executive shall devote substantially all of Executive’s working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the Board, provided that Executive shall be permitted to (i) manage Executive’s personal, financial and legal affairs, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations,

and (iv) with the prior consent of the Board, such consent not to be unreasonably withheld or delayed, serve on the board of directors of one for-profit company that does not compete with the Company, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case, as amended from time to time, and as delivered or made available to Executive (each, a "Policy").

2. Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of \$610,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Annual Cash Bonus Opportunity. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 60% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Annual Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company, subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right (but not the obligation) to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document and shall have no interest in any such policy.

3. **Termination.**

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death.* Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability.* If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause.* The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause.* The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company with Good Reason.* Executive may resign Executive's employment with the Company with Good Reason, as defined below.

(vi) *Resignation from the Company without Good Reason.* Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to Section 3(a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least thirty (30) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination, but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company. The failure by either Party to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause or Good Reason shall not waive any right of the Party hereunder or preclude the Party from asserting such fact or circumstance in enforcing the Party's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in

accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the “Company Arrangements”). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive’s rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive’s employment hereunder. In the event that Executive’s employment is terminated by the Company for any reason, Executive’s sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive’s employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive’s employment shall terminate as a result of Executive’s death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive’s resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company with Good Reason. If Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, then except as otherwise provided under Section 4(c) and subject to Executive signing on or before the 21st day following Executive’s Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the “Release”) and Executive’s continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the Annual Base Salary, payable in the form of salary continuation in regular installments over the twelve (12)-month period following the date of Executive’s Separation from Service (the “Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company’s fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company;

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company’s group medical, dental or vision plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (“COBRA”), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive’s covered dependents under such plans, during the period commencing on Executive’s Separation from Service and ending upon the earliest of (A) the last day of the Severance Period, (B) the date that Executive and/or Executive’s covered dependents become no longer eligible for COBRA and (C) the date Executive becomes eligible to receive medical, dental or vision coverage, as applicable, from a subsequent employer (and Executive agrees to promptly notify the Company

of such eligibility) (the “COBRA Continuation Period”). Notwithstanding the foregoing, if the Company determines it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive’s and Executive’s covered dependents’ group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall continue for the remainder of the COBRA Continuation Period; and

(iv) an amount in cash equal to 1.0 times the Target Annual Bonus, payable in a lump sum on the Company’s first ordinary payroll date that occurs after the Date of Termination.

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, in either case, within three (3) months prior to or eighteen (18) months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive’s Separation from Service, and not revoking, the Release and Executive’s continued compliance with Section 5, Executive shall receive, in addition to the payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.5 times the Annual Base Salary, payable in equal installments over the eighteen (18)-month period following the date of Executive’s Separation from Service (the “CIC Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) the payment set forth in Section 4(b)(ii);

(iii) the benefits set forth in Section 4(b)(iii), provided that for this purpose, the “Severance Period” will mean the CIC Severance Period;

(iv) the payment set forth in Section 4(b)(iv);

(v) an amount in cash equal to 0.5 times the Target Annual Bonus, payable in a lump sum on the Company’s first ordinary payroll date that occurs after the Date of Termination; and

(vi) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on continued employment or service shall immediately become 100% vested (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive’s employment and the termination of the Term.

5. Restrictive Covenants. Executive and the Company are party to restrictive covenants contained in that certain employment letter agreement dated July 1, 2011, attached as Exhibit B (the “Restrictive Covenant Agreement”). Executive agrees to abide by the terms of the Restrictive Covenant Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Restrictive Covenant Agreement will survive the termination of Executive’s employment and the termination of the Term for the periods set forth in the Restrictive Covenant Agreement.

6. Assignment and Successors.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise) and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive’s rights or obligations may be assigned or transferred by Executive, other than Executive’s rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive’s death by giving written notice thereof to the Company.

7. Certain Definitions.

(a) Cause. The Company shall have “Cause” to terminate Executive’s employment hereunder upon:

(i) The Board’s reasonable, good faith determination that Executive has refused to (A) substantially perform the duties associated with Executive’s position with the Company or (B) carry out the reasonable and lawful instructions of the Board concerning duties or actions consistent with the Executive’s position with the Company;

(ii) Executive’s breach of a material provision of this Agreement that, to the extent capable of cure, has remained uncured for a period of thirty (30) days following written notice from the Company;

(iii) Executive’s conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(iv) Executive’s unlawful use (including being under the influence) or possession of illegal drugs on the Company’s (or any of its affiliate’s) premises or while performing Executive’s duties and responsibilities under this Agreement; or

(v) Executive’s commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) Change in Control. “Change in Control” shall have the meaning set forth in the Fractyl Health, Inc. 2024 Incentive Award Plan, as in effect on the Effective Date.

(c) Code. “Code” shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) **Date of Termination.** “Date of Termination” shall mean (i) if Executive’s employment is terminated by Executive’s death, the date of Executive’s death; or (ii) if Executive’s employment is terminated pursuant to Section 3(a)(ii) – (vi) either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) **Disability.** “Disability” shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company’s employees, “disability” as defined in such long-term disability plan for the purpose of determining a participant’s eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, “Disability” shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, “Disability” shall mean Executive’s inability to perform, with or without reasonable accommodation, the essential functions of Executive’s positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive’s legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive’s Disability.

(f) **Good Reason.** For the sole purpose of determining Executive’s right to severance payments and benefits as described above, Executive’s resignation will be with “Good Reason” if Executive resigns within ninety (90) days after any of the following events, unless Executive consents in writing to the applicable event: (i) a material reduction in Executive’s Annual Base Salary or Target Annual Bonus (excluding any reduction in Annual Base Salary that is proportionate to a reduction of base salaries affecting substantially all other executive officers of the Company), (ii) a material decrease in Executive’s authority or areas of responsibility as are commensurate with Executive’s title or position with the Company, (iii) the relocation of Executive’s primary office to a location more than twenty-five (25) miles from the Executive’s primary office as of the date of this Agreement or (iv) the Company’s breach of a material provision of this Agreement. Notwithstanding the foregoing, no Good Reason will have occurred unless and until: (a) Executive has provided the Company, within sixty (60) days of Executive’s knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) the Company has had an opportunity to cure the same within thirty (30) days after the receipt of such notice; and (c) the Company shall have failed to so cure within such period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4 hereof, being hereinafter referred to as the “Total Payments”), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total

Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro rata basis of any cash severance payments that are exempt from Section 409A of the Code ("Section 409A"), (ii) reduction on a pro rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the "Independent Advisors"). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, to the General Counsel of the Company at the Company's headquarters,

(ii) If to Executive, to the last address that the Company has in its personnel records for Executive, or

(iii) At any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Restrictive Covenant Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including any prior employment offer letter (other than the portion thereof constituting the Restrictive Covenant Agreement), employment agreement, or change in control severance agreement between Executive and the Company. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(h) Arbitration. Except as excluded herein below, any controversy, dispute or claim arising out of or relating to this Agreement, or breach thereof, or Executive’s employment with or termination of employment from the Company (each, a “Covered Claim”) shall be resolved by final and binding arbitration administered by JAMS. The arbitration shall be conducted by a single, neutral arbitrator, pursuant to JAMS’s Employment Arbitration Rules & Procedures, available at <https://www.jamsadr.com/rules-employment-arbitration/English>, as in effect at the time of the initiation of arbitration, which the Company will provide to Executive upon reasonable request, in Boston, Massachusetts. Notwithstanding anything in

this Agreement to the contrary, the arbitration provisions of this Agreement shall be governed by and enforceable pursuant to the Federal Arbitration Act, and, in all other respects, the arbitrator shall apply the substantive laws of the Commonwealth of Massachusetts or applicable Federal law, with the same statutes of limitation and available remedies that would apply if the claims were brought in a court of law of competent jurisdiction. The costs unique to arbitration, including the arbitration administrative fees, arbitrator compensation and expenses, and any costs of any witnesses call by the arbitrator, that would not be incurred in a court proceeding shall be borne by the Company. Unless otherwise ordered by the arbitrator under applicable law, the Company and Executive shall each bear its, their, his, or her own expenses, such as expert witness fees, filing fees, and attorneys' fees and costs. Nothing herein shall prevent the Company or Executive from seeking a statutory award of reasonable attorneys' fees and costs under applicable law. THE COMPANY AND EXECUTIVE RECOGNIZE THAT, BY AGREEING TO ARBITRATE THEIR DISPUTES, EACH WAIVE ITS, THEIR, HIS, OR HER RIGHT TO A TRIAL BY JURY OF ANY COVERED CLAIM. THE COMPANY AND EXECUTIVE WAIVE ITS, THEIR, HIS, OR HER RIGHT TO BRING ANY COVERED CLAIM AS PART OF OR IN CONNECTION WITH A CLASS OR COLLECTIVE ACTION.

Notwithstanding the foregoing, this Section shall not preclude either party from seeking a temporary restraining order or a preliminary injunction from a court of competent jurisdiction if such relief is not available in a timely fashion through arbitration. Further, this arbitration agreement shall not apply to: (a) claims for unemployment and workers' compensation benefits; (b) sexual harassment and sexual assault disputes arising under federal, state, local, or tribal law, unless Executive elects to arbitrate such disputes; (c) claims arising under the National Labor Relations Act or which are brought before the National Labor Relations Board; (d) claims brought before the Equal Employment Opportunity Commission or similar state or local agency, if Executive is required to exhaust Executive's administrative remedies; provided, that any appeal from an award or denial of an award by any such agency or any further action upon receipt of a right-to-sue letter shall be arbitrated pursuant to the terms of this Agreement; and (e) any other claim, which by law cannot be subject to mandatory arbitration.

(i) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(j) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(k) Section 409A.

(i) *General*. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon

Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10. Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

FRACTYL HEALTH, INC.

By: /s/ Sarah Toomey

Name: Sarah Toomey

Title: General Counsel and Corporate Secretary

EXECUTIVE

/s/ Harith Rajagopalan

Harith Rajagopalan

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Harith Rajagopalan ("Executive") and Fractyl Health, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of _____, 2024 (the "Employment Agreement") and the restrictive covenants contained in that certain employment letter agreement, dated as of July 1, 2011 (the "Restrictive Covenant Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company, vested benefits or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in [Section 4(b)/4(c)] of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their current and former officers, directors, equityholders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from Parent, the Company or any other Releasee), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans

pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not prevent Executive from (i) reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of any whistleblower protection provisions of state or federal law or regulation (including the right to receive an award for information provided to any such government agencies), (ii) exercising any rights Executive may have under Section 7 of the U.S. National Labor Relations Act, such as the right to engage in concerted activity, including collective action or discussion concerning wages or working conditions, or (iii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Executive has reason to believe is unlawful. This release further does not release claims for breach of Section 3(c) or Section 4 of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Restrictive Covenants.

(a) Executive acknowledges and agrees that the restrictive covenants and other post-termination obligations set forth in the Restrictive Covenant Agreement, including without limitation Executive's obligations relating to confidentiality, non-use and non-disclosure of Proprietary Information (as defined in the Restrictive Covenant Agreement), cooperation and return of property, non-competition and non-solicitation, are hereby incorporated by reference and shall remain in full force and effect pursuant to their terms to the maximum extent permitted by applicable law.

(b) Executive's continued compliance with the terms of the Restrictive Covenant Agreement (as modified in Section 4(a) above) (collectively, the "Restrictive Covenants") is a material condition to receipt of the severance payments and benefits set forth in Section 1 of this Agreement. In the event Executive breaches any part of such Restrictive Covenants, then, in addition to any remedies and enforcement mechanisms set forth in the Employment Agreement and this Agreement, and any other remedies available to the Company (including equitable and injunctive remedies), Executive shall forfeit any additional consideration owing and shall be obligated to promptly return to the Company (within fifteen (15) business days of any breach) the full gross amount of all severance payments and benefits provided.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c), and 9(h) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective on the day immediately following the seventh business day after Executive signed this Agreement (the "Effective Date"). For the avoidance of doubt, if Executive revokes this Agreement as provided herein, the Parties' modification to the Restrictive Covenant Agreement set forth in Section 4(a) above shall be void and of no effect and, unless the Company has elected or elects in writing to expressly waive Executive's noncompetition obligations set forth in Section 1(a) of the Restrictive Covenant Agreement as provided in Section 3(g) of the Restrictive Covenant Agreement, including without limitation Section 1 of the Restrictive Covenant Agreement, shall remain in full force and effect.

9. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

EXECUTIVE

Dated: _____

Harith Rajagopalan

FRACTYL HEALTH, INC.

Dated: _____

By: _____

Name:

Title:

EXHIBIT B

Restrictive Covenant Agreement

[attached]

Employment Agreement

This Employment Agreement (this “Agreement”), dated as of January 26, 2024, is made by and between Fractyl Health, Inc. a Delaware corporation (together with any successor thereto, the “Company”), and Lisa Davidson (“Executive”) (collectively referred to herein as the “Parties” or individually referred to as a “Party”), and will become effective, if at all, upon the date of the Company’s initial public offering of stock (“IPO”) pursuant to an effective registration statement filed under the Securities Act of 1933, as amended (the “Effective Date”).

RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement.
- B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1. Employment.

(a) General. Effective on the Effective Date, the Company shall employ Executive, and Executive shall be employed by the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided; provided, however, that this Agreement is expressly conditioned upon the IPO closing before June 30, 2024, and will be null and void if this condition is not satisfied.

(b) At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law, and that Executive’s employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This “at-will” nature of Executive’s employment shall remain unchanged during Executive’s tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive’s employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the “Term”) shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as Chief Financial Officer of the Company, with such responsibilities, duties and authority normally associated with such position and as may from time to time be assigned to Executive by the Chief Executive Officer of the Company (the “CEO”). Executive shall devote substantially all of Executive’s working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the Board of Directors of the Company or an authorized committee of the Board (in either case, the “Board”), provided that Executive shall be permitted to (i) manage Executive’s personal, financial and legal affairs, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or tax-

exempt charitable organizations, and (iv) with the prior consent of the Board, such consent not to be unreasonably withheld or delayed, serve on the board of directors of one for-profit company that does not compete with the Company, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case, as amended from time to time, and as delivered or made available to Executive (each, a "Policy").

2. Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of \$450,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Annual Cash Bonus Opportunity. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Annual Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company, subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right (but not the obligation) to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document and shall have no interest in any such policy.

3. Termination.

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death.* Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability.* If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause.* The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause.* The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company with Good Reason.* Executive may resign Executive's employment with the Company with Good Reason, as defined below.

(vi) *Resignation from the Company without Good Reason.* Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to Section 3(a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least thirty (30) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination, but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company. The failure by either Party to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause or Good Reason shall not waive any right of the Party hereunder or preclude the Party from asserting such fact or circumstance in enforcing the Party's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in

accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the “Company Arrangements”). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive’s rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive’s employment hereunder. In the event that Executive’s employment is terminated by the Company for any reason, Executive’s sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive’s employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive’s employment shall terminate as a result of Executive’s death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive’s resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company with Good Reason. If Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, then except as otherwise provided under Section 4(c) and subject to Executive signing on or before the 21st day following Executive’s Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the “Release”) and Executive’s continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the Annual Base Salary, payable in the form of salary continuation in regular installments over the twelve (12)-month period following the date of Executive’s Separation from Service (the “Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company’s fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company’s group medical, dental or vision plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (“COBRA”), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive’s covered dependents under such plans, during the period commencing on Executive’s Separation from Service and ending upon the earliest of (A) the last day of the Severance Period, (B) the date that Executive and/or Executive’s covered dependents become no longer eligible for COBRA and (C) the date Executive becomes eligible to receive medical, dental or vision coverage, as applicable, from a subsequent employer (and Executive agrees to promptly notify the Company

of such eligibility) (the “COBRA Continuation Period”). Notwithstanding the foregoing, if the Company determines it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive’s and Executive’s covered dependents’ group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall continue for the remainder of the COBRA Continuation Period.

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, in either case, within three (3) months prior to or eighteen (18) months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive’s Separation from Service, and not revoking, the Release and Executive’s continued compliance with Section 5, Executive shall receive, in addition to the payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the Annual Base Salary, payable in equal installments over the twelve (12)-month period following the date of Executive’s Separation from Service (the “CIC Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) the payment set forth in Section 4(b)(ii);

(iii) the benefits set forth in Section 4(b)(iii), provided that for this purpose, the “Severance Period” will mean the CIC Severance Period;

(iv) an amount in cash equal to 1.0 times the Target Annual Bonus, payable in a lump sum on the Company’s first ordinary payroll date that occurs after the Date of Termination; and

(v) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on continued employment or service shall immediately become 100% vested (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive’s employment and the termination of the Term.

5. Restrictive Covenants. Executive and the Company are party to that certain Non-Competition and Non-Solicitation Agreement, attached as Exhibit B (the “Restrictive Covenant Agreement”). Executive agrees to abide by the terms of the Restrictive Covenant Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Restrictive Covenant Agreement will survive the termination of Executive’s employment and the termination of the Term for the periods set forth in the Restrictive Covenant Agreement.

6. Assignment and Successors.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise) and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7. Certain Definitions.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) The Company's reasonable, good faith determination that Executive has refused to (A) substantially perform the duties associated with Executive's position with the Company or (B) carry out the reasonable and lawful instructions of the CEO or the Board concerning duties or actions consistent with the Executive's position with the Company;

(ii) Executive's breach of a material provision of this Agreement that, to the extent capable of cure, has remained uncured for a period of thirty (30) days following written notice from the Company;

(iii) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(iv) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or

(v) Executive's commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the Fractyl Health, Inc. 2024 Incentive Award Plan, as in effect on the Effective Date.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii) – (vi) either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) **Disability.** “Disability” shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company’s employees, “disability” as defined in such long-term disability plan for the purpose of determining a participant’s eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, “Disability” shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, “Disability” shall mean Executive’s inability to perform, with or without reasonable accommodation, the essential functions of Executive’s positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive’s legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive’s Disability.

(f) **Good Reason.** For the sole purpose of determining Executive’s right to severance payments and benefits as described above, Executive’s resignation will be with “Good Reason” if Executive resigns within ninety (90) days after any of the following events, unless Executive consents in writing to the applicable event: (i) a material reduction in Executive’s Annual Base Salary or Target Annual Bonus (excluding any reduction in Annual Base Salary that is proportionate to a reduction of base salaries affecting substantially all other executive officers of the Company), (ii) a material decrease in Executive’s authority or areas of responsibility as are commensurate with Executive’s title or position with the Company, (iii) the relocation of Executive’s primary office to a location more than twenty-five (25) miles from the Executive’s primary office as of the date of this Agreement or (iv) the Company’s breach of a material provision of this Agreement. Notwithstanding the foregoing, no Good Reason will have occurred unless and until: (a) Executive has provided the Company, within sixty (60) days of Executive’s knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) the Company has had an opportunity to cure the same within thirty (30) days after the receipt of such notice; and (c) the Company shall have failed to so cure within such period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4 hereof, being hereinafter referred to as the “Total Payments”), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro rata basis of any cash severance payments that are exempt from Section 409A of the Code (“Section 409A”), (ii) reduction on a pro rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the “Independent Advisors”). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a “parachute payment” within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the “base amount” (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, to the CEO of the Company at the Company’s headquarters,
- (ii) If to Executive, to the last address that the Company has in its personnel records for Executive, or
- (iii) At any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Restrictive Covenant Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including any prior employment offer letter, employment agreement, or change in control severance agreement between Executive and the Company. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(h) Arbitration. Except as excluded herein below, any controversy, dispute or claim arising out of or relating to this Agreement, or breach thereof, or Executive’s employment with or termination of employment from the Company (each, a “Covered Claim”) shall be resolved by final and binding arbitration administered by JAMS. The arbitration shall be conducted by a single, neutral arbitrator, pursuant to JAMS’s Employment Arbitration Rules & Procedures, available at <https://www.jamsadr.com/rules-employment-arbitration/English>, as in effect at the time of the initiation of arbitration, which the Company will provide to Executive upon reasonable request, in Boston, Massachusetts. Notwithstanding anything in this Agreement to the contrary, the arbitration provisions of this Agreement shall be governed by and enforceable pursuant to the Federal Arbitration Act, and, in all other respects, the arbitrator shall apply the substantive laws of the Commonwealth of Massachusetts or applicable Federal law, with the same statutes of limitation and available remedies that would apply if the claims were brought in a court of law of competent jurisdiction. The costs unique to arbitration, including the arbitration administrative fees, arbitrator compensation and expenses, and any costs of any witnesses call by the arbitrator, that would not be incurred in a court proceeding shall be borne by the Company. Unless otherwise ordered by the arbitrator

under applicable law, the Company and Executive shall each bear its, their, his, or her own expenses, such as expert witness fees, filing fees, and attorneys' fees and costs. Nothing herein shall prevent the Company or Executive from seeking a statutory award of reasonable attorneys' fees and costs under applicable law. THE COMPANY AND EXECUTIVE RECOGNIZE THAT, BY AGREEING TO ARBITRATE THEIR DISPUTES, EACH WAIVE ITS, THEIR, HIS, OR HER RIGHT TO A TRIAL BY JURY OF ANY COVERED CLAIM. THE COMPANY AND EXECUTIVE WAIVE ITS, THEIR, HIS, OR HER RIGHT TO BRING ANY COVERED CLAIM AS PART OF OR IN CONNECTION WITH A CLASS OR COLLECTIVE ACTION. Notwithstanding the foregoing, this Section shall not preclude either party from seeking a temporary restraining order or a preliminary injunction from a court of competent jurisdiction if such relief is not available in a timely fashion through arbitration. Further, this arbitration agreement shall not apply to: (a) claims for unemployment and workers' compensation benefits; (b) sexual harassment and sexual assault disputes arising under federal, state, local, or tribal law, unless Executive elects to arbitrate such disputes; (c) claims arising under the National Labor Relations Act or which are brought before the National Labor Relations Board; (d) claims brought before the Equal Employment Opportunity Commission or similar state or local agency, if Executive is required to exhaust Executive's administrative remedies; provided, that any appeal from an award or denial of an award by any such agency or any further action upon receipt of a right-to-sue letter shall be arbitrated pursuant to the terms of this Agreement; and (e) any other claim, which by law cannot be subject to mandatory arbitration.

(i) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(j) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(k) Section 409A.

(i) *General*. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10. Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

FRACTYL HEALTH, INC.

By: /s/ Harith Rajagopalan
Name: Harith Rajagopalan
Title: Chief Executive Officer

EXECUTIVE

/s/ Lisa Davidson
Lisa Davidson

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Lisa Davidson ("Executive") and Fractyl Health, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of _____, 2024 (the "Employment Agreement") and that certain Non-Competition and Non-Solicitation Agreement, dated as of August 6, 2015 (the "Restrictive Covenant Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company, vested benefits or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section [4(b)/4(c)] of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their current and former officers, directors, equityholders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from Parent, the Company or any other Releasee), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans

pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not prevent Executive from (i) reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of any whistleblower protection provisions of state or federal law or regulation (including the right to receive an award for information provided to any such government agencies), (ii) exercising any rights Executive may have under Section 7 of the U.S. National Labor Relations Act, such as the right to engage in concerted activity, including collective action or discussion concerning wages or working conditions, or (iii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Executive has reason to believe is unlawful. This release further does not release claims for breach of Section 3(c) or Section 4 of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Restrictive Covenants.

(a) Executive acknowledges and agrees that the restrictive covenants and other post-termination obligations set forth in the Restrictive Covenant Agreement, including without limitation Executive's obligations relating to confidentiality, non-use and non-disclosure of Proprietary Information (as defined in the Restrictive Covenant Agreement), cooperation and return of property, non-competition and non-solicitation, are hereby incorporated by reference and shall remain in full force and effect pursuant to their terms to the maximum extent permitted by applicable law.

(b) Executive's continued compliance with the terms of the Restrictive Covenant Agreement (as modified in Section 4(a) above) (collectively, the "Restrictive Covenants") is a material condition to receipt of the severance payments and benefits set forth in Section 1 of this Agreement. In the event Executive breaches any part of such Restrictive Covenants, then, in addition to any remedies and enforcement mechanisms set forth in the Employment Agreement and this Agreement, and any other remedies available to the Company (including equitable and injunctive remedies), Executive shall forfeit any additional consideration owing and shall be obligated to promptly return to the Company (within fifteen (15) business days of any breach) the full gross amount of all severance payments and benefits provided.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c), and 9(h) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective on the day immediately following the seventh business day after Executive signed this Agreement (the "Effective Date"). For the avoidance of doubt, if Executive revokes this Agreement as provided herein, the Parties' modification to the Restrictive Covenant Agreement set forth in Section 4(a) above shall be void and of no effect and, unless the Company has elected or elects in writing to expressly waive Executive's noncompetition obligations set forth in Section 1(a) of the Restrictive Covenant Agreement as provided in Section 3(g) of the Restrictive Covenant Agreement, including without limitation Section 1 of the Restrictive Covenant Agreement, shall remain in full force and effect.

9. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

EXECUTIVE

Dated: _____

Lisa Davidson

FRACTYL HEALTH, INC.

Dated: _____

By: _____

Name:

Title:

EXHIBIT B

Restrictive Covenant Agreement

[attached]

Employment Agreement

This Employment Agreement (this “Agreement”), dated as of January 26, 2024, is made by and between Fractyl Health, Inc. a Delaware corporation (together with any successor thereto, the “Company”), and Jay Caplan (“Executive”) (collectively referred to herein as the “Parties” or individually referred to as a “Party”), and will become effective, if at all, upon the date of the Company’s initial public offering of stock (“IPO”) pursuant to an effective registration statement filed under the Securities Act of 1933, as amended (the “Effective Date”).

RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement.
- B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1. Employment.

(a) General. Effective on the Effective Date, the Company shall employ Executive, and Executive shall be employed by the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided; provided, however, that this Agreement is expressly conditioned upon the IPO closing before June 30, 2024, and will be null and void if this condition is not satisfied.

(b) At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law, and that Executive’s employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This “at-will” nature of Executive’s employment shall remain unchanged during Executive’s tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive’s employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the “Term”) shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as President and Chief Product Officer of the Company, with such responsibilities, duties and authority normally associated with such position and as may from time to time be assigned to Executive by the Chief Executive Officer of the Company (the “CEO”). Executive shall devote substantially all of Executive’s working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the Board of Directors of the Company or an authorized committee of the Board (in either case, the “Board”), provided that Executive shall be permitted to (i) manage Executive’s personal, financial and legal affairs, (ii) participate in trade associations, (iii) serve on the board of directors of not-for-profit or

tax-exempt charitable organizations, and (iv) with the prior consent of the Board, such consent not to be unreasonably withheld or delayed, serve on the board of directors of one for-profit company that does not compete with the Company, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case, as amended from time to time, and as delivered or made available to Executive (each, a "Policy").

2. Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of \$475,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Annual Cash Bonus Opportunity. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Annual Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company, subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right (but not the obligation) to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document and shall have no interest in any such policy.

3. Termination.

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death.* Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability.* If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause.* The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause.* The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company with Good Reason.* Executive may resign Executive's employment with the Company with Good Reason, as defined below.

(vi) *Resignation from the Company without Good Reason.* Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to Section 3(a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least thirty (30) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination, but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company. The failure by either Party to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause or Good Reason shall not waive any right of the Party hereunder or preclude the Party from asserting such fact or circumstance in enforcing the Party's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in

accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the “Company Arrangements”). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive’s rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive’s employment hereunder. In the event that Executive’s employment is terminated by the Company for any reason, Executive’s sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive’s employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive’s employment shall terminate as a result of Executive’s death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive’s resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company with Good Reason. If Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, then except as otherwise provided under Section 4(c) and subject to Executive signing on or before the 21st day following Executive’s Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the “Release”) and Executive’s continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the Annual Base Salary, payable in the form of salary continuation in regular installments over the twelve (12)-month period following the date of Executive’s Separation from Service (the “Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company’s fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company’s group medical, dental or vision plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (“COBRA”), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive’s covered dependents under such plans, during the period commencing on Executive’s Separation from Service and ending upon the earliest of (A) the last day of the Severance Period, (B) the date that Executive and/or Executive’s covered dependents become no longer eligible for COBRA and (C) the date Executive becomes eligible to receive medical, dental or vision coverage, as applicable, from a subsequent employer (and Executive agrees to promptly notify the Company

of such eligibility) (the “COBRA Continuation Period”). Notwithstanding the foregoing, if the Company determines it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive’s and Executive’s covered dependents’ group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall continue for the remainder of the COBRA Continuation Period.

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, in either case, within three (3) months prior to or eighteen (18) months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive’s Separation from Service, and not revoking, the Release and Executive’s continued compliance with Section 5, Executive shall receive, in addition to the payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the Annual Base Salary, payable in equal installments over the twelve (12)-month period following the date of Executive’s Separation from Service (the “CIC Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) the payment set forth in Section 4(b)(ii);

(iii) the benefits set forth in Section 4(b)(iii), provided that for this purpose, the “Severance Period” will mean the CIC Severance Period;

(iv) an amount in cash equal to 1.0 times the Target Annual Bonus, payable in a lump sum on the Company’s first ordinary payroll date that occurs after the Date of Termination; and

(v) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on continued employment or service shall immediately become 100% vested (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive’s employment and the termination of the Term.

5. Restrictive Covenants. Executive and the Company are party to restrictive covenants contained in that certain employment letter agreement dated June 21, 2011, attached as Exhibit B (the “Restrictive Covenant Agreement”). Executive agrees to abide by the terms of the Restrictive Covenant Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Restrictive Covenant Agreement will survive the termination of Executive’s employment and the termination of the Term for the periods set forth in the Restrictive Covenant Agreement.

6. Assignment and Successors.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise) and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7. Certain Definitions.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) The Company's reasonable, good faith determination that Executive has refused to (A) substantially perform the duties associated with Executive's position with the Company or (B) carry out the reasonable and lawful instructions of the CEO or the Board concerning duties or actions consistent with the Executive's position with the Company;

(ii) Executive's breach of a material provision of this Agreement that, to the extent capable of cure, has remained uncured for a period of thirty (30) days following written notice from the Company;

(iii) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(iv) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or

(v) Executive's commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the Fractyl Health, Inc. 2024 Incentive Award Plan, as in effect on the Effective Date.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(ii) – (vi) either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) **Disability.** “Disability” shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company’s employees, “disability” as defined in such long-term disability plan for the purpose of determining a participant’s eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, “Disability” shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, “Disability” shall mean Executive’s inability to perform, with or without reasonable accommodation, the essential functions of Executive’s positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive’s legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive’s Disability.

(f) **Good Reason.** For the sole purpose of determining Executive’s right to severance payments and benefits as described above, Executive’s resignation will be with “Good Reason” if Executive resigns within ninety (90) days after any of the following events, unless Executive consents in writing to the applicable event: (i) a material reduction in Executive’s Annual Base Salary or Target Annual Bonus (excluding any reduction in Annual Base Salary that is proportionate to a reduction of base salaries affecting substantially all other executive officers of the Company), (ii) a material decrease in Executive’s authority or areas of responsibility as are commensurate with Executive’s title or position with the Company, (iii) the relocation of Executive’s primary office to a location more than twenty-five (25) miles from the Executive’s primary office as of the date of this Agreement or (iv) the Company’s breach of a material provision of this Agreement. Notwithstanding the foregoing, no Good Reason will have occurred unless and until: (a) Executive has provided the Company, within sixty (60) days of Executive’s knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) the Company has had an opportunity to cure the same within thirty (30) days after the receipt of such notice; and (c) the Company shall have failed to so cure within such period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4 hereof, being hereinafter referred to as the “Total Payments”), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro rata basis of any cash severance payments that are exempt from Section 409A of the Code (“Section 409A”), (ii) reduction on a pro rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the “Independent Advisors”). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a “parachute payment” within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the “base amount” (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, to the CEO of the Company at the Company’s headquarters,
- (ii) If to Executive, to the last address that the Company has in its personnel records for Executive, or
- (iii) At any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Restrictive Covenant Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including any prior employment offer letter (other than the portion thereof constituting the Restrictive Covenant Agreement), employment agreement, or change in control severance agreement between Executive and the Company. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(h) Arbitration. Except as excluded herein below, any controversy, dispute or claim arising out of or relating to this Agreement, or breach thereof, or Executive’s employment with or termination of employment from the Company (each, a “Covered Claim”) shall be resolved by final and binding arbitration administered by JAMS. The arbitration shall be conducted by a single, neutral arbitrator, pursuant to JAMS’s Employment Arbitration Rules & Procedures, available at <https://www.jamsadr.com/rules-employment-arbitration/English>, as in effect at the time of the initiation of arbitration, which the Company will provide to Executive upon reasonable request, in Boston, Massachusetts. Notwithstanding anything in this Agreement to the contrary, the arbitration provisions of this Agreement shall be governed by and enforceable pursuant to the Federal Arbitration Act, and, in all other respects, the arbitrator shall apply the substantive laws of the Commonwealth of Massachusetts or applicable Federal law, with the same statutes of limitation and available remedies that would apply if the claims were brought in a court of law of competent jurisdiction. The costs unique to arbitration, including the arbitration administrative fees, arbitrator compensation and expenses, and any costs of any witnesses call by the arbitrator, that would not

be incurred in a court proceeding shall be borne by the Company. Unless otherwise ordered by the arbitrator under applicable law, the Company and Executive shall each bear its, their, his, or her own expenses, such as expert witness fees, filing fees, and attorneys' fees and costs. Nothing herein shall prevent the Company or Executive from seeking a statutory award of reasonable attorneys' fees and costs under applicable law. THE COMPANY AND EXECUTIVE RECOGNIZE THAT, BY AGREEING TO ARBITRATE THEIR DISPUTES, EACH WAIVE ITS, THEIR, HIS, OR HER RIGHT TO A TRIAL BY JURY OF ANY COVERED CLAIM. THE COMPANY AND EXECUTIVE WAIVE ITS, THEIR, HIS, OR HER RIGHT TO BRING ANY COVERED CLAIM AS PART OF OR IN CONNECTION WITH A CLASS OR COLLECTIVE ACTION. Notwithstanding the foregoing, this Section shall not preclude either party from seeking a temporary restraining order or a preliminary injunction from a court of competent jurisdiction if such relief is not available in a timely fashion through arbitration. Further, this arbitration agreement shall not apply to: (a) claims for unemployment and workers' compensation benefits; (b) sexual harassment and sexual assault disputes arising under federal, state, local, or tribal law, unless Executive elects to arbitrate such disputes; (c) claims arising under the National Labor Relations Act or which are brought before the National Labor Relations Board; (d) claims brought before the Equal Employment Opportunity Commission or similar state or local agency, if Executive is required to exhaust Executive's administrative remedies; provided, that any appeal from an award or denial of an award by any such agency or any further action upon receipt of a right-to-sue letter shall be arbitrated pursuant to the terms of this Agreement; and (e) any other claim, which by law cannot be subject to mandatory arbitration.

(i) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(j) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(k) Section 409A.

(i) *General*. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee.* Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements.* To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments.* Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10. Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

FRACTYL HEALTH, INC.

By: /s/ Harith Rajagopalan

Name: Harith Rajagopalan

Title: Chief Executive Officer

EXECUTIVE

/s/ Jay Caplan

Jay Caplan

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Jay Caplan ("Executive") and Fractyl Health, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of _____, 2024 (the "Employment Agreement") and the restrictive covenants in that certain employment letter agreement, dated as of June 21, 2011 (the "Restrictive Covenant Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20____, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company, vested benefits or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section [4(b)/4(c)] of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their current and former officers, directors, equityholders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from Parent, the Company or any other Releasee), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans

pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not prevent Executive from (i) reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of any whistleblower protection provisions of state or federal law or regulation (including the right to receive an award for information provided to any such government agencies), (ii) exercising any rights Executive may have under Section 7 of the U.S. National Labor Relations Act, such as the right to engage in concerted activity, including collective action or discussion concerning wages or working conditions, or (iii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Executive has reason to believe is unlawful. This release further does not release claims for breach of Section 3(c) or Section 4 of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Restrictive Covenants.

(a) Executive acknowledges and agrees that the restrictive covenants and other post-termination obligations set forth in the Restrictive Covenant Agreement, including without limitation Executive's obligations relating to confidentiality, non-use and non-disclosure of Proprietary Information (as defined in the Restrictive Covenant Agreement), cooperation and return of property, non-competition and non-solicitation, are hereby incorporated by reference and shall remain in full force and effect pursuant to their terms to the maximum extent permitted by applicable law.

(b) Executive's continued compliance with the terms of the Restrictive Covenant Agreement (as modified in Section 4(a) above) (collectively, the "Restrictive Covenants") is a material condition to receipt of the severance payments and benefits set forth in Section 1 of this Agreement. In the event Executive breaches any part of such Restrictive Covenants, then, in addition to any remedies and enforcement mechanisms set forth in the Employment Agreement and this Agreement, and any other remedies available to the Company (including equitable and injunctive remedies), Executive shall forfeit any additional consideration owing and shall be obligated to promptly return to the Company (within fifteen (15) business days of any breach) the full gross amount of all severance payments and benefits provided.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c), and 9(h) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective on the day immediately following the seventh business day after Executive signed this Agreement (the "Effective Date"). For the avoidance of doubt, if Executive revokes this Agreement as provided herein, the Parties' modification to the Restrictive Covenant Agreement set forth in Section 4(a) above shall be void and of no effect and, unless the Company has elected or elects in writing to expressly waive Executive's noncompetition obligations set forth in Section 1(a) of the Restrictive Covenant Agreement as provided in Section 3(g) of the Restrictive Covenant Agreement, including without limitation Section 1 of the Restrictive Covenant Agreement, shall remain in full force and effect.

9. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

EXECUTIVE

Dated: _____

Jay Caplan

FRACTYL HEALTH, INC.

Dated: _____

By: _____
Name:
Title:

EXHIBIT B

Restrictive Covenant Agreement

[attached]

Employment Agreement

This Employment Agreement (this “Agreement”), dated as of January 26, 2024, is made by and between Fractyl Health, Inc. a Delaware corporation (together with any successor thereto, the “Company”), and Sarah Toomey (“Executive”) (collectively referred to herein as the “Parties” or individually referred to as a “Party”), and will become effective, if at all, upon the date of the Company’s initial public offering of stock (“IPO”) pursuant to an effective registration statement filed under the Securities Act of 1933, as amended (the “Effective Date”).

RECITALS

- A. It is the desire of the Company to assure itself of the services of Executive as of the Effective Date and thereafter by entering into this Agreement.
- B. Executive and the Company mutually desire that Executive provide services to the Company on the terms herein provided.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements set forth below, the Parties hereto agree as follows:

1. Employment.

(a) General. Effective on the Effective Date, the Company shall employ Executive, and Executive shall be employed by the Company, for the period and in the positions set forth in this Section 1, and subject to the other terms and conditions herein provided; provided, however, that this Agreement is expressly conditioned upon the IPO closing before June 30, 2024, and will be null and void if this condition is not satisfied.

(b) At-Will Employment. The Company and Executive acknowledge that Executive’s employment is and shall continue to be at-will, as defined under applicable law, and that Executive’s employment with the Company may be terminated by either Party at any time for any or no reason (subject to the notice requirements of Section 3(b)). This “at-will” nature of Executive’s employment shall remain unchanged during Executive’s tenure as an employee and may not be changed, except in an express writing signed by Executive and a duly authorized officer of the Company. If Executive’s employment terminates for any reason, Executive shall not be entitled to any payments, benefits, damages, award or compensation other than as provided in this Agreement or otherwise agreed to in writing by the Company or as provided by applicable law. The term of this Agreement (the “Term”) shall commence on the Effective Date and end on the date this Agreement is terminated under Section 3.

(c) Positions and Duties. During the Term, Executive shall serve as General Counsel and Corporate Secretary of the Company, with such responsibilities, duties and authority normally associated with such position and as may from time to time be assigned to Executive by the Chief Executive Officer of the Company (the “CEO”). Executive shall devote substantially all of Executive’s working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the Board of Directors of the Company or an authorized committee of the Board (in either case, the “Board”), provided that Executive shall be permitted to (i) manage Executive’s personal, financial and legal affairs, (ii) participate in trade associations, (iii) serve on the board of directors of not-

for-profit or tax-exempt charitable organizations, and (iv) with the prior consent of the Board, such consent not to be unreasonably withheld or delayed, serve on the board of directors of one for-profit company that does not compete with the Company, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with Executive's performance of Executive's duties and responsibilities hereunder. Executive agrees to observe and comply with the rules and policies of the Company as adopted by the Company from time to time, in each case, as amended from time to time, and as delivered or made available to Executive (each, a "Policy").

2. Compensation and Related Matters.

(a) Annual Base Salary. During the Term, Executive shall receive a base salary at a rate of \$420,000 per annum, which shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. Such annual base salary shall be reviewed (and may be adjusted) from time to time by the Board (such annual base salary, as it may be adjusted from time to time, the "Annual Base Salary").

(b) Annual Cash Bonus Opportunity. During the Term, Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 40% of Executive's Annual Base Salary (such target, as may be adjusted by the Board from time to time, the "Target Annual Bonus"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to Executive's continued employment with the Company through the date of payment, except as otherwise provided in Section 4(b).

(c) Benefits. During the Term, Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company, subject to the terms and eligibility requirements thereof and as such plans, programs and arrangements may be amended or in effect from time to time. In no event shall Executive be eligible to participate in any severance plan or program of the Company, except as set forth in Section 4 of this Agreement.

(d) Vacation. During the Term, Executive shall be entitled to paid personal leave in accordance with the Company's Policies. Any vacation shall be taken at the reasonable and mutual convenience of the Company and Executive.

(e) Business Expenses. During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive's duties to the Company in accordance with the Company's expense reimbursement Policy.

(f) Key Person Insurance. At any time during the Term, the Company shall have the right (but not the obligation) to insure the life of Executive for the Company's sole benefit. The Company shall have the right to determine the amount of insurance and the type of policy. Executive shall reasonably cooperate with the Company in obtaining such insurance by submitting to physical examinations, by supplying all information reasonably required by any insurance carrier, and by executing all necessary documents reasonably required by any insurance carrier, provided that any information provided to an insurance company or broker shall not be provided to the Company without the prior written authorization of Executive. Executive shall incur no financial obligation by executing any required document and shall have no interest in any such policy.

3. **Termination.**

Executive's employment hereunder and the Term may be terminated by the Company or Executive, as applicable, without any breach of this Agreement under the following circumstances and the Term will end on the Date of Termination:

(a) Circumstances.

(i) *Death.* Executive's employment hereunder shall terminate upon Executive's death.

(ii) *Disability.* If Executive has incurred a Disability, as defined below, the Company may terminate Executive's employment.

(iii) *Termination for Cause.* The Company may terminate Executive's employment for Cause, as defined below.

(iv) *Termination without Cause.* The Company may terminate Executive's employment without Cause.

(v) *Resignation from the Company with Good Reason.* Executive may resign Executive's employment with the Company with Good Reason, as defined below.

(vi) *Resignation from the Company without Good Reason.* Executive may resign Executive's employment with the Company for any reason other than Good Reason or for no reason.

(b) Notice of Termination. Any termination of Executive's employment by the Company or by Executive under this Section 3 (other than termination pursuant to Section 3(a)(i)) shall be communicated by a written notice to the other Party hereto (i) indicating the specific termination provision in this Agreement relied upon, (ii) setting forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of Executive's employment under the provision so indicated, if applicable, and (iii) specifying a Date of Termination which, if submitted by Executive, shall be at least thirty (30) days following the date of such notice (a "Notice of Termination"); *provided, however*, that in the event that Executive delivers a Notice of Termination to the Company, the Company may, in its sole discretion, change the Date of Termination to any date that occurs following the date of the Company's receipt of such Notice of Termination and is prior to the date specified in such Notice of Termination, but the termination will still be considered a resignation by Executive. A Notice of Termination submitted by the Company may provide for a Date of Termination on the date Executive receives the Notice of Termination, or any date thereafter elected by the Company. The failure by either Party to set forth in the Notice of Termination any fact or circumstance which contributes to a showing of Cause or Good Reason shall not waive any right of the Party hereunder or preclude the Party from asserting such fact or circumstance in enforcing the Party's rights hereunder.

(c) Company Obligations upon Termination. Upon termination of Executive's employment pursuant to any of the circumstances listed in this Section 3, Executive (or Executive's estate) shall be entitled to receive the sum of: (i) the portion of Executive's Annual Base Salary earned through the Date of Termination, but not yet paid to Executive; (ii) any expense reimbursements owed to Executive pursuant to Section 2(e); and (iii) any amount accrued and arising from Executive's participation in, or benefits accrued under any employee benefit plans, programs or arrangements, which amounts shall be payable in

accordance with the terms and conditions of such employee benefit plans, programs or arrangements (collectively, the “Company Arrangements”). Except as otherwise expressly required by law (e.g., COBRA) or as specifically provided herein, all of Executive’s rights to salary, severance, benefits, bonuses and other compensatory amounts hereunder (if any) shall cease upon the termination of Executive’s employment hereunder. In the event that Executive’s employment is terminated by the Company for any reason, Executive’s sole and exclusive remedy shall be to receive the payments and benefits described in this Section 3(c) or Section 4, as applicable.

(d) Deemed Resignation. Upon termination of Executive’s employment for any reason, Executive shall be deemed to have resigned from all offices and directorships, if any, then held with the Company or any of its subsidiaries.

4. Severance Payments.

(a) Termination for Cause, or Termination Upon Death, Disability or Resignation from the Company Without Good Reason. If Executive’s employment shall terminate as a result of Executive’s death pursuant to Section 3(a)(i) or Disability pursuant to Section 3(a)(ii), pursuant to Section 3(a)(iii) for Cause, or pursuant to Section 3(a)(vi) for Executive’s resignation from the Company without Good Reason, then Executive shall not be entitled to any severance payments or benefits, except as provided in Section 3(c).

(b) Termination without Cause, or Resignation from the Company with Good Reason. If Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, then except as otherwise provided under Section 4(c) and subject to Executive signing on or before the 21st day following Executive’s Separation from Service (as defined below), and not revoking, a release of claims substantially in the form attached as Exhibit A to this Agreement (the “Release”) and Executive’s continued compliance with Section 5, Executive shall receive, in addition to payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the Annual Base Salary, payable in the form of salary continuation in regular installments over the twelve (12)-month period following the date of Executive’s Separation from Service (the “Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) to the extent unpaid as of the Date of Termination, an amount of cash equal to any Annual Bonus earned by Executive for the Company’s fiscal year prior to the fiscal year in which the Date of Termination occurs, as determined by the Board in its discretion based upon actual performance achieved, which Annual Bonus, if any, shall be paid to Executive in the fiscal year in which the Date of Termination occurs when bonuses for such prior fiscal year are paid in the ordinary course to actively employed senior executives of the Company; and

(iii) if Executive timely elects to receive continued medical, dental or vision coverage under one or more of the Company’s group medical, dental or vision plans pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (“COBRA”), then the Company shall directly pay, or reimburse Executive for, the COBRA premiums for Executive and Executive’s covered dependents under such plans, during the period commencing on Executive’s Separation from Service and ending upon the earliest of (A) the last day of the Severance Period, (B) the date that Executive and/or Executive’s covered dependents become no longer eligible for COBRA and (C) the date Executive becomes eligible to receive medical, dental or vision coverage, as applicable, from a subsequent employer (and Executive agrees to promptly notify the Company

of such eligibility) (the “COBRA Continuation Period”). Notwithstanding the foregoing, if the Company determines it cannot provide the foregoing benefit without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act) or incurring an excise tax, the Company shall in lieu thereof provide to Executive a taxable monthly payment in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive’s and Executive’s covered dependents’ group health coverage in effect on the Date of Termination (which amount shall be based on the premium for the first month of COBRA coverage), which payments shall continue for the remainder of the COBRA Continuation Period.

(c) Change in Control. In lieu of the payments and benefits set forth in Section 4(b), in the event Executive’s employment terminates without Cause pursuant to Section 3(a)(iv), or pursuant to Section 3(a)(v) due to Executive’s resignation with Good Reason, in either case, within three (3) months prior to or eighteen (18) months following the date of a Change in Control, subject to Executive signing on or before the 21st day following Executive’s Separation from Service, and not revoking, the Release and Executive’s continued compliance with Section 5, Executive shall receive, in addition to the payments and benefits set forth in Section 3(c), the following:

(i) an amount in cash equal to 1.0 times the Annual Base Salary, payable in equal installments over the twelve (12)-month period following the date of Executive’s Separation from Service (the “CIC Severance Period”) in accordance with the Company’s normal payroll practices;

(ii) the payment set forth in Section 4(b)(ii);

(iii) the benefits set forth in Section 4(b)(iii), provided that for this purpose, the “Severance Period” will mean the CIC Severance Period;

(iv) an amount in cash equal to 1.0 times the Target Annual Bonus, payable in a lump sum on the Company’s first ordinary payroll date that occurs after the Date of Termination; and

(v) all unvested equity or equity-based awards held by Executive under any Company equity compensation plans that vest solely based on continued employment or service shall immediately become 100% vested (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

(d) Survival. Notwithstanding anything to the contrary in this Agreement, the provisions of Sections 5 through 9 will survive the termination of Executive’s employment and the termination of the Term.

5. Restrictive Covenants. Executive and the Company are party to that certain Non-Disclosure, Non-Solicitation and Invention Agreement, attached as Exhibit B (the “Restrictive Covenant Agreement”). Executive agrees to abide by the terms of the Restrictive Covenant Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Restrictive Covenant Agreement will survive the termination of Executive’s employment and the termination of the Term for the periods set forth in the Restrictive Covenant Agreement.

6. Assignment and Successors.

The Company may assign its rights and obligations under this Agreement to any of its affiliates or to any successor to all or substantially all of the business or the assets of the Company (by merger or otherwise) and may assign or encumber this Agreement and its rights hereunder as security for indebtedness of the Company and its affiliates. This Agreement shall be binding upon and inure to the benefit of the Company, Executive and their respective successors, assigns, personal and legal representatives, executors, administrators, heirs, distributees, devisees, and legatees, as applicable. None of Executive's rights or obligations may be assigned or transferred by Executive, other than Executive's rights to payments hereunder, which may be transferred only by will or operation of law. Notwithstanding the foregoing, Executive shall be entitled, to the extent permitted under applicable law and applicable Company Arrangements, to select and change a beneficiary or beneficiaries to receive compensation hereunder following Executive's death by giving written notice thereof to the Company.

7. Certain Definitions.

(a) Cause. The Company shall have "Cause" to terminate Executive's employment hereunder upon:

(i) The Company's reasonable, good faith determination that Executive has refused to (A) substantially perform the duties associated with Executive's position with the Company or (B) carry out the reasonable and lawful instructions of the CEO or the Board concerning duties or actions consistent with the Executive's position with the Company;

(ii) Executive's breach of a material provision of this Agreement that, to the extent capable of cure, has remained uncured for a period of thirty (30) days following written notice from the Company;

(iii) Executive's conviction, plea of no contest, plea of *nolo contendere*, or imposition of unadjudicated probation for any felony or crime involving moral turpitude;

(iv) Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing Executive's duties and responsibilities under this Agreement; or

(v) Executive's commission of any act of fraud, embezzlement, misappropriation, willful misconduct, or breach of fiduciary duty against the Company or any of its affiliates.

(b) Change in Control. "Change in Control" shall have the meaning set forth in the Fractyl Health, Inc. 2024 Incentive Award Plan, as in effect on the Effective Date.

(c) Code. "Code" shall mean the Internal Revenue Code of 1986, as amended, and the regulations and guidance promulgated thereunder.

(d) Date of Termination. "Date of Termination" shall mean (i) if Executive's employment is terminated by Executive's death, the date of Executive's death; or (ii) if Executive's employment is terminated pursuant to Section 3(a)(i) – (vi) either the date indicated in the Notice of Termination or the date specified by the Company pursuant to Section 3(b), whichever is earlier.

(e) **Disability.** “Disability” shall mean, at any time the Company or any of its affiliates sponsors a long-term disability plan for the Company’s employees, “disability” as defined in such long-term disability plan for the purpose of determining a participant’s eligibility for benefits, *provided, however*, if the long-term disability plan contains multiple definitions of disability, “Disability” shall refer to that definition of disability which, if Executive qualified for such disability benefits, would provide coverage for the longest period of time. The determination of whether Executive has a Disability shall be made by the person or persons required to make disability determinations under the long-term disability plan. At any time the Company does not sponsor a long-term disability plan for its employees, “Disability” shall mean Executive’s inability to perform, with or without reasonable accommodation, the essential functions of Executive’s positions hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive’s legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive’s Disability.

(f) **Good Reason.** For the sole purpose of determining Executive’s right to severance payments and benefits as described above, Executive’s resignation will be with “Good Reason” if Executive resigns within ninety (90) days after any of the following events, unless Executive consents in writing to the applicable event: (i) a material reduction in Executive’s Annual Base Salary or Target Annual Bonus (excluding any reduction in Annual Base Salary that is proportionate to a reduction of base salaries affecting substantially all other executive officers of the Company), (ii) a material decrease in Executive’s authority or areas of responsibility as are commensurate with Executive’s title or position with the Company, (iii) the relocation of Executive’s primary office to a location more than twenty-five (25) miles from the Executive’s primary office as of the date of this Agreement or (iv) the Company’s breach of a material provision of this Agreement. Notwithstanding the foregoing, no Good Reason will have occurred unless and until: (a) Executive has provided the Company, within sixty (60) days of Executive’s knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; (b) the Company has had an opportunity to cure the same within thirty (30) days after the receipt of such notice; and (c) the Company shall have failed to so cure within such period.

8. Parachute Payments.

(a) Notwithstanding any other provisions of this Agreement or any Company equity plan or agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 4 hereof, being hereinafter referred to as the “Total Payments”), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then the Total Payments shall be reduced (in the order provided in Section 8(b)) to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments).

(b) The Total Payments shall be reduced in the following order: (i) reduction on a pro rata basis of any cash severance payments that are exempt from Section 409A of the Code (“Section 409A”), (ii) reduction on a pro rata basis of any non-cash severance payments or benefits that are exempt from Section 409A, (iii) reduction on a pro rata basis of any other payments or benefits that are exempt from Section 409A, and (iv) reduction of any payments or benefits otherwise payable to Executive on a pro rata basis or such other manner that complies with Section 409A; provided, in case of clauses (ii), (iii) and (iv), that reduction of any payments attributable to the acceleration of vesting of Company equity awards shall be first applied to Company equity awards that would otherwise vest last in time.

(c) All determinations regarding the application of this Section 8 shall be made by an accounting firm or consulting group with experience in performing calculations regarding the applicability of Section 280G of the Code and the Excise Tax selected by the Company (the “Independent Advisors”). For purposes of determinations, no portion of the Total Payments shall be taken into account which, in the opinion of the Independent Advisors, (i) does not constitute a “parachute payment” within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) or (ii) constitutes reasonable compensation for services actually rendered, within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the “base amount” (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation. The costs of obtaining such determination and all related fees and expenses (including related fees and expenses incurred in any later audit) shall be borne by the Company.

(d) In the event it is later determined that a greater reduction in the Total Payments should have been made to implement the objective and intent of this Section 8, the excess amount shall be returned promptly by Executive to the Company.

9. Miscellaneous Provisions.

(a) Governing Law. This Agreement shall be governed, construed, interpreted and enforced in accordance with its express terms, and otherwise in accordance with the substantive laws of the Commonwealth of Massachusetts without reference to the principles of conflicts of law of the Commonwealth of Massachusetts or any other jurisdiction that would result in the application of the laws of a jurisdiction other than the Commonwealth of Massachusetts, and where applicable, the laws of the United States.

(b) Validity. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

(c) Notices. Any notice, request, claim, demand, document and other communication hereunder to any Party shall be effective upon receipt (or refusal of receipt) and shall be in writing and delivered personally or sent by facsimile or certified or registered mail, postage prepaid, as follows:

- (i) If to the Company, to the CEO of the Company at the Company’s headquarters,
- (ii) If to Executive, to the last address that the Company has in its personnel records for Executive, or
- (iii) At any other address as any Party shall have specified by notice in writing to the other Party.

(d) Counterparts. This Agreement may be executed in several counterparts, each of which shall be deemed to be an original, but all of which together will constitute one and the same Agreement. Signatures delivered by facsimile or PDF shall be deemed effective for all purposes.

(e) Entire Agreement. The terms of this Agreement, and the Restrictive Covenant Agreement incorporated herein by reference as set forth in Section 5, are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and supersede all prior understandings and agreements, whether written or oral, including any prior employment offer letter, employment agreement, or change in control severance agreement between Executive and the Company. The Parties further intend that this Agreement shall constitute the complete and exclusive statement of their terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative, or other legal proceeding to vary the terms of this Agreement.

(f) Amendments; Waivers. This Agreement may not be modified, amended, or terminated except by an instrument in writing, signed by Executive and a duly authorized officer of Company. By an instrument in writing similarly executed, Executive or a duly authorized officer of the Company may waive compliance by the other Party with any specifically identified provision of this Agreement that such other Party was or is obligated to comply with or perform; *provided, however*, that such waiver shall not operate as a waiver of, or estoppel with respect to, any other or subsequent failure. No failure to exercise and no delay in exercising any right, remedy, or power hereunder will preclude any other or further exercise of any other right, remedy, or power provided herein or by law or in equity.

(g) Construction. This Agreement shall be deemed drafted equally by both the Parties. Its language shall be construed as a whole and according to its fair meaning. Any presumption or principle that the language is to be construed against any Party shall not apply. The headings in this Agreement are only for convenience and are not intended to affect construction or interpretation. Any references to paragraphs, subparagraphs, sections or subsections are to those parts of this Agreement, unless the context clearly indicates to the contrary. Also, unless the context clearly indicates to the contrary, (i) the plural includes the singular and the singular includes the plural; (ii) “and” and “or” are each used both conjunctively and disjunctively; (iii) “any,” “all,” “each,” or “every” means “any and all,” and “each and every”; (iv) “includes” and “including” are each “without limitation”; (v) “herein,” “hereof,” “hereunder” and other similar compounds of the word “here” refer to the entire Agreement and not to any particular paragraph, subparagraph, section or subsection; and (vi) all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural as the identity of the entities or persons referred to may require.

(h) Arbitration. Except as excluded herein below, any controversy, dispute or claim arising out of or relating to this Agreement, or breach thereof, or Executive’s employment with or termination of employment from the Company (each, a “Covered Claim”) shall be resolved by final and binding arbitration administered by JAMS. The arbitration shall be conducted by a single, neutral arbitrator, pursuant to JAMS’s Employment Arbitration Rules & Procedures, available at <https://www.jamsadr.com/rules-employment-arbitration/English>, as in effect at the time of the initiation of arbitration, which the Company will provide to Executive upon reasonable request, in Boston, Massachusetts. Notwithstanding anything in this Agreement to the contrary, the arbitration provisions of this Agreement shall be governed by and enforceable pursuant to the Federal Arbitration Act, and, in all other respects, the arbitrator shall apply the substantive laws of the Commonwealth of Massachusetts or applicable Federal law, with the same statutes of limitation and available remedies that would apply if the claims were brought in a court of law of competent jurisdiction. The costs unique to arbitration, including the arbitration administrative fees, arbitrator compensation and expenses, and any costs of any witnesses call by the arbitrator, that would not be incurred in a court proceeding shall be borne by the Company. Unless otherwise ordered by the arbitrator

under applicable law, the Company and Executive shall each bear its, their, his, or her own expenses, such as expert witness fees, filing fees, and attorneys' fees and costs. Nothing herein shall prevent the Company or Executive from seeking a statutory award of reasonable attorneys' fees and costs under applicable law. THE COMPANY AND EXECUTIVE RECOGNIZE THAT, BY AGREEING TO ARBITRATE THEIR DISPUTES, EACH WAIVE ITS, THEIR, HIS, OR HER RIGHT TO A TRIAL BY JURY OF ANY COVERED CLAIM. THE COMPANY AND EXECUTIVE WAIVE ITS, THEIR, HIS, OR HER RIGHT TO BRING ANY COVERED CLAIM AS PART OF OR IN CONNECTION WITH A CLASS OR COLLECTIVE ACTION. Notwithstanding the foregoing, this Section shall not preclude either party from seeking a temporary restraining order or a preliminary injunction from a court of competent jurisdiction if such relief is not available in a timely fashion through arbitration. Further, this arbitration agreement shall not apply to: (a) claims for unemployment and workers' compensation benefits; (b) sexual harassment and sexual assault disputes arising under federal, state, local, or tribal law, unless Executive elects to arbitrate such disputes; (c) claims arising under the National Labor Relations Act or which are brought before the National Labor Relations Board; (d) claims brought before the Equal Employment Opportunity Commission or similar state or local agency, if Executive is required to exhaust Executive's administrative remedies; provided, that any appeal from an award or denial of an award by any such agency or any further action upon receipt of a right-to-sue letter shall be arbitrated pursuant to the terms of this Agreement; and (e) any other claim, which by law cannot be subject to mandatory arbitration.

(i) Enforcement. If any provision of this Agreement is held to be illegal, invalid or unenforceable under present or future laws effective during the Term, such provision shall be fully severable; this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a portion of this Agreement; and the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance from this Agreement. Furthermore, in lieu of such illegal, invalid or unenforceable provision there shall be added automatically as part of this Agreement a provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and be legal, valid and enforceable.

(j) Withholding. The Company shall be entitled to withhold from any amounts payable under this Agreement any federal, state, local or foreign withholding or other taxes or charges which the Company is required to withhold. The Company shall be entitled to rely on the advice of counsel if any questions as to the amount or requirement of withholding shall arise.

(k) Section 409A.

(i) *General*. The intent of the Parties is that the payments and benefits under this Agreement comply with or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(ii) *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that is designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 4 shall not be paid, or, in the case of installments, shall not commence payment, until the thirtieth (30th) day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the thirty (30) day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

(iii) *Specified Employee*. Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the six-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

(iv) *Expense Reimbursements*. To the extent that any reimbursements under this Agreement are subject to Section 409A, (i) any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, (ii) Executive shall submit Executive's reimbursement request promptly following the date the expense is incurred, (iii) the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and (iv) Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(v) *Installments*. Executive's right to receive any installment payments under this Agreement, including without limitation any continuation salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10. Executive Acknowledgement.

Executive acknowledges that Executive has read and understands this Agreement, is fully aware of its legal effect, has not acted in reliance upon any representations or promises made by the Company other than those contained in writing herein, and has entered into this Agreement freely based on Executive's own judgment.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the date and year first above written.

FRACTYL HEALTH, INC.

By: /s/ Harith Rajagopalan
Name: Harith Rajagopalan
Title: Chief Executive Officer

EXECUTIVE

/s/ Sarah Toomey
Sarah Toomey

[Signature Page to Employment Agreement]

EXHIBIT A

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Sarah Toomey ("Executive") and Fractyl Health, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of _____, 2024 (the "Employment Agreement") and that certain Non-Disclosure, Non-Solicitation and Invention Agreement, dated as of April 29, 2022 (the "Restrictive Covenant Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective _____, 20__, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company, vested benefits or Executive's right to indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims").

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Severance Payments and Benefits; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section [4(b)/4(c)] of the Employment Agreement, payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof.

2. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of its or their current and former officers, directors, equityholders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Labor Standards Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; and the Sarbanes-Oxley Act of 2002;

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates (including without limitation the Massachusetts Payment of Wages Law); and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to file a charge with or participate in a charge by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering such monetary relief from Parent, the Company or any other Releasee), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans

pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law, and any Retained Claims. This release further does not prevent Executive from (i) reporting possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of any whistleblower protection provisions of state or federal law or regulation (including the right to receive an award for information provided to any such government agencies), (ii) exercising any rights Executive may have under Section 7 of the U.S. National Labor Relations Act, such as the right to engage in concerted activity, including collective action or discussion concerning wages or working conditions, or (iii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Executive has reason to believe is unlawful. This release further does not release claims for breach of Section 3(c) or Section 4 of the Employment Agreement.

3. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the Parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement; (c) Executive has seven business days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

4. Restrictive Covenants.

(a) Executive acknowledges and agrees that the restrictive covenants and other post-termination obligations set forth in the Restrictive Covenant Agreement, including without limitation Executive's obligations relating to confidentiality, non-use and non-disclosure of Proprietary Information (as defined in the Restrictive Covenant Agreement), cooperation and return of property, non-competition and non-solicitation, are hereby incorporated by reference and shall remain in full force and effect pursuant to their terms to the maximum extent permitted by applicable law.

(b) Executive's continued compliance with the terms of the Restrictive Covenant Agreement (as modified in Section 4(a) above) (collectively, the "Restrictive Covenants") is a material condition to receipt of the severance payments and benefits set forth in Section 1 of this Agreement. In the event Executive breaches any part of such Restrictive Covenants, then, in addition to any remedies and enforcement mechanisms set forth in the Employment Agreement and this Agreement, and any other remedies available to the Company (including equitable and injunctive remedies), Executive shall forfeit any additional consideration owing and shall be obligated to promptly return to the Company (within fifteen (15) business days of any breach) the full gross amount of all severance payments and benefits provided.

5. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

6. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company.

7. Governing Law; Dispute Resolution. This Agreement shall be subject to the provisions of Sections 9(a), 9(c), and 9(h) of the Employment Agreement.

8. Effective Date. Executive has seven business days after Executive signs this Agreement to revoke it and this Agreement will become effective on the day immediately following the seventh business day after Executive signed this Agreement (the "Effective Date"). For the avoidance of doubt, if Executive revokes this Agreement as provided herein, the Parties' modification to the Restrictive Covenant Agreement set forth in Section 4(a) above shall be void and of no effect and, unless the Company has elected or elects in writing to expressly waive Executive's noncompetition obligations set forth in Section 1(a) of the Restrictive Covenant Agreement as provided in Section 3(g) of the Restrictive Covenant Agreement, including without limitation Section 1 of the Restrictive Covenant Agreement, shall remain in full force and effect.

9. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

EXECUTIVE

Dated: _____

Sarah Toomey

FRACTYL HEALTH, INC.

Dated: _____

By: _____
Name: Harith Rajagopalan
Title: Chief Executive Officer

EXHIBIT B

Restrictive Covenant Agreement

[attached]



Tim Kieffer
Delivered by email

September 12, 2023

Dear **Tim**:

On behalf of Fractyl Health, Inc. (the "**Company**"), I am pleased to offer you the position of **Chief Scientific Officer**, contingent upon the successful completion of reference and background checks as applicable. Your anticipated start date is on or about **September 12, 2023** ("**Start Date**"). In this position, you will report to **Harith Rajagopalan, Chief Executive Officer** ("**Manager**") and will have such duties as Manager shall determine from time to time, including, but not limited to, those listed on the job description attached as Exhibit A.

You will be employed on a part-time basis, which is estimated to be 20 hours per week. Your base rate of pay will initially be **\$7,692.31** per bi-weekly pay period (representing an annualized rate of **\$200,000**) ("**Base Salary**"), less all applicable federal, state and local taxes and withholdings, to be paid in installments in accordance with the Company's standard payroll practices.

At the commencement of your employment, you will work out of the Company's headquarters approximately one week per month and be permitted to work remotely for the balance of the month. However, it is expected that you will transition to full-time employment and be relocated to Lexington or Burlington, Massachusetts within approximately twelve (12) months following the Start Date. In connection with this transition, you will be required to execute a new or amended employment agreement with the Company. Your Base Salary will also be increased to **\$15,384.62** (representing an annualized rate of **\$400,000**), prorated to reflect any portion of the pay period in which you were working part-time. Such Base Salary may be further adjusted from time to time in accordance with business practices and in the sole discretion of the Company.

You will have the opportunity to earn a one-time bonus of \$25,000 ("**Signing Bonus**"), subject to taxes and other withholdings as required by law. The Signing Bonus will be advanced to you within thirty (30) days of the Start Date. You will earn, and be permitted to retain, the full amount of the Signing Bonus if you remain actively employed with the Company for twelve (12) months following your Start Date. Should your employment with the Company end within twelve (12) months from Start Date due to voluntary resignation or termination for Cause (as defined herein), you agree to repay to the Company the gross amount of the Signing Bonus.

In this position, you will be eligible for an annual target performance bonus of up to **40%** of your Base Salary for the applicable calendar year, adjusted to reflect any portion of the year in which you were working part-time, based upon the achievement of individual goals as defined by Manager and Company milestones established by the Company's Board of Directors ("**Bonus**"). The Bonus, if any, will be determined at the sole discretion of the Company, and will be prorated for each fiscal year based on employment start date or other

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dates as determined by the Company. Should your Start Date fall on or between October 1 and December 31 of the calendar year, you will be eligible for a Bonus consideration with the calendar year following your start date. Bonus payments, if any, will be subject to all applicable federal, state and local taxes and withholdings, and will be paid in accordance with the Company's standard payment practices.

The Company will reimburse expenses incurred by you related to reasonable travel to and lodging incurred by you in connection with your commute to the Company's headquarters ("**Commuter Reimbursement**"). We ask that you provide the Company with supporting documentation outlining details associated with any reasonable expenses. The Company does not make any representations regarding the tax consequences associated with the Commuter Reimbursement. As such, please note that you remain responsible for the filing and payment of taxes associated with these sums. We suggest that you obtain your own tax counsel to assist you with your tax obligations arising from working in the United States.

You will be eligible to participate in benefit programs that the Company establishes and makes available to its employees from time to time, provided that you are eligible under (and subject to all provisions of) the plan documents governing those programs. Such benefits may include: participation in group medical and dental insurance programs, group life insurance, disability insurance, participation in the Company's 401(k) plan. The benefits made available by the Company, and the terms, and conditions for participation in such benefit plans, may change by the Company at any time.

Subject to approval by the Company's Board of Directors, it is expected that you will be awarded an incentive stock option to purchase **1,068,721** shares of the Company's common stock, subject to adjustment for any stock splits, recapitalizations or similar events (the "Option"). The Option would be subject to the terms and conditions of the Company's 2011 Stock Incentive Plan or any successor plan adopted by the Company and the Company's standard form of incentive stock option agreement that you will sign in connection with receiving the option, providing for the vesting of the Option over four years, with 25% of the shares vesting on the first anniversary of the date of grant of the Option and the remaining 75% of the shares vesting on a monthly basis thereafter. The Option exercise price per share will be equal to the fair market value of a share of common stock on the date of grant as determined by the Board of Directors. In the event you do not convert to full time status (40 hours per week) within twelve months of your Start Date, then, immediately prior to the first anniversary of the date of grant of the Option (such date, the "Option Determination Date"), the total number of shares initially subject to the Option shall be adjusted downward to equal the product of (1) such total number of shares and (2) a fraction, (a) the numerator of which is the lesser of 40 and the number of hours you are providing services to the Company on a weekly basis as of the Option Determination Date, determined in the Company's sole discretion, and (b) the denominator of which is 40 (and, for the avoidance of doubt, the remaining shares initially subject to the Option will be immediately forfeited as of the Option Determination Date without consideration).

As a condition of your employment with the Company, you will be required to sign the Company's Non-Disclosure, Non-Solicitation and Invention Agreement, a copy of which is enclosed. The Company is aware that you are and intend to remain employed as a Professor by the University of British Columbia (University) during your employment with the Company, and that you are obligated to abide by the University's Inventions Policy (Policy No.: LR11). This offer is conditioned upon your representation that you are not subject to any other confidentiality, noncompetition or other agreement that restricts your post-employment activities or that may affect your ability to devote time and attention to your work at the Company on a part-time basis. If you have entered into any agreement with a party other than the University that may restrict your activities on behalf of the Company, please provide me with a copy of the related documentation as soon as possible.

You may resign from your employment with the Company at any time by providing 30 days of advance notice to the Company. However, following receipt of your notice, the Company may, in its sole discretion, excuse you from further performance of any duties or responsibilities and may restrict you from attending its premises and / or accessing its systems. In such event, you will receive only your minimum entitlements pursuant to applicable employment standards legislation for the resignation notice period.

The enclosed Severance Agreement and Change in Control Agreement contains terms and conditions respecting the involuntary termination of your employment. The Company may terminate your employment at its sole discretion at any time and for any reason without Cause as defined in the Severance Agreement and Change in Control Agreement by providing you with: (i) accrued and unpaid wages and vacation pay, if any, earned by you up to and including the date of termination; (ii) the minimum amount of notice, pay in lieu of notice, or a combination thereof, required by applicable employment standards legislation, and (iii) a payment equal one month of your then current Base Salary, subject to applicable deductions and withholdings (the “**Additional Entitlement**”). The Additional Entitlement is conditional upon you executing a full and final release in favor of the Company, in a form acceptable to the Company.

We understand that you are a dual Canadian and US citizen. Please provide evidence confirming your lawful right to work in Canada and the United States. Such documentation must be provided to the Company within three business days of your start date. If you require work-authorization sponsorship, your employment with the Company will be conditioned upon the approval of such application and as determined by the Company.

By signing and returning a copy of this letter, you agree to devote your professional time, on a part-time basis, to the Company and to focus your efforts, skills, knowledge, attention and energies to the advancement of the Company’s business and interests. Your engagement in any other business activities requires the Company’s advance written approval.

We look forward to having you join our team. To accept our offer of employment, please sign and return one original copy of this letter to Jeremy Trelstad, Executive Director, Human Resources, by Tuesday, September 12, 2023.

Sincerely yours,

FRACTYL HEALTH, INC.

Signature: /s/ Harith Rajagopalan
Name: Harith Rajagopalan
Title: CEO & Co-Founder

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ACKNOWLEDGED AND AGREED:

Signature: /s/ Timothy Kieffer

Name: **Timothy Kieffer**

Date: 2023-Sep-12 1 13:52:07 PDT

Fractyl Health, Inc. | 17 Hartwell Avenue | Lexington, MA 02421

EXHIBIT A

JOB DESCRIPTION

Primary Responsibilities

- Help oversee scientific projects on MOA via Erase Task Force projects for Revita and Rejuva; help define and execute publication and dissemination strategy for these academic collaborations
- Inform metabolic peptide selection (individually/combinatorially) and mechanistic explication of Rejuva candidates in R&D
- Strategically guide and participate in engagement with external audiences on Fractyl science - including publications, scientific exchanges with external audiences/KOLs, investor meetings, etc.
- Oversee the scientific vision for the development of the Revita and Rejuva candidates and additional downstream pipeline opportunities

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NON-DISCLOSURE, NON-SOLICITATION AND INVENTION AGREEMENT

This Non-Disclosure, Non-Solicitation and Invention Agreement (the “Agreement”) is made by and between Fractyl Health, Inc., a Delaware corporation (hereinafter referred to collectively with its subsidiaries as the “Company”), and **Timothy Kieffer** (the “Employee”).

In consideration of the part-time employment of the Employee by the Company, the compensation Employee shall receive from the Company, and other good and valuable consideration, the Company and the Employee agree as follows:

1. Condition of Employment.

Employee acknowledges that his/her employment and/or the continuance of that employment with the Company is contingent upon his/her agreement to sign and adhere to the provisions of this Agreement. The Employee further acknowledges that the nature of the Company’s business is such that protection of its proprietary and confidential information, trade secrets and customer goodwill is critical to the business’ survival and success.

2. Proprietary and Confidential Information.

(a) Employee agrees that all information and know-how, whether or not in writing, of a private, secret or confidential nature concerning the Company’s business or financial affairs (collectively, “Proprietary Information”) is and shall be the exclusive property of the Company. By way of illustration, but not limitation, Proprietary Information includes, without limitation, discoveries, inventions, trade secrets, designs, apparatuses, products, product improvements, product enhancements, processes, methods, techniques, formulas, structures, compositions, compounds, negotiation strategies and positions, projects, developments, plans (including business and marketing plans), research data, clinical data, financial data (including sales costs, profits, pricing methods), personnel data, computer programs (including software used pursuant to a license agreement), customer, prospect and supplier lists, and contacts at or knowledge of customers or prospective customers of the Company. Proprietary Information also includes information received in confidence from third parties.

(b) Employee will not disclose any Proprietary Information to any person or entity other than employees of the Company or use the same for any purposes (other than in the performance of his/her duties as an employee of the Company) without written approval by an officer of the Company, either during or after his/her employment with the Company, unless and until such Proprietary Information has become public knowledge without fault by the Employee. While employed by the Company, the Employee will use the Employee’s best efforts to prevent unauthorized publication or disclosure of any of the Company’s Proprietary Information.

3. Documents; Company Property.

(a) Employee agrees to maintain adequate and current records of Proprietary Information and all documentation regarding Employee's job duties. These records will be available to and remain the Company's sole property.

(b) Employee agrees that the Company exclusively owns: all files, documents, letters, memoranda, reports, records, data, sketches, drawings, models, laboratory notebooks, program listings, computer equipment or devices, computer programs or other written, photographic, or other tangible or intangible material (whether or not it contains Proprietary Information), whether created by Employee or others, which come into Employee's custody or possession, as well as all computers, storage media, keys, passwords, email accounts, and any other electronic media provided for Employee's use (including cell phones, information on such phones, and records related to such phones) ("Property"). Employee agrees that only Employee may use such Property in performing his or her duties for the Company.

(c) All Property on the Company's premises, owned or purchased by the Company, disseminated by the Company, and/or used or created by Employee for business purposes during his or her employment with the Company, including without limitation, filing cabinets or other work areas, is subject to inspection by the Company at any time with or without notice. All such Property, including, without limitation, all Proprietary Information (including all client information) of the Company in the custody or possession of the Employee shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) termination of his/her employment. After such delivery, the Employee shall not retain any such Property or Proprietary Information or copies thereof (electronic or hard-copy).

(d) Employee agrees that his/her obligation not to disclose or to use Proprietary Information or Property as set forth in paragraphs 2(a), 2(b) and 3(b) above, and Employee's obligation to return Proprietary Information and Property, set forth in paragraph 3(c) above, also extends to such types of information, materials and tangible property of customers of the Company or suppliers to the Company or other third parties who may have disclosed or entrusted the same to the Company or to the Employee in the course of the Company's business.

4. Developments.

(a) Employee will make full and prompt disclosure to the Company of all discoveries, inventions, improvements, enhancements, processes, methods, techniques, developments, trade secrets, computer programs, software, and other works of authorship, whether or not patentable or copyrightable, (i) which have been created, made, conceived or reduced to practice by the Employee or under his/her direction or jointly with others prior to the date hereof and which relate directly or indirectly to the business of the Company, except those "Prior Developments" listed and described on Schedule I attached hereto, or (ii) which are created, made, conceived or reduced to practice by him/her or under his/her direction or jointly with others during his/her employment by the Company, whether or not during normal working hours or on the premises of the Company (all of which are collectively referred to in this Agreement as "Developments"). For clarity, Developments are not University Research Products (see Paragraph 7).

Notice: Employee represents that the Prior Developments identified in Schedule I attached hereto, if any, comprise all the Prior Developments that Employee has made or conceived prior to his/her employment by the Company. IF THERE IS ANY SUCH PRIOR DEVELOPMENTS TO BE EXCLUDED, EMPLOYEE SHOULD INITIAL HERE; OTHERWISE IT WILL BE DEEMED THAT THERE ARE NO SUCH EXCLUSIONS._____

(b) Employee agrees that all work performed by Employee is on a “work for hire” basis, and Employee agrees to assign and does hereby assign to the Company (or any person or entity designated by the Company) all his/her right, title and interest in and to all Developments and all related patents, patent applications, copyrights and copyright applications arising from the performance of his/her duties as an employee of the Company (“Intellectual Property Rights”). However, this paragraph 4(b) shall not apply to Developments or Intellectual Property Rights described in clause 4(a) (ii) above which do not relate to the business or research and development conducted or planned to be conducted by the Company at the time such Development is created, made, conceived or reduced to practice and which are made and conceived by the Employee not during normal working hours, not on the Company’s premises and not using the Company’s tools, devices, equipment or Proprietary Information. The Employee understands that, to the extent this Agreement shall be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this paragraph 4(b) shall be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes. The Employee also hereby waives all claims to moral rights in any Developments.

(c) Employee agrees to cooperate fully with the Company, both during and after his/her employment with the Company, with respect to the procurement, maintenance and enforcement of copyrights, patents and other Intellectual Property Rights (in the United States, foreign countries, and under the Patent Cooperation Treaty) relating to Developments. The Employee shall sign all papers, including, without limitation, copyright applications, patent applications, declarations, oaths, formal assignments, assignments of priority rights, and powers of attorney, which the Company may deem necessary or desirable in order to protect its Intellectual Property Rights in any Development. The Employee further agrees that if the Company is unable, after reasonable effort, to secure the signature of the Employee on any such papers, any executive officer of the Company shall be entitled to execute any such papers as the agent and the attorney-in-fact of the Employee, and the Employee hereby irrevocably designates and appoints each executive officer of the Company as his/her agent and attorney-in-fact to execute any such papers on his/her behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its Intellectual Property Rights in any Development, under the conditions described in this sentence.

5. Protected Activity Not Prohibited. Employee understands that nothing in this Agreement shall in any way limit or prohibit him/her from engaging in any Protected Activity. For purposes of this Agreement, “Protected Activity” shall mean (i) filing a charge, complaint, or report with, or otherwise communicating, cooperating, or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission (“Government Agencies”), (ii) exercising any rights Employee may have under Section 7 of the U.S. National Labor Relations Act, such as the right to engage in concerted activity, including collective action or discussion concerning wages or working conditions, or (iii) discussing or disclosing information about unlawful acts in the workplace, such as harassment or discrimination based on a protected characteristic or any other conduct that Employee has reason to believe is unlawful. Employee understands that in connection with such Protected Activity, s/he is permitted to disclose documents or other information as permitted by law, and without giving notice to, or receiving authorization from, the Company. Further, Employee shall not be held criminally or civilly liable under any federal or state trade secret law if s/he discloses a Company trade secret in confidence to a

Government Agency, either directly or indirectly, or to an attorney, solely for the purposes of reporting or investigating a suspected violation of law, or in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Notwithstanding the foregoing, Employee agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Confidential Information to any parties other than the Government Agencies. Employee further understands that “Protected Activity” does not include the disclosure of any Company attorney-client privileged communications. To be clear, nothing in this Agreement is intended to conflict with the Defense of Trade Secrets Act, specifically 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by 18 U.S.C. § 1833(b).

6. Non-Solicitation. Employee acknowledges and recognizes the highly competitive nature of the industry in which the Company is involved and agrees that he/she shall (i) have access to the Company’s Proprietary Information (as defined in Section 2), (ii) benefit from the Company’s goodwill, and (iii) obtain a competitive advantage as to the Company, its customers and prospective customers. Accordingly, Employee agrees that during the “Restricted Period” (defined as the period of Employee’s employment and one year after Employee’s employment ends, regardless of the reason for it ending), Employee will not directly or indirectly, on Employee’s own behalf or on behalf of another:

(a) solicit any customers or prospective customers of the Company, including those with whom Employee had professional “Contact” during his/her engagement with the Company, for the purpose of providing or seeking to provide any products or services that relate, directly or indirectly, to the Company’s business (the “Competitive Services”). “Contact” means any interaction, whether direct or indirect, between Employee and a Company customer or prospective customer that takes place in an effort to establish, maintain, service, provide services and/or further a business relationship on behalf of the Company;

(b) solicit any customer or prospective customer of the Company — about whom Employee obtained information, or became familiar with through Proprietary Information, during his/her employment with the Company — for the purpose of providing or seeking to provide Competitive Services;

(c) interfere in any way with the Company’s relationship with any customer, business partner, supplier or vendor; or

(d) either alone or in association with others (i) solicit, induce or attempt to induce, any employee or independent contractor of the Company to terminate his or her employment or other engagement with the Company, provided, that this clause (ii) shall not apply to the recruitment or hiring or other engagement of any individual whose employment or other engagement with the Company has been terminated for a period of six months or longer.

(e) Extension. If the Employee violates the provisions of any of the preceding paragraphs of this Section 6, the Employee shall continue to be bound by the restrictions set forth in such paragraph until a period of one year has expired without any violation of such provisions.

7. Other Agreements.

The Employee represents that he is employed as a Professor with the University and intends to remain as such during his employment with the Company. The Employee also represents that he (i) is obligated to abide by the University's Inventions Policy (Policy No.: LR11) and (ii) is not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of his/her employment with the Company, to refrain from competing, directly or indirectly, with the business of such previous employer or any other party or to refrain from soliciting employees, customers or suppliers of such previous employer or other party. The Employee further represents that his/her performance of all the terms of this Agreement and the performance of his/her duties as an employee of the Company do not and will not conflict with or breach any agreement with the University, any prior employer or other party to which the Employee is a party (including without limitation any nondisclosure or non-competition agreement), and that the Employee will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others. All inventions arising solely from the Employee's work with the University (i.e., any Invention that is created, developed, discovered, conceived or invented solely by Employee or jointly with other University employees (i) involving or utilizing the facilities, equipment or financial aid (including any grant funding) provided or administered by the University; or (ii) while acting within the scope of the Employee's duties or employment by the University, collectively referred to as "University Research Products") will be assigned to the University. All inventions arising solely from the Employee's work with the Company that is not a University Research Product will be assigned to the Company. The Employee further represents that he will not involve or utilize the facilities, equipment or financial aid provided or administered by the University for the Employee's work with the Company unless and until the University and the Company have entered into an appropriate agreement.

8. U.S. Government Obligations.

The Employee acknowledges that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such agreements or regarding the confidential nature of such work. The Employee agrees to be bound by all such obligations and restrictions which are made known to the Employee and to take all action necessary to discharge the obligations of the Company under such agreements.

9. Miscellaneous.

(a) Equitable Remedies. The restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach of this Agreement is likely to cause the Company substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies which may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach and the right to specific performance of the provisions of this Agreement without posting a bond and the Employee hereby waives the adequacy of a remedy at law as a defense to such relief. If Employee breaches or threaten to breach this Agreement, Employee agree that the Company shall be entitled to recover its reasonable attorneys' fees and costs incurred in enforcing its rights. This remedy shall be in addition to, and not as an alternative to, any other remedies.

(b) Obligations to Third Parties. The Employee acknowledges and represents that this agreement and the Employee's employment with the Company will not violate any continuing obligation the Employee has to any former employer or other third party.

(c) Disclosure of this Agreement. The Employee hereby authorizes the Company to notify others, including but not limited to customers of the Company and any of the Employee's future employers or prospective business associates, of the terms and existence of this Agreement and the Employee's continuing obligations to the Company hereunder.

(d) Not Employment Contract. The Employee acknowledges that this Agreement does not constitute a contract of employment, does not imply that the Company will continue his/her employment for any period of time and does not change the at-will nature of his/her employment.

(e) Survival; Successors and Assigns. Employee's obligations under this Agreement will continue regardless of any changes to Employee's role and/or terms and conditions of employment. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of the Employee are personal and shall not be assigned by him or her. The Employee expressly consents to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employ the Employee may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

(f) Severability. In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

(g) Waivers. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(h) Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflicts of laws provisions thereof). Any action, suit, or other legal proceeding which is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within Massachusetts), and the Company and the Employee each consents to the jurisdiction of such a court. THE COMPANY AND THE EMPLOYEE EACH HEREBY IRREVOCABLY WAIVE ANY RIGHT TO A TRIAL BY JURY IN ANY ACTION, SUIT OR OTHER LEGAL PROCEEDING ARISING UNDER OR RELATING TO ANY PROVISION OF THIS AGREEMENT.

(i) Entire Agreement; Amendment. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by the Employee and the Company. The Employee agrees that any change or changes in his/her duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

(j) Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

THE EMPLOYEE ACKNOWLEDGES THAT HE/SHE HAS CAREFULLY READ THIS AGREEMENT AND UNDERSTANDS AND AGREES TO ALL OF THE PROVISIONS IN THIS AGREEMENT.

WITNESS our hands and seals:

Fractyl Health, Inc.

Date: 2023-Sep-12 I 13:19:11 PDT

By: /s/ Harith Rajagopalan

Name: Harith Rajagopalan

Title: President & Co-Founder

Date: 2023-Sep-12 I 13:52:07 PDT

/s/ Timothy Kieffer

Name: Timothy Kieffer

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SCHEDULE I

As used in this Agreement, the term “Prior Developments” shall mean any invention, modification, discovery, design, development, improvement, process, software program, work of authorship, documentation, formula, data, technique, know-how, trade secret or intellectual property right whatsoever or any interest therein (whether or not patentable or registrable under copyright, trademark or similar statutes or subject to analogous protection) created, made or conceived by Employee prior to Employee’s employment with the Company. Employee understands that it is only necessary to list the title of such Prior Developments and the purpose thereof, but not the details of the Prior Developments.

The following is a complete list of all Prior Developments and the purpose of the Prior Developments (please list any patents by patent number and any patents pending):

- Riedel MJ et al. DsAAV8-mediated expression of glucagon-like peptide-1 in pancreatic beta-cells ameliorates streptozotocin-induced diabetes. Gene Ther. 2010 Feb;17(2):171-80 (PMID 19865180)
- Provisional patent filing “Pancreatic islet cells that express therapeutic Proteins and methods of making the same”
- Zhao J et al. Differentiation of Human Pluripotent Stem Cells into Insulin-Producing Islet Clusters. Differentiation of Human Pluripotent Stem Cells into Insulin-Producing Islet Clusters. J Vis Exp. 2023 Jun 23;(196) (PMID: 37427943)

/s/ Timothy Kieffer

Employee Signature

Date: 2023-Sep-12 I 13:52:07 PDT

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**FIRST AMENDMENT
TO
OFFER LETTER AGREEMENT**

THIS FIRST AMENDMENT TO OFFER LETTER AGREEMENT (this “*Amendment*”) is entered into by and between Fractyl Health, Inc. (the “*Company*”) and Tim Kieffer (the “*Executive*”) and will become effective, if at all, as of the date of the Company’s initial public offering of stock (“*IPO*”) pursuant to an effective registration statement filed under the Securities Act of 1933 (the “*Amendment Effective Date*”). Capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to them in the Offer Letter Agreement (as defined below).

RECITALS

WHEREAS, the Company and the Executive are parties to that certain offer letter, dated as of September 12, 2023 (the “*Offer Letter Agreement*”), which sets forth the terms and conditions of the Executive’s employment as Chief Scientific Officer; and

WHEREAS, the Company and the Executive mutually desire to amend the Offer Letter Agreement as set forth herein.

NOW, THEREFORE, in consideration of the Executive’s continued service with the Company and its subsidiaries and affiliates, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, effective as of the Amendment Effective Date, the Company and the Executive hereby agree as follows:

AMENDMENT

1. The second paragraph of the Offer Letter Agreement is hereby amended by deleting “\$7,692.31” and replacing it with “\$8,653.85.”
2. The second paragraph of the Offer Letter Agreement is hereby amended by deleting “\$200,000” and replacing it with “\$225,000.”

All other provisions of the Offer Letter Agreement shall remain in full force and effect according to their respective terms, and nothing contained herein shall be deemed a waiver of any right or abrogation of any obligation otherwise existing under the Offer Letter Agreement except to the extent specifically provided for herein. This Amendment may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document. To the extent that the IPO does not close before June 30, 2024, this Amendment will be null and void.

[signature page follows]

IN WITNESS WHEREOF, the Company and Executive have executed this Amendment effective as of the Amendment Effective Date.

COMPANY

Fractyl Health, Inc.

/s/ Harith Rajagopalan

Name:

Title:

EXECUTIVE

/s/ Tim Kieffer

Tim Kieffer



FRACTYL HEALTH, INC.

SEVERANCE AGREEMENT AND CHANGE IN CONTROL AGREEMENT

This Severance Agreement and Change in Control Agreement (the "**Agreement**") is made and entered into by and between Timothy Kieffer ("**Employee**") and Fractyl Health, Inc. (the "**Company**"), effective as of the latest date set forth by the signatures of the parties hereto below (the "**Effective Date**").

RECITALS

A. The Board of Directors of the Company (the "**Board**") agrees to provide Employee with severance benefits as outlined below upon certain terminations of Employee's service to the Company.

B. Unless otherwise defined herein, capitalized terms used in this Agreement are defined in Section 9 below.

The parties hereto agree as follows:

1. Term of Agreement. This Agreement shall become effective as of the Effective Date and terminate upon the date that all obligations of the parties hereto with respect to this Agreement have been satisfied.

2. Covered Termination Other Than During a Change in Control Period. If Employee experiences a Covered Termination after 12 months of continuous employment with the Company and other than during a Change in Control Period, and if Employee executes and delivers to the Company a comprehensive separation agreement (to be presented to Employee at the time of the Covered Termination) that includes general release of all claims against the Company and its affiliates as well as certain restrictive covenants (a "**Release of Claims**") that becomes effective and irrevocable within sixty (60) days, or such shorter period specified by the Company, following such Covered Termination, then in addition to any accrued but unpaid salary, bonus, benefits, vacation and expense reimbursement payable in accordance with applicable law, the Company shall provide Employee with the following:

(a) Severance. Employee shall be entitled to receive an amount equal to 6 months of Employee's base salary at the rate in effect immediately prior to the Termination Date payable in a cash lump sum, less applicable withholdings, on the first payroll date following the date the Release of Claims becomes effective and irrevocable.

(b) Continued Healthcare. If Employee elects to receive continued healthcare coverage pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**"), the Company shall directly pay the related premium for Employee and Employee's covered dependents through the earlier of (i) the 6 months anniversary of the Termination Date, (ii) the date Employee and Employee's covered dependents, if any, obtains healthcare coverage through other plan(s), or (iii) the date Employee becomes ineligible for COBRA benefits. Stated differently, if Employee experiences a Covered Termination before the conclusion of 12 months of continuous employment with the Company and such Termination occurs other than during a Change in Control Period, Employee is not eligible for the severance payments and benefits described in this Section 3.

3. Covered Termination During a Change in Control Period. If Employee experiences a Covered Termination during a Change in Control Period (regardless of the length of Employee's employment with the Company), and if Employee executes, and fails to revoke during any applicable revocation period, a Release of Claims within sixty (60) days, or such shorter period specified by the Company, following such Covered Termination, then in addition to any accrued but unpaid salary, bonus, benefits, vacation and expense reimbursement payable in accordance with applicable law, the Company shall provide Employee with the following:

(a) Severance. Employee shall be entitled to receive an amount equal to 9 months of Employee's base salary at the rate in effect immediately prior to the Termination Date, payable in a cash lump sum, less applicable withholdings, on the first payroll date following the date the Release of Claims becomes effective and irrevocable.

(b) Continued Healthcare. If Employee elects to receive continued healthcare coverage pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**"), the Company shall directly pay the related premium for Employee and Employee's covered dependents through the earlier of (i) the 9 months anniversary of the Termination Date, (ii) the date Employee and Employee's covered dependents, if any, obtains healthcare coverage through other plan(s), or (iii) the date Employee becomes ineligible for COBRA benefits.

(c) Equity Awards. Each outstanding and unvested equity award, including, without limitation, each stock option and restricted stock award, held by Employee shall automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to one hundred percent (100%) of the unvested shares underlying Employee's equity awards as of the Termination Date.

Stated differently, if Employee experiences a Covered Termination during a Change in Control Period, Employee is eligible for the severance payments and benefits described in this Section 4 regardless of the length of Employee's employment with the Company.

4. Certain Reductions. Notwithstanding anything herein to the contrary, the Company shall reduce Employee's severance benefits under this Agreement, in whole or in part, by any other severance benefits, pay in lieu of notice, or other similar benefits payable to Employee by the Company in connection with Employee's termination, including but not limited to payments or benefits pursuant to (a) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act, or (b) any Company agreement, arrangement, policy or practice relating to Employee's termination of employment with the Company. The benefits provided under this Agreement are intended to satisfy, to the greatest extent possible, any and all statutory obligations that may arise out of Employee's termination of employment. Such reductions shall be applied on a retroactive basis, with severance benefits previously paid being recharacterized as payments pursuant to the Company's statutory obligation.

5. Deemed Resignation. Upon termination of Employee's employment for any reason, Employee shall be deemed to have resigned from all offices and directorships, if any, and then held with the Company or any of its affiliates, and, at the Company's request, Employee shall execute such documents as are necessary or desirable to effectuate such resignations.

6. **Other Terminations.** If Employee's service with the Company is terminated by the Company or by Employee for any or no reason other than as a Covered Termination, then Employee shall not be entitled to any benefits hereunder other than accrued but unpaid salary, bonus, vacation and expense reimbursement in accordance with applicable law and to elect any continued healthcare coverage, if eligible and as may be required under COBRA or similar state law.

7. **Limitation on Payments.** Notwithstanding anything in this Agreement to the contrary, if any payment or distribution Employee would receive pursuant to this Agreement or otherwise ("**Payment**") would (a) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "**Code**"), and (b) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then such Payment shall either be (i) delivered in full, or (ii) delivered as to such lesser extent which would result in no portion of such Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Excise Tax, results in the receipt by Employee on an after-tax basis, of the largest payment, notwithstanding that all or some portion of the Payment may be taxable under Section 4999 of the Code. The accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder. The accounting firm shall provide its calculations to the Company and Employee within fifteen (15) calendar days after the date on which Employee's right to a Payment is triggered (if requested at that time by the Company or Employee) or such other time as requested by the Company or Employee. Any good faith determinations of the accounting firm made hereunder shall be final, binding and conclusive upon the Company and Employee. Any reduction in payments and/or benefits pursuant to this Section 8 will occur in the following order: (1) reduction of cash payments; (2) cancellation of accelerated vesting of equity awards other than stock options; (3) cancellation of accelerated vesting of stock options; and (4) reduction of other benefits payable to Employee.

8. **Definition of Terms.** The following terms referred to in this Agreement shall have the following meanings:

(a) **Cause.** "**Cause**" means (i) Employee's gross negligence or willful misconduct in the performance of the duties and services required of Employee pursuant to this Agreement or Employee's employment or offer letter agreement with the Company (the "**Employment Agreement**"); (ii) Employee's conviction of, or plea of guilty or *nolo contendere* to, a felony or crime involving moral turpitude (or any similar crime in any jurisdiction outside the United States); (iii) Employee's willful refusal to perform the duties and responsibilities required of Employee under this Agreement or the Employment Agreement which, if susceptible to being corrected, remains uncorrected for thirty (30) days following written notice to Employee by the Company of such breach; (iv) Employee's material breach of any material provision of this Agreement, the Employment Agreement, the Confidential Information Agreement (as defined below) or corporate code or policy which, if susceptible to being corrected, remains uncorrected for thirty (30) days following written notice to Employee by the Company of such breach; (v) any act of fraud, embezzlement, material misappropriation or dishonesty committed by Employee against the Company; or (vi) any acts, omissions or statements by Employee which the Company determines to be materially detrimental or damaging to the reputation, operations, prospects or business relations of the Company. For purposes of this Section 9(a), an act or failure to act shall be considered "willful" only if done or omitted to be done without a good faith reasonable belief that such act or failure to act was in the best interests of the Company.

The foregoing definition shall not be deemed to be inclusive of all the acts or omissions that the Company (or any parent or subsidiary or acquiror or successor) may consider as reasonable grounds for Employee's dismissal or discharge.

(b) **Change in Control.** "**Change in Control**" shall mean the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events: (i) a transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or (ii) during any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new director(s) (other than a director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 9(b)(i) or 9(b)(iii)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or (iii) the consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction: (1) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "**Successor Entity**")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and (2) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this Section 9(b)(iii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; or (iv) the Company's stockholders approve a liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event for any amount that constitutes deferred compensation that is subject to Section 409A of the Code, the transaction or event described in subsection (i), (ii), (iii) or (iv) with respect to such amount (or portion thereof) must also constitute a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5) to the extent required by Section 409A.

(c) **Change in Control Period.** "**Change in Control Period**" means the period of time commencing three months prior to a Change in Control and ending eighteen (18) months following the Change in Control.

(d) Good Reason Resignation. “**Good Reason Resignation**” means Employee’s resignation from employment with the Company that is effective within sixty (60) days after the occurrence, without Employee’s written consent, of any of the following: (i) a material diminution in Employee’s base compensation that is not proportionately applicable to other officers and key employees of the Company generally; (ii) a material diminution in Employee’s job responsibilities or duties; (iii) the relocation of Employee’s principal office to a facility or a location more than fifty (50) miles from Employee’s then- present principal office location; or (iv) the Company’s (or any successor entity or corporation following a Change in Control) breach of any provision under this Agreement. Notwithstanding the foregoing, a resignation shall not constitute a “Good Reason Resignation” unless the condition giving rise to such resignation continues uncured by the Company more than thirty (30) days following Employee’s written notice of such condition provided to the Company within sixty (60) days of the first occurrence of such condition and such resignation is effective within thirty (30) days following the end of such notice period.

(e) Covered Termination. “**Covered Termination**” means the termination of Employee’s employment by the Company other than for Cause, or Employee’s Good Reason Resignation, in each case, that, to the extent necessary, constitutes a “Separation from Service” (as defined below).

(f) Termination Date. “**Termination Date**” means the date Employee experiences a Covered Termination.

9. Successors.

(a) Company’s Successors. Except as set forth above, any successor to the Company (whether direct or indirect and whether by purchase, merger, consolidation, liquidation or otherwise) to all or substantially all of the Company’s business and/or assets must assume the obligations under this Agreement and agree expressly to perform the obligations under this Agreement in the same manner and to the same extent as the Company would be required to perform such obligations in the absence of a succession. For all purposes under this Agreement, the term “**Company**” shall include any successor to the Company’s business and/or assets which executes and delivers the assumption agreement described in this Section 10(a) or which becomes bound by the terms of this Agreement by operation of law.

(b) Employee’s Successors. The terms of this Agreement and all rights of Employee hereunder shall inure to the benefit of, and be enforceable by, Employee’s personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees.

10. Notices. Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or one day following mailing via Federal Express or similar overnight courier service. In the case of Employee, mailed notices shall be addressed to Employee at Employee’s home address that the Company has on file for Employee. In the case of the Company, mailed notices shall be addressed to its corporate headquarters, and all notices shall be directed to the attention of its Human Resources.

11. Confidentiality; Non-Disparagement.

(a) Confidentiality. Employee hereby expressly confirms Employee’s continuing obligations to the Company pursuant to Employee’s Non-Disclosure, Non-Solicitation and Invention Agreement with the Company (the “**Confidential Information Agreement**”).

(b) Non-Disparagement. Employee agrees that Employee shall not disparage, criticize or defame the Company, its affiliates and their respective affiliates, directors, officers, agents, partners, stockholders or employees, either publicly or privately. Nothing in this Section 12(b) shall have application to any evidence or testimony required by any court, arbitrator or government agency. Further, Employee understands that nothing in this Agreement shall in any way limit or prohibit him/her from engaging in any Protected Activity. For purposes of this Agreement, "**Protected Activity**" shall mean filing a charge, complaint, or report with, or otherwise communicating, cooperating, or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission. Further, nothing herein intended to interfere with Employee's Section 7 rights under the National Labor Relations Act.

12. Dispute Resolution.

(a) Mutual Agreement to Arbitrate. To ensure the timely and economical resolution of disputes that arise in connection with this Agreement, and in consideration of the Company's offer of severance benefits described herein and/or continued employment to Employee, Employee and the Company agree that any and all disputes, claims, or causes of action arising from or relating to the enforcement, breach, performance or interpretation of this Agreement, Employee's employment, or the termination of Employee's employment (collectively, "**Claims**"), shall be resolved to the fullest extent permitted by law by final, binding and confidential arbitration before one arbitrator mutually agreed to by Employee and the Company, sitting in Boston, Massachusetts or such other location agreed to by Employee and the Company, in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association then in effect; provided, however, that if Employee and the Company are unable to agree on the arbitrator within 30 days of the demand by a party for arbitration, an arbitrator will be designated by the Office of the American Arbitration Association which administers arbitrations in Boston, Massachusetts. **By agreeing to this arbitration procedure, both Employee and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** The arbitrator shall: (a) have the authority to interpret this Agreement, and this power and authority to determine arbitrability is hereby expressly delegated to the appointed arbitrator and not to any judge or court.; (ii) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision, to include the arbitrator's essential findings and conclusions and a statement of the award. The Company shall pay all arbitration fees in excess of the amount of court fees that would be required if the dispute were decided in a court of law. Each party is responsible for his/her/its attorneys' fees and costs.

(b) Timing. The parties agree that any and all claims subject to arbitration under this agreement must be initiated with the AAA within 300 days of the date that the cause of action accrued. The parties agree that expeditiously resolving disputes is in their mutual interests and therefore agree that all arbitrable claims should be subject to this 300-day limitations period regardless of the statute of limitations period otherwise prescribed for such claims under the law.

(c) Scope of Claims to be arbitrated. "Claims" subject to this arbitration clause also include the following:

(i) Claims under any Massachusetts, state, federal and/or municipal statute, regulation, ordinance and/or executive order (as amended) relating to employment, discrimination (including discrimination on the basis of race, color, religion, creed, sex, sex harassment, sexual orientation, age, gender identity, marital status, familial status, pregnancy, national origin, ancestry, alienage, handicap, disability, present or past history of mental disorders or physical disability, veteran's status, candidacy for or activity in a general assembly or other public office, or constitutionally protected acts of speech), fair employment practices, or other terms and conditions of employment, including but not limited to the Age Discrimination in Employment Act and Older Workers Benefit Protection Act (29 U.S.C. § 621 et seq.), the Civil Rights Acts of 1866 and 1871, Title VII of the Civil Rights Act of 1964 and the Civil Rights Act of 1991 (42 U.S.C. § 2000e et seq.), the Equal Pay Act (29 U.S.C. § 201 et seq.), the Americans With Disabilities Act (42 U.S.C. § 12101 et seq.), the Immigration Reform and Control Act (8 U.S.C. § 1101 et seq.), the Massachusetts Fair Employment Practices Statute (M.G.L. c. 151B § 1 et seq.), the Massachusetts Equal Rights Act (M.G.L. c. 93 §102), the Massachusetts Civil Rights Act (M.G.L. c. 12 §§ 11H & 11I), the Massachusetts Privacy Statute (M.G.L. c. 214 § 1B), the Massachusetts Sexual Harassment Statute (M.G.L. c. 214 § 1C), the Massachusetts law against retaliation (M.G.L. c. 19C, §11), and any similar state, federal or municipal statute, law, ordinance or regulation;

(ii) Claims under any Massachusetts, state, federal and/or municipal statute, regulation, ordinance and/or executive order (as amended) relating to leaves of absence, layoffs or reductions-in- force, wages, hours, or other terms and conditions of employment, including but not limited to the National Labor Relations Act (29 U.S.C. § 151 et seq.), the Family and Medical Leave Act (29 U.S.C. § 2601 et seq.), the Employee Retirement Income Security Act of 1974 (29 U.S.C. § 1000 et seq.), COBRA (29 U.S.C. § 1161 et seq.), the Fair Labor Standards Act (29 U.S.C. § 201 et seq.), the Occupational Safety and Health Act (29 U.S.C. § 651 et seq.), the Worker Adjustment and Retraining Notification Act (29 U.S.C. § 2101 et seq.), the Massachusetts Small Necessities Leave Act (M.G.L. c. 149, §52D), the Massachusetts Parental Leave law (M.G.L. c. 149, §105D), the Massachusetts Wage Act (M.G.L. c. 149 § 148 et. seq.), the Massachusetts Minimum Fair Wages Act (M.G.L. c. 151 § 1 et. seq.), the Massachusetts Equal Pay Act (M.G.L. c. 149 § 105A), the Massachusetts Paid Sick Leave law (M.G.L. c. 149, §§ 148C; 148D), and any similar state, federal or municipal statute, law, regulation or ordinance. **Please note that this section specifically includes claims that you have or may have regarding payments or amounts covered by the Massachusetts Wage Act or Massachusetts Minimum Fair Wages Act (including, for instance, hourly wages, salary, overtime, minimum wages, commissions, vacation pay, holiday pay, sick leave pay, dismissal pay, bonus pay or severance pay), as well as claims for retaliation under these laws;**

(iii) Claims under any Massachusetts, state, federal and/or any other common law theory, including, without limitation, wrongful discharge, breach of express or implied contract, promissory estoppel, unjust enrichment, breach of a covenant of good faith and fair dealing, violation of public policy, defamation, interference with contractual relations, intentional or negligent infliction of emotional distress, invasion of privacy, misrepresentation, deceit, fraud, negligence, or any claim to attorneys' fees under any applicable statute or common law theory of recovery;

(iv) Claims under any Massachusetts, state, federal and/or municipal statute, regulation, ordinance or executive order (as amended) relating to whistleblower protections, violation of public policy, or any other form of retaliation or wrongful termination, and any similar state, federal and/or municipal statute, law, regulation or ordinance;

(v) Claims under any Company compensation, benefit, stock option, incentive compensation, bonus, restricted stock, and/or equity plan, program, policy, practice or agreement; and/or (vi) Any other claim arising under other state, federal, municipal or other local law.

(d) Claims Excluded. This agreement to arbitrate does not apply to claims for benefits under state unemployment insurance or workers compensation programs. In addition, this Agreement does not prohibit:

(i) Employee from filing a claim or participating in an investigation, hearing or proceeding with a local, state or federal administrative agency, including the EEOC, the MCAD, and/or any other the state anti-discrimination agency. (However, this Agreement does preclude Employee from pursuing any such claim in court); or

(e) (ii) The Company from filing claims against Employee in which the Company seeks equitable relief against Employee for breach of his/her Confidential Information Agreement, breach of state or federal trade secret laws, and/or breach of state or federal intellectual property laws. Employee understands and agrees that his/her violation of the Confidential Information Agreement, state or federal trade secret laws and/or state or federal intellectual property laws would cause irreparable injury to the Company and that money damages would not provide an adequate remedy for such injury. Accordingly, Employee agrees that the Company could not effectively pursue all available rights and remedies against Employee for such claims in an arbitration proceeding and that such claims must therefore be excluded from the agreement to arbitrate. All such claims for equitable relief against Employee for breach of the Confidential Information Agreement, breach of state or federal trade secret laws, and/or breach of state or federal intellectual property laws shall be commenced and maintained in any state or federal court located within the Commonwealth of Massachusetts.

(f) No Class Actions or Arbitrations. Employee and the Company agree that the arbitrator may only hear the parties' individual claims and will not have the authority: (i) to consolidate the claims of other employees; (ii) to fashion a proceeding as a class or collective action; and/or (iii) to award relief to a group or class of employees in one arbitration proceeding. **In other words, Employee must pursue all claims subject to arbitration as an individual and may not pursue such claims as part of a class.** Employee represents, agrees, and acknowledges that s/he will be able to effectively pursue her/his rights and any and all claims against the Company in an individual arbitration according the terms of this agreement.

13. Miscellaneous Provisions.

(a) Section 409A.

(i) Separation from Service. Notwithstanding any provision to the contrary in this Agreement, no amount deemed deferred compensation subject to Section 409A of the Code shall be payable pursuant to Sections 3 or 4 above unless Employee's termination of employment constitutes a "separation from service" with the Company within the meaning of Section 409A of the Code and the Department of Treasury regulations and other guidance promulgated thereunder ("**Separation from Service**") and, except as provided under Section 14(a)(ii) of this Agreement, any such amount shall not be paid, or in the case of installments, commence payment, until the sixtieth (60th) day following Employee's Separation from Service. Any installment payments that would have been made to Employee during the sixty (60) day period immediately following Employee's Separation from Service but for the preceding sentence shall be paid to Employee on the sixtieth (60th) day following Employee's Separation from Service and the remaining payments shall be made as provided in this Agreement.

(ii) Specified Employee. Notwithstanding any provision to the contrary in this Agreement, if Employee is deemed at the time of his separation from service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, to the extent delayed commencement of any portion of the benefits to which Employee is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code, such portion of Employee's benefits shall not be provided to Employee prior to the earlier of (A) the expiration of the six (6)-month period measured from the date of Employee's Separation from Service or (B) the date of Employee's death. Upon the first business day following the expiration of the applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 14(a)(ii) shall be paid in a lump sum to Employee, and any remaining payments due under this Agreement shall be paid as otherwise provided herein.

(iii) Expense Reimbursements. To the extent that any reimbursements payable pursuant to this Agreement are subject to the provisions of Section 409A of the Code, any such reimbursements payable to Employee pursuant to this Agreement shall be paid to Employee no later than December 31st of the year following the year in which the expense was incurred, the amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, and Employee's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(iv) Installments. For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Employee's right to receive any installment payments under this Agreement shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment.

(b) Waiver. No provision of this Agreement shall be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Employee and by an authorized officer of the Company (other than Employee). No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party shall be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Whole Agreement. This Agreement, the Confidential Information Agreement and any offer letter by and between the Company and Employee represent the entire understanding of the parties hereto with respect to the subject matter hereof and supersede all prior promises, arrangements and understandings regarding same, whether written or written, including, without limitation, any severance or change in control benefits in Employee's offer letter and employment agreement or previously approved by the Board.

(d) Choice of Law. The validity, interpretation, construction and performance of this Agreement shall be governed by the laws of the Commonwealth of Massachusetts.

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision hereof, which shall remain in full force and effect.

(f) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together will constitute one and the same instrument.

(Signature page follows)

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year set forth below.

FRACTYL HEALTH, INC.

By: /s/ Harith Rajagopalan

Title: CEO

Date: 2023-Sep-12 I 13:19:11 PDT

EMPLOYEE

/s/ Timothy Kieffer

Timothy Kieffer

Date: 2023-Sep-12 I 13:52:07 PDT

Signature Page to Severance Agreement and Change in Control Agreement

**FIRST AMENDMENT TO
SEVERANCE AGREEMENT AND CHANGE IN CONTROL AGREEMENT**

THIS AMENDMENT TO SEVERANCE AGREEMENT AND CHANGE IN CONTROL AGREEMENT (this “*Amendment*”) is entered into by and between Fractyl Health, Inc. (the “*Company*”), and Tim Kieffer (the “*Executive*”) and will become effective, if at all, as of the date of the Company’s initial public offering of stock (“*IPO*”) pursuant to an effective registration statement filed under the Securities Act of 1933 (the “*Amendment Effective Date*”). Capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed to them in the CIC Severance Agreement (as defined below).

RECITALS

WHEREAS, the Company and the Executive are parties to that certain Severance Agreement and Change in Control Agreement, dated as of September 12, 2023 (the “*CIC Severance Agreement*”), which provides the Executive with severance benefits upon certain terminations of his employment; and

WHEREAS, the Company and the Executive mutually desire to amend the CIC Severance Agreement as set forth herein.

NOW, THEREFORE, in consideration of the Executive’s continued service with the Company and its subsidiaries and affiliates, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, effective as of the Amendment Effective Date, the Company and the Executive hereby agree as follows:

AMENDMENT

1. Section 2(a) of the CIC Severance Agreement is hereby amended by deleting “6” and replacing it with “12.”
2. Section 2(b) of the CIC Severance Agreement is hereby amended by deleting “6” and replacing it with “12.”
3. Section 3(a) of the CIC Severance Agreement is hereby amended by deleting “9” and replacing it with “12.”
4. Section 3(b) of the CIC Severance Agreement is hereby amended by deleting “9” and replacing it with “12.”
5. Section 3(c) of the CIC Severance Agreement is hereby amended and restated in its entirety to read as follows:

Equity Awards. Each outstanding and unvested equity award held by Employee under any Company equity compensation plan that vests solely based on continued employment or service, including, without limitation, a stock option or restricted stock award, shall automatically become vested and, if applicable, exercisable and any forfeiture restrictions or rights of repurchase thereon shall immediately lapse, in each case, with respect to one hundred percent (100%) of the unvested shares underlying such equity award as of the Termination Date (for the avoidance of doubt, with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

6. A new Section 3(d) is hereby added to the CIC Severance Agreement to read as follows:
Target Bonus. Employee shall be entitled to receive an amount in cash equal to 1.0 times the Employee's then-current target annual bonus, payable in a cash lump sum, less applicable withholdings, on the first payroll date following the date the Release of Claims becomes effective and irrevocable.
7. All other provisions of the CIC Severance Agreement shall remain in full force and effect according to their respective terms, and nothing contained herein shall be deemed a waiver of any right or abrogation of any obligation otherwise existing under the CIC Severance Agreement except to the extent specifically provided for herein. The validity, interpretation, construction and performance of this Amendment and the CIC Severance Agreement, as amended herein, shall be governed by the laws of the Commonwealth of Massachusetts without regard to principles of conflict of laws of such state that would require the application of the laws of any other jurisdiction. This Amendment may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document. To the extent that the IPO does not close before June 30, 2024, this Amendment will be null and void.

[Signature Page Follows]

IN WITNESS WHEREOF, the Company and Executive have executed this Amendment effective as of the Amendment Effective Date.

COMPANY

Fractyl Health, Inc.

Name:

Title:

EXECUTIVE

Tim Kieffer

(Signature Page to Amendment to CIC Severance Agreement)

**FRACTYL HEALTH, INC.
2024 INCENTIVE AWARD PLAN**

**ARTICLE I.
PURPOSE**

The Plan's purpose is to enhance the Company's ability to attract, retain and motivate persons who make (or are expected to make) important contributions to the Company by providing these individuals with equity ownership opportunities and/or equity-linked compensatory opportunities. Capitalized terms used in the Plan are defined in Article XI.

**ARTICLE II.
ELIGIBILITY**

Service Providers are eligible to be granted Awards under the Plan, subject to the limitations described herein.

**ARTICLE III.
ADMINISTRATION AND DELEGATION**

3.1 Administration. The Plan is administered by the Administrator. The Administrator has authority to determine which Service Providers receive Awards, grant Awards and set Award terms and conditions, subject to the conditions and limitations in the Plan. The Administrator also has the authority to take all actions and make all determinations under the Plan, to interpret the Plan and Award Agreements and to adopt, amend and repeal Plan administrative rules, guidelines and practices as it deems advisable. The Administrator may correct defects and ambiguities, supply omissions and reconcile inconsistencies in the Plan or any Award Agreement as it deems necessary or appropriate to administer the Plan and any Awards. The Administrator's determinations under the Plan are in its sole discretion and will be final and binding on all persons having or claiming any interest in the Plan or any Award.

3.2 Appointment of Committees. To the extent Applicable Laws permit, the Board may delegate any or all of its powers under the Plan to one or more Committees or officers of the Company or any of its Subsidiaries. The Board may abolish any Committee or re-vest in itself any previously delegated authority at any time.

**ARTICLE IV.
STOCK AVAILABLE FOR AWARDS**

4.1 Number of Shares. Subject to adjustment under Article VIII and the terms of this Article IV, Awards may be made under the Plan covering up to the Overall Share Limit. As of the Plan's effective date under Section 10.3, the Company will cease granting awards under the Prior Plan; however, Prior Plan Awards will remain subject to the terms and conditions of the Prior Plan. Shares issued under the Plan may consist of authorized but unissued Shares, Shares purchased on the open market or treasury Shares.

4.2 Share Recycling. If all or any part of an Award or Prior Plan Award expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, canceled without having been fully exercised/settled or forfeited, in any case, in a manner that results in the Company acquiring Shares covered by the Award or Prior Plan Award at a price not greater than the price (as adjusted to reflect any Equity Restructuring) paid by the Participant for such Shares or not issuing any Shares covered by the Award or

Prior Plan Award, the unused Shares covered by the Award or Prior Plan Award will, as applicable, become or again be available for Award grants under the Plan. Further, Shares delivered (either by actual delivery or attestation) to the Company by a Participant to satisfy the applicable exercise or purchase price of an Award or Prior Plan Award and/or to satisfy any applicable tax withholding obligation (including Shares retained by the Company from the Award or Prior Plan Award being exercised or purchased and/or creating the tax obligation) will, as applicable, become or again be available for Award grants under the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards or Prior Plan Awards shall not count against the Overall Share Limit.

4.3 Incentive Stock Option Limitations. Notwithstanding anything to the contrary herein, no more than 34,740,825 Shares may be issued pursuant to the exercise of Incentive Stock Options.

4.4 Substitute Awards. In connection with an entity's merger or consolidation with the Company or the Company's acquisition of an entity's property or stock, the Administrator may grant Awards in substitution for any options or other stock or stock-based awards granted before such merger or consolidation by such entity or its affiliate. Substitute Awards may be granted on such terms as the Administrator deems appropriate, notwithstanding limitations on Awards in the Plan. Substitute Awards will not count against the Overall Share Limit (nor shall Shares subject to a Substitute Award be added to the Shares available for Awards under the Plan as provided above), except that Shares acquired by exercise of substitute Incentive Stock Options will count against the maximum number of Shares that may be issued pursuant to the exercise of Incentive Stock Options under the Plan. Additionally, in the event that a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines has shares available under a pre-existing plan approved by stockholders and not adopted in contemplation of such acquisition or combination, the shares available for grant pursuant to the terms of such pre-existing plan (as adjusted, to the extent appropriate, using the exchange ratio or other adjustment or valuation ratio or formula used in such acquisition or combination to determine the consideration payable to the holders of common stock of the entities party to such acquisition or combination) may be used for Awards under the Plan and shall not reduce the Shares authorized for grant under the Plan (and Shares subject to such Awards shall not be added to the Shares available for Awards under the Plan as provided above); provided that Awards using such available shares shall not be made after the date awards or grants could have been made under the terms of the pre-existing plan, absent the acquisition or combination, and shall only be made to individuals who were not Service Providers prior to such acquisition or combination.

4.5 Non-Employee Director Compensation. Notwithstanding any provision to the contrary in the Plan, the Administrator may establish compensation for non-employee Directors from time to time, subject to the limitations in the Plan. The Administrator will from time to time determine the terms, conditions and amounts of all such non-employee Director compensation in its discretion and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time; provided that, the sum of any cash compensation, or other compensation, and the value (determined as of the grant date in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) of Awards granted to a non-employee Director as compensation for services as a non-employee Director during any fiscal year of the Company may not exceed \$750,000, increased to \$1,000,000 in the fiscal year in which the Plan's effective date occurs or in the fiscal year of a non-employee Director's initial service as a non-employee Director. The Administrator may make exceptions to this limit for individual non-employee Directors in extraordinary circumstances, as the Administrator may determine in its discretion, provided that the non-employee Director receiving such additional compensation may not participate in the decision to award such compensation or in other contemporaneous compensation decisions involving non-employee Directors.

ARTICLE V.
STOCK OPTIONS AND STOCK APPRECIATION RIGHTS

5.1 General. The Administrator may grant Options or Stock Appreciation Rights to Service Providers subject to the limitations in the Plan, including any limitations in the Plan that apply to Incentive Stock Options. The Administrator will determine the number of Shares covered by each Option and Stock Appreciation Right, the exercise price of each Option and Stock Appreciation Right and the conditions and limitations applicable to the exercise of each Option and Stock Appreciation Right. A Stock Appreciation Right will entitle the Participant (or other person entitled to exercise the Stock Appreciation Right) to receive from the Company upon exercise of the exercisable portion of the Stock Appreciation Right an amount determined by multiplying the excess, if any, of the Fair Market Value of one Share on the date of exercise over the exercise price per Share of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right is exercised, subject to any limitations of the Plan or that the Administrator may impose and payable in cash, Shares valued at Fair Market Value or a combination of the two as the Administrator may determine or provide in the Award Agreement.

5.2 Exercise Price. The Administrator will establish each Option's and Stock Appreciation Right's exercise price and specify the exercise price in the Award Agreement. Unless otherwise determined by the Administrator, the exercise price will not be less than 100% of the Fair Market Value on the grant date of the Option or Stock Appreciation Right.

5.3 Duration. Each Option or Stock Appreciation Right will be exercisable at such times and as specified in the Award Agreement, provided that the term of an Option or Stock Appreciation Right will not exceed ten years. Notwithstanding the foregoing and unless determined otherwise by the Company, in the event that on the last business day of the term of an Option or Stock Appreciation Right (other than an Incentive Stock Option) (i) the exercise of the Option or Stock Appreciation Right is prohibited by Applicable Laws, as determined by the Company, or (ii) Shares may not be purchased or sold by the applicable Participant due to any Company insider trading policy (including blackout periods) or a "lock-up" agreement undertaken in connection with an issuance of securities by the Company, the term of the Option or Stock Appreciation Right shall be automatically extended until the date that is thirty (30) days after the end of the legal prohibition, black-out period or lock-up agreement, as determined by the Company; provided, however, in no event shall the extension last beyond the ten year term of the applicable Option or Stock Appreciation Right. Notwithstanding the foregoing, if the Participant, prior to the end of the term of an Option or Stock Appreciation Right, violates the non-competition, non-solicitation, confidentiality or other similar restrictive covenant provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company or any of its Subsidiaries, the right of the Participant and the Participant's transferees to exercise any Option or Stock Appreciation Right issued to the Participant shall terminate immediately upon such violation, unless the Company otherwise determines. In addition, if, prior to the end of the term of an Option or Stock Appreciation Right, the Participant is given notice by the Company or any of its Subsidiaries of the Participant's Termination of Service by the Company or any of its Subsidiaries for Cause, and the effective date of such Termination of Service is subsequent to the date of the delivery of such notice, the right of the Participant and the Participant's transferees to exercise any Option or Stock Appreciation Right issued to the Participant shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service as a Service Provider will not be terminated for Cause as provided in such notice or (ii) the effective date of the Participant's Termination of Service by the Company or any of its Subsidiaries for Cause (in which case the right of the Participant and the Participant's transferees to exercise any Option or Stock Appreciation Right issued to the Participant will terminate immediately upon the effective date of such Termination of Service).

5.4 Exercise. Options and Stock Appreciation Rights may be exercised by delivering to the Company a written notice of exercise, in a form the Administrator approves (which may be electronic), signed by the person authorized to exercise the Option or Stock Appreciation Right, together with, as applicable, payment in full (i) as specified in Section 5.5 for the number of Shares for which the Award is exercised and (ii) as specified in Section 9.5 for any applicable taxes. Unless the Administrator otherwise determines, an Option or Stock Appreciation Right may not be exercised for a fraction of a Share.

5.5 Payment Upon Exercise. Subject to Section 10.8, any Company insider trading policy (including blackout periods) and Applicable Laws, the exercise price of an Option must be paid by:

(a) cash, wire transfer of immediately available funds or by check payable to the order of the Company, provided that the Company may limit the use of one of the foregoing payment forms if one or more of the payment forms below is permitted;

(b) if there is a public market for Shares at the time of exercise, unless the Company otherwise determines, (A) delivery (including electronically or telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to pay the exercise price, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to pay the exercise price; provided that such amount is paid to the Company at such time as may be required by the Administrator;

(c) to the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of Shares owned by the Participant valued at their Fair Market Value;

(d) to the extent permitted by the Administrator, surrendering Shares then issuable upon the Option's exercise valued at their Fair Market Value on the exercise date;

(e) to the extent permitted by the Administrator, delivery of a promissory note or any other property that the Administrator determines is good and valuable consideration; or

(f) to the extent permitted by the Company, any combination of the above payment forms approved by the Administrator.

ARTICLE VI. RESTRICTED STOCK; RESTRICTED STOCK UNITS

6.1 General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Service Provider, subject to the Company's right to repurchase all or part of such Shares at their issue price or other stated or formula price from the Participant (or to require forfeiture of such Shares) if conditions the Administrator specifies in the Award Agreement are not satisfied before the end of the applicable restriction period or periods that the Administrator establishes for such Award. In addition, the Administrator may grant to Service Providers Restricted Stock Units, which may be subject to vesting and forfeiture conditions during the applicable restriction period or periods, as set forth in an Award Agreement. The Administrator will determine and set forth in the Award Agreement the terms and conditions for each Restricted Stock and Restricted Stock Unit Award, subject to the conditions and limitations contained in the Plan.

6.2 Restricted Stock.

(a) Dividends. Participants holding Shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such Shares, unless the Administrator provides otherwise in the Award Agreement. In addition, unless the Administrator provides otherwise, if any dividends or distributions are paid in Shares, or consist of a dividend or distribution to holders of Common Stock of property other than an ordinary cash dividend, the Shares or other property will be subject to the same restrictions on transferability and forfeitability as the Shares of Restricted Stock with respect to which they were paid.

(b) Stock Certificates. The Company may require that the Participant deposit in escrow with the Company (or its designee) any stock certificates issued in respect of Shares of Restricted Stock, together with a stock power endorsed in blank.

6.3 Restricted Stock Units.

(a) Settlement. The Administrator may provide that settlement of Restricted Stock Units will occur upon or as soon as reasonably practicable after the Restricted Stock Units vest or will instead be deferred, on a mandatory basis or at the Participant's election, in a manner intended to comply with Section 409A.

(b) Stockholder Rights. A Participant will have no rights of a stockholder with respect to Shares subject to any Restricted Stock Unit unless and until the Shares are delivered in settlement of the Restricted Stock Unit.

(c) Dividend Equivalents. If the Administrator provides, a grant of Restricted Stock Units may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant, settled in cash or Shares and subject to the same restrictions on transferability and forfeitability as the Restricted Stock Units with respect to which the Dividend Equivalents are granted and subject to other terms and conditions as set forth in the Award Agreement.

ARTICLE VII. OTHER STOCK OR CASH BASED AWARDS

Other Stock or Cash Based Awards may be granted to Participants, including Awards entitling Participants to receive Shares to be delivered in the future and including annual or other periodic or long-term cash bonus awards (whether based on specified Performance Criteria or otherwise), in each case subject to any conditions and limitations in the Plan. Such Other Stock or Cash Based Awards will also be available as a payment form in the settlement of other Awards, as standalone payments and as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock or Cash Based Awards may be paid in Shares, cash or other property, or any combination of the foregoing, as the Administrator determines. Subject to the provisions of the Plan, the Administrator will determine the terms and conditions of each Other Stock or Cash Based Award, including any purchase price, performance goal(s) (which may be based on the Performance Criteria), transfer restrictions, and vesting conditions, which will be set forth in the applicable Award Agreement.

**ARTICLE VIII.
ADJUSTMENTS FOR CHANGES IN COMMON STOCK
AND CERTAIN OTHER EVENTS**

8.1 Equity Restructuring(a). In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Article VIII, the Administrator will equitably adjust each outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include adjusting the number and type of securities subject to each outstanding Award and/or the Award's exercise price or grant price (if applicable), granting new Awards to Participants, and making a cash payment to Participants. The adjustments provided under this Section 8.1 will be nondiscretionary and final and binding on the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

8.2 Corporate Transactions. In the event of any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, combination, amalgamation, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, Change in Control, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Laws or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Laws or accounting principles may be made within a reasonable period of time after such change), is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Laws or accounting principles:

(a) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;

(b) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all Shares covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(c) To provide that such Award be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and/or applicable exercise or purchase price, in all cases, as determined by the Administrator;

(d) To make adjustments in the number and type of Shares (or other securities or property) subject to outstanding Awards and/or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Article IV hereof on the maximum number and kind of shares which may be issued) and/or in the terms and conditions of (including the grant or exercise price or applicable performance goals), and the criteria included in, outstanding Awards;

(e) To replace such Award with other rights or property selected by the Administrator; and/or

(f) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

8.3 Non-Assumption of Awards. Notwithstanding Section 8.2 above, if a Change in Control occurs and a Participant's Award(s) are not continued, converted, assumed, or replaced with a substantially similar award by (i) the Company, or (ii) a successor entity or its parent or subsidiary (an "Assumption"), and provided that the Participant has not had a Termination of Service, then immediately prior to the Change in Control such Awards (other than any portion that is subject to performance-based vesting) shall become fully vested, exercisable and/or payable, as applicable, and all forfeiture, repurchase and other restrictions thereon shall lapse, in which case, such Awards shall be canceled upon the consummation of the Change in Control in exchange for the right to receive the Change in Control consideration payable to other holders of Common Stock (A) which may be on such terms and conditions as apply generally to holders of Common Stock under the Change in Control documents (including, without limitation, any earn-out or other deferred consideration provisions) or such other terms and conditions as the Administrator may provide, and (B) determined by reference to the number of Shares subject to such Awards and net of any applicable exercise price; provided that (1) to the extent that any such Awards constitute "nonqualified deferred compensation" that may not be paid upon the Change in Control under Section 409A without the imposition of taxes thereon under Section 409A, the timing of such payments shall be governed by the applicable Award Agreement (subject to any deferred consideration provisions applicable under the Change in Control documents), (2) the portion of any Award subject to performance-based vesting shall be governed by the terms and conditions of the applicable Award Agreement and, in the absence of applicable terms and conditions, the Administrator's discretion, and (3) if the amount to which a Participant would be entitled upon the settlement or exercise of an Award at the time of the Change in Control is equal to or less than zero, then such Award may be terminated without payment. The Administrator shall determine whether an Assumption of an Award has occurred in connection with a Change in Control.

8.4 Administrative Stand Still. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of Common Stock, including any Equity Restructuring or any securities offering or other similar transaction, for administrative convenience, the Administrator may refuse to permit the exercise of any Award for up to sixty days before or after such transaction.

8.5 General. Except as expressly provided in the Plan or the Administrator's action under the Plan, no Participant will have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section 8.1 above or the Administrator's action under the Plan, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to an Award or the Award's grant or exercise price. The existence of the Plan, any Award Agreements and the Awards granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares. The Administrator may treat Participants and Awards (or portions thereof) differently under this Article VIII.

ARTICLE IX.
GENERAL PROVISIONS APPLICABLE TO AWARDS

9.1 Transferability. Except as the Administrator may determine or provide in an Award Agreement or otherwise for Awards other than Incentive Stock Options, Awards may not be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law, except by will or the laws of descent and distribution, or, subject to the Administrator's consent, pursuant to a domestic relations order, and, during the life of the Participant, will be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, will include references to a Participant's authorized transferee that the Administrator specifically approves.

9.2 Documentation. Each Award will be evidenced in an Award Agreement, which may be written or electronic, as the Administrator determines. Each Award may contain terms and conditions in addition to those set forth in the Plan.

9.3 Discretion. Except as the Plan otherwise provides, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.

9.4 Termination of Status. The Administrator will determine how a Participant's Disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's Service Provider status affects an Award (including whether and when a Termination of Service has occurred) and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable.

9.5 Withholding. Each Participant must pay the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by Applicable Laws to be withheld in connection with such Participant's Awards by the date of the event creating the tax liability. The Company may deduct an amount sufficient to satisfy such tax obligations based on the applicable statutory withholding rates (or such other rate as may be determined by the Company after considering any accounting consequences or costs) from any payment of any kind otherwise due to a Participant. Subject to Section 10.8 and any Company insider trading policy (including blackout periods), Participants may satisfy such tax obligations (i) in cash, by wire transfer of immediately available funds, by check made payable to the order of the Company, provided that the Company may limit the use of the foregoing payment forms if one or more of the payment forms below is permitted, (ii) to the extent permitted by the Administrator, in whole or in part by delivery of Shares, including Shares retained from the Award creating the tax obligation, valued at their fair market value, (iii) if there is a public market for Shares at the time the tax obligations are satisfied, unless the Company otherwise determines, (A) delivery (including electronically or telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the tax obligations, or (B) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company cash or a check sufficient to satisfy the tax withholding; provided that such amount is paid to the Company at such time as may be required by the Administrator, or (iv) to the extent permitted by the Administrator, any combination of the foregoing payment forms approved by the Company. If any tax withholding obligation will be satisfied under clause (ii) of the immediately preceding sentence by the Company's retention of Shares from the Award creating the tax obligation and there is a public market for Shares at the time the tax obligation is satisfied, the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on the applicable Participant's behalf some or all of the Shares retained and to remit the proceeds of the sale to the Company or its designee, and each Participant's acceptance of an Award under the Plan will constitute the Participant's authorization to the Company and instruction and authorization to such brokerage firm to complete the transactions described in this sentence.

9.6 Amendment of Award; Repricing. The Administrator may amend, modify or terminate any outstanding Award, including by substituting another Award of the same or a different type, changing the exercise or settlement date, and converting an Incentive Stock Option to a Non-Qualified Stock Option. The Participant's consent to such action will be required unless (i) the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Award, or (ii) the change is permitted under Article VIII or pursuant to Section 10.6. Further, the Administrator may, without the approval of the stockholders of the Company, reduce the exercise price per share of outstanding Options or Stock Appreciation Rights or cancel outstanding Options or Stock Appreciation Rights in exchange for cash, other Awards or Options or Stock Appreciation Rights with an exercise price per share that is less than the exercise price per share of the original Options or Stock Appreciation Rights.

9.7 Conditions on Delivery of Stock. The Company will not be obligated to deliver any Shares under the Plan or remove restrictions from Shares previously delivered under the Plan until (i) all Award conditions have been met or removed to the Company's satisfaction, (ii) as determined by the Company, all other legal matters regarding the issuance and delivery of such Shares have been satisfied, including any applicable securities laws and stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy any Applicable Laws. The Company's inability to obtain authority from any regulatory body having jurisdiction, which the Administrator determines is necessary to the lawful issuance and sale of any securities, will relieve the Company of any liability for failing to issue or sell such Shares as to which such requisite authority has not been obtained.

9.8 Acceleration. The Administrator may at any time provide that any Award will become immediately vested and fully or partially exercisable, free of some or all restrictions or conditions, or otherwise fully or partially realizable.

9.9 Additional Terms of Incentive Stock Options. The Administrator may grant Incentive Stock Options only to employees of the Company, any of its present or future parent or subsidiary corporations, as defined in Sections 424(e) or (f) of the Code, respectively, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code. If an Incentive Stock Option is granted to a Greater Than 10% Stockholder, the exercise price will not be less than 110% of the Fair Market Value on the Option's grant date, and the term of the Option will not exceed five years. All Incentive Stock Options will be subject to and construed consistently with Section 422 of the Code. By accepting an Incentive Stock Option, the Participant agrees to give prompt notice to the Company of dispositions or other transfers (other than in connection with a Change in Control) of Shares acquired under the Option made within (i) two years from the grant date of the Option or (ii) one year after the transfer of such Shares to the Participant, specifying the date of the disposition or other transfer and the amount the Participant realized, in cash, other property, assumption of indebtedness or other consideration, in such disposition or other transfer. Neither the Company nor the Administrator will be liable to a Participant, or any other party, if an Incentive Stock Option fails or ceases to qualify as an "incentive stock option" under Section 422 of the Code. Any Incentive Stock Option or portion thereof that fails to qualify as an "incentive stock option" under Section 422 of the Code for any reason, including becoming exercisable with respect to Shares having a fair market value exceeding the \$100,000 limitation under Treasury Regulation Section 1.422-4, will be a Non-Qualified Stock Option.

ARTICLE X. MISCELLANEOUS

10.1 No Right to Employment or Other Status. No person will have any claim or right to be granted an Award, and the grant of an Award will not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an Award Agreement.

10.2 No Rights as Stockholder; Certificates. Subject to the Award Agreement, no Participant or Designated Beneficiary will have any rights as a stockholder with respect to any Shares to be distributed under an Award until becoming the record holder of such Shares. Notwithstanding any other provision of the Plan, unless the Administrator otherwise determines or Applicable Laws require, the Company will not be required to deliver to any Participant certificates evidencing Shares issued in connection with any Award and instead such Shares may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on stock certificates issued under the Plan that the Administrator deems necessary or appropriate to comply with Applicable Laws.

10.3 Effective Date and Term of Plan. Unless earlier terminated by the Board, the Plan will become effective on the day prior to the Public Trading Date and will remain in effect until the tenth anniversary of the earlier of (i) the date the Board adopted the Plan or (ii) the date the Company's stockholders approved the Plan, but Awards previously granted may extend beyond that date in accordance with the Plan. If the Plan is not approved by the Company's stockholders, the Plan will not become effective, no Awards will be granted under the Plan, and the Prior Plan will continue in full force and effect in accordance with its terms.

10.4 Amendment of Plan. The Administrator may amend, suspend or terminate the Plan at any time; provided that no amendment, other than an increase to the Overall Share Limit, may materially and adversely affect any Award outstanding at the time of such amendment without the affected Participant's consent. No Awards may be granted under the Plan during any suspension period or after Plan termination. Awards outstanding at the time of any Plan suspension or termination will continue to be governed by the Plan and the Award Agreement, as in effect before such suspension or termination. The Board will obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Laws.

10.5 Provisions for Foreign Participants. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to address differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

10.6 Section 409A.

(a) General. The Company intends that all Awards be structured to comply with, or be exempt from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply. Notwithstanding anything in the Plan or any Award Agreement to the contrary, the Administrator may, without a Participant's consent, amend this Plan or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and retroactive actions) as are necessary or appropriate to preserve the intended tax treatment of Awards, including any such actions intended to (A) exempt this Plan or any Award from Section 409A, or (B) comply with Section 409A, including regulations, guidance, compliance programs and other interpretative authority that may be issued after an Award's grant date. The Company makes no representations or warranties as to an Award's tax treatment under Section 409A or otherwise. The Company will have no obligation under this Section 10.6 or otherwise to avoid the taxes, penalties or interest under Section 409A with respect to any Award and will have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute noncompliant "nonqualified deferred compensation" subject to taxes, penalties or interest under Section 409A. Notwithstanding any contrary provision of the Plan or any Award Agreement, any payment of "nonqualified deferred compensation" under the Plan that may be made in installments shall be treated as a right to receive a series of separate and distinct payments.

(b) Separation from Service. If an Award constitutes “nonqualified deferred compensation” under Section 409A, any payment or settlement of such Award upon a termination of a Participant’s Service Provider relationship will, to the extent necessary to avoid taxes under Section 409A, be made only upon the Participant’s “separation from service” (within the meaning of Section 409A), whether such “separation from service” occurs upon or after the termination of the Participant’s Service Provider relationship. For purposes of this Plan or any Award Agreement relating to any such payments or benefits, references to a “termination,” “termination of employment” or like terms means a “separation from service.”

(c) Payments to Specified Employees. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of “nonqualified deferred compensation” required to be made under an Award to a “specified employee” (as defined under Section 409A and as the Administrator determines) due to his or her “separation from service” will, to the extent necessary to avoid taxes under Section 409A(a)(2)(B)(i) of the Code, be delayed for the six-month period immediately following such “separation from service” (or, if earlier, until the specified employee’s death) and will instead be paid (as set forth in the Award Agreement) on the day immediately following such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of “nonqualified deferred compensation” under such Award payable more than six months following the Participant’s “separation from service” will be paid at the time or times the payments are otherwise scheduled to be made.

10.7 Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company or any Subsidiary will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in his or her capacity as an Administrator, director, officer, other employee or agent of the Company or any Subsidiary. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company or any Subsidiary that has been or will be granted or delegated any duty or power relating to the Plan’s administration or interpretation, against any cost or expense (including attorneys’ fees) or liability (including any sum paid in settlement of a claim with the Administrator’s approval) arising from any act or omission concerning this Plan unless arising from such person’s own fraud or bad faith.

10.8 Lock-Up Period. The Company may, at the request of any underwriter representative or otherwise, in connection with registering the offering of any Company securities under the Securities Act, prohibit Participants from, directly or indirectly, selling or otherwise transferring any Shares or other Company securities during a period of up to one hundred eighty days following the effective date of a Company registration statement filed under the Securities Act, or such longer period as determined by the underwriter.

10.9 Data Privacy. As a condition for receiving any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this section by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing the Participant’s participation in the Plan. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant’s name, address and telephone number; birthdate; social security number, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer the Plan and Awards (the “*Data*”). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant’s participation in the Plan, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in the

Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. By accepting an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or withdraw the consents in this Section 10.9 in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws the consents in this Section 10.9. For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

10.10 Severability. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

10.11 Governing Documents. If any contradiction occurs between the Plan and any Award Agreement or other written agreement between a Participant and the Company (or any Subsidiary) that the Administrator has approved, the Plan will govern, unless it is expressly specified in such Award Agreement or other written document that a specific provision of the Plan will not apply.

10.12 Governing Law. The Plan and all Awards will be governed by and interpreted in accordance with the laws of the State of Delaware, disregarding any state's choice-of-law principles requiring the application of a jurisdiction's laws other than the State of Delaware.

10.13 Claw-back Provisions. All Awards (including any proceeds, gains or other economic benefit the Participant actually or constructively receives upon receipt or exercise of any Award or the receipt or resale of any Shares underlying the Award) will be subject to any Company claw-back policy, including any claw-back policy adopted to comply with Applicable Laws (including the Dodd-Frank Wall Street Reform and Consumer Protection Act and any rules or regulations promulgated thereunder) as set forth in such claw-back policy or the Award Agreement.

10.14 Titles and Headings. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.

10.15 Conformity to Securities Laws. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Laws. Notwithstanding anything herein to the contrary, the Plan and all Awards will be administered only in conformance with Applicable Laws. To the extent Applicable Laws permit, the Plan and all Award Agreements will be deemed amended as necessary to conform to Applicable Laws.

10.16 Relationship to Other Benefits. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except as expressly provided in writing in such other plan or an agreement thereunder.

10.17 **Broker-Assisted Sales.** In the event of a broker-assisted sale of Shares in connection with the payment of amounts owed by a Participant under or with respect to the Plan or Awards, including amounts to be paid under the final sentence of Section 9.5: (a) any Shares to be sold through the broker-assisted sale will be sold on the day the payment first becomes due, or as soon thereafter as practicable; (b) such Shares may be sold as part of a block trade with other Participants in the Plan in which all participants receive an average price; (c) the applicable Participant will be responsible for all broker's fees and other costs of sale, and by accepting an Award, each Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (d) to the extent the Company or its designee receives proceeds of such sale that exceed the amount owed, the Company will pay such excess in cash to the applicable Participant as soon as reasonably practicable; (e) the Company and its designees are under no obligation to arrange for such sale at any particular price; and (f) in the event the proceeds of such sale are insufficient to satisfy the Participant's applicable obligation, the Participant may be required to pay immediately upon demand to the Company or its designee an amount in cash sufficient to satisfy any remaining portion of the Participant's obligation.

ARTICLE XI. DEFINITIONS

As used in the Plan, the following words and phrases will have the following meanings:

11.1 "**Administrator**" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

11.2 "**Applicable Laws**" means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where Awards are granted.

11.3 "**Award**" means, individually or collectively, a grant under the Plan of Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Dividend Equivalents or Other Stock or Cash Based Awards.

11.4 "**Award Agreement**" means a written agreement evidencing an Award, which may be electronic, that contains such terms and conditions as the Administrator determines, consistent with and subject to the terms and conditions of the Plan.

11.5 "**Board**" means the Board of Directors of the Company.

11.6 "**Cause**" means (i) if a Participant is a party to a written employment or consulting agreement with the Company or any of its Subsidiaries or an Award Agreement in which the term "cause" is defined (a "**Relevant Agreement**"), "Cause" as defined in the Relevant Agreement, and (ii) if no Relevant Agreement exists, (A) the Administrator's determination that the Participant failed to substantially perform the Participant's duties (other than a failure resulting from the Participant's Disability); (B) the Administrator's determination that the Participant failed to carry out, or comply with any lawful and reasonable directive of the Board or the Participant's immediate supervisor; (C) the occurrence of any act or omission by the Participant that could reasonably be expected to result in (or has resulted in) the Participant's conviction, plea of no contest, plea of nolo contendere, or imposition of unadjudicated probation for any felony or indictable offense or crime involving moral turpitude; (D) the Participant's unlawful use (including being under the influence) or possession of illegal drugs on the premises of the Company or any of its Subsidiaries or while performing the Participant's duties and responsibilities for the Company or any of its Subsidiaries; or (E) the Participant's commission of an act of fraud, embezzlement, misappropriation, misconduct, or breach of fiduciary duty against the Company or any of its Subsidiaries.

11.7 “**Change in Control**” means and includes each of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of transactions that meets the requirements of clauses (i) and (ii) of subsection (c) below) whereby any “person” or related “group” of “persons” (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than the Company, any of its Subsidiaries, an employee benefit plan maintained by the Company or any of its Subsidiaries or a “person” that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company’s securities outstanding immediately after such acquisition; or

(b) During any period of two consecutive years, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in subsections (a) or (c)) whose election by the Board or nomination for election by the Company’s stockholders was approved by a vote of at least two-thirds of the Directors then still in office who either were Directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company’s assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company’s voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company’s assets or otherwise succeeds to the business of the Company (the Company or such person, the “**Successor Entity**”)) directly or indirectly, at least a majority of the combined voting power of the Successor Entity’s outstanding voting securities immediately after the transaction, and

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or portion of any Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (a), (b) or (c) with respect to such Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of such Award if such transaction also constitutes a “change in control event,” as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a “change in control event” as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

11.8 “**Code**” means the Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.

11.9 “**Committee**” means one or more committees or subcommittees of the Board, which may include one or more Company directors or executive officers, to the extent Applicable Laws permit. To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3, a “non-employee director” within the meaning of Rule 16b-3; however, a Committee member’s failure to qualify as a “non-employee director” within the meaning of Rule 16b-3 will not invalidate any Award granted by the Committee that is otherwise validly granted under the Plan.

11.10 “**Common Stock**” means the common stock of the Company.

11.11 “**Company**” means Fractyl Health, Inc., a Delaware corporation, or any successor.

11.12 “**Consultant**” means any person, including any adviser, engaged by the Company or its parent or Subsidiary to render services to such entity if the consultant or adviser: (i) renders bona fide services to the Company; (ii) renders services not in connection with the offer or sale of securities in a capital-raising transaction and does not directly or indirectly promote or maintain a market for the Company’s securities; and (iii) is a natural person.

11.13 “**Designated Beneficiary**” means the beneficiary or beneficiaries the Participant designates, in a manner the Administrator determines, to receive amounts due or exercise the Participant’s rights if the Participant dies or becomes incapacitated. Without a Participant’s effective designation, “Designated Beneficiary” will mean the Participant’s estate.

11.14 “**Director**” means a Board member.

11.15 “**Disability**” means a permanent and total disability under Section 22(e)(3) of the Code, as amended.

11.16 “**Dividend Equivalents**” means a right granted to a Participant under the Plan to receive the equivalent value (in cash or Shares) of dividends paid on Shares.

11.17 “**Employee**” means any employee of the Company or its Subsidiaries.

11.18 “**Equity Restructuring**” means a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split, spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other Company securities) or the share price of Common Stock (or other Company securities) and causes a change in the per share value of the Common Stock underlying outstanding Awards.

11.19 “**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

11.20 “**Fair Market Value**” means, as of any date, the value of a Share determined as follows: (i) if the Common Stock is listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Common Stock as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; (ii) if the Common Stock is not traded on a stock exchange but is quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; or (iii) without an established market for the Common Stock, the Administrator will determine the Fair Market Value in its discretion. Notwithstanding the foregoing, with respect to any Award granted on the pricing date of the Company’s initial public offering, the Fair Market Value shall mean the initial public offering price of a Share as set forth in the Company’s final prospectus relating to its initial public offering filed with the Securities and Exchange Commission.

11.21 “**Greater Than 10% Stockholder**” means an individual then owning (within the meaning of Section 424(d) of the Code) more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary corporation, as defined in Section 424(e) and (f) of the Code, respectively.

11.22 “**Incentive Stock Option**” means an Option intended to qualify as an “incentive stock option” as defined in Section 422 of the Code.

11.23 “**Non-Qualified Stock Option**” means an Option not intended or not qualifying as an Incentive Stock Option.

11.24 “**Option**” means an option to purchase Shares, which will either be an Incentive Stock Option or a Non-Qualified Stock Option.

11.25 “**Other Stock or Cash Based Awards**” means cash awards, awards of Shares, and other awards valued wholly or partially by referring to, or are otherwise based on, Shares or other property.

11.26 “**Overall Share Limit**” means the sum of (i) 4,298,825 Shares; (ii) any Shares which are subject to Prior Plan Awards which become available for issuance under the Plan pursuant to Article IV and (iii) an annual increase on the first day of each calendar year beginning January 1, 2025 and ending on and including January 1, 2034, equal to the lesser of (A) 5% of the aggregate number of Shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of Shares as is determined by the Board.

11.27 “**Participant**” means a Service Provider who has been granted an Award.

11.28 “**Performance Criteria**” means the criteria (and adjustments) that the Administrator may select for an Award to establish performance goals for a performance period, which may include (but is not limited to) the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders’ equity; total stockholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share;

price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the Company's performance or the performance of a Subsidiary, division, business segment or business unit of the Company or a Subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. The Administrator may provide for exclusion of the impact of an event or occurrence which the Administrator determines should appropriately be excluded, including (a) restructurings, discontinued operations, extraordinary items, and other unusual, infrequently occurring or non-recurring charges or events, (b) asset write-downs, (c) litigation or claim judgments or settlements, (d) acquisitions or divestitures, (e) reorganization or change in the corporate structure or capital structure of the Company, (f) an event either not directly related to the operations of the Company, Subsidiary, division, business segment or business unit or not within the reasonable control of management, (g) foreign exchange gains and losses, (h) a change in the fiscal year of the Company, (i) the refinancing or repurchase of bank loans or debt securities, (j) unbudgeted capital expenditures, (k) the issuance or repurchase of equity securities and other changes in the number of outstanding shares, (l) conversion of some or all of convertible securities to Common Stock, (m) any business interruption event (n) the cumulative effects of tax or accounting changes in accordance with U.S. generally accepted accounting principles, or (o) the effect of changes in other laws or regulatory rules affecting reported results.

11.29 "**Plan**" means this 2024 Incentive Award Plan.

11.30 "**Prior Plan**" means the Fractyl Health, Inc. 2011 Stock Incentive Plan, as amended and restated.

11.31 "**Prior Plan Award**" means an award outstanding under the Prior Plan as of the Plan's effective date in Section 10.3.

11.32 "**Public Trading Date**" means the first date upon which the Common Stock is listed (or approved for listing) upon notice of issuance on any securities exchange or designated (or approved for designation) upon notice of issuance as a national market security on an interdealer quotation system, or, if earlier, the date on which the Company becomes a "publicly held corporation" for purposes of Treasury Regulation Section 1.162-27(c)(1).

11.33 "**Restricted Stock**" means Shares awarded to a Participant under Article VI subject to certain vesting conditions and other restrictions.

11.34 "**Restricted Stock Unit**" means an unfunded, unsecured right to receive, on the applicable settlement date, one Share or an amount in cash or other consideration determined by the Administrator to be of equal value as of such settlement date awarded to a Participant under Article VI, subject to certain vesting conditions and other restrictions.

11.35 "**Rule 16b-3**" means Rule 16b-3 promulgated under the Exchange Act.

11.36 “**Section 409A**” means Section 409A of the Code and all regulations, guidance, compliance programs and other interpretative authority thereunder.

11.37 “**Securities Act**” means the Securities Act of 1933, as amended.

11.38 “**Service Provider**” means an Employee, Consultant or Director.

11.39 “**Shares**” means shares of Common Stock.

11.40 “**Stock Appreciation Right**” means a stock appreciation right granted under Article V.

11.41 “**Subsidiary**” means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

11.42 “**Substitute Awards**” means Awards granted or Shares issued by the Company in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company acquired by the Company or any Subsidiary or with which the Company or any Subsidiary combines.

11.43 “**Termination of Service**” means Participant ceasing to be a Service Provider.

* * * * *

**FRACTYL HEALTH, INC.
2024 INCENTIVE AWARD PLAN**

STOCK OPTION GRANT NOTICE

Capitalized terms not specifically defined in this Stock Option Grant Notice (the “*Grant Notice*”) have the meanings given to them in the 2024 Incentive Award Plan (as amended from time to time, the “*Plan*”) of Fractyl Health, Inc. (the “*Company*”).

The Company has granted to the participant listed below (“*Participant*”) the stock option described in this Grant Notice (the “*Option*”), subject to the terms and conditions of the Plan and the Stock Option Agreement attached as **Exhibit A** (the “*Agreement*”), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Exercise Price per Share:

Shares Subject to the Option:

Final Expiration Date:

Vesting Commencement Date:

Vesting Schedule:

Type of Option:

By Participant’s signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

FRACTYL HEALTH, INC.

PARTICIPANT

By: _____

Name: _____

Title: _____

STOCK OPTION AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

**ARTICLE XII.
GENERAL**

12.1 Grant of Option. The Company has granted to Participant the Option effective as of the grant date set forth in the Grant Notice (the “*Grant Date*”).

12.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

**ARTICLE XIII.
PERIOD OF EXERCISABILITY**

13.1 Commencement of Exercisability. The Option will vest and become exercisable according to the vesting schedule in the Grant Notice (the “*Vesting Schedule*”) except that any fraction of a Share as to which the Option would be vested or exercisable will be accumulated and will vest and become exercisable only when a whole Share has accumulated. Notwithstanding anything in the Grant Notice, the Plan or this Agreement to the contrary, unless the Administrator otherwise determines, the Option will immediately expire and be forfeited as to any portion that is not vested and exercisable as of Participant’s Termination of Service for any reason.

13.2 Duration of Exercisability. The Vesting Schedule is cumulative. Any portion of the Option which vests and becomes exercisable will remain vested and exercisable until the Option expires. The Option will be forfeited immediately upon its expiration.

13.3 Expiration of Option. The Option may not be exercised to any extent by anyone after, and will expire on, the first of the following to occur:

(a) The final expiration date in the Grant Notice;

(b) Except as the Administrator may otherwise approve, the expiration of ninety (90) days from the date of Participant’s Termination of Service, unless Participant’s Termination of Service is for Cause or by reason of Participant’s death or Disability;

(c) Except as the Administrator may otherwise approve, the expiration of one (1) year from the date of Participant’s Termination of Service by reason of Participant’s death or Disability; and

(d) Except as the Administrator may otherwise approve, Participant’s Termination of Service for Cause.

**ARTICLE XIV.
EXERCISE OF OPTION**

14.1 Person Eligible to Exercise. During Participant’s lifetime, only Participant may exercise the Option. After Participant’s death, any exercisable portion of the Option may, prior to the time the Option expires, be exercised by Participant’s Designated Beneficiary as provided in the Plan.

14.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised, in whole or in part, according to the procedures in the Plan at any time prior to the time the Option or portion thereof expires, except that the Option may only be exercised for whole Shares.

14.3 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Option as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Option.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

ARTICLE XV. OTHER PROVISIONS

15.1 Adjustments. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

15.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is then deceased, to the person entitled to exercise the Option) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

15.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

15.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

15.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

15.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Option will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

15.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

15.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

15.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

15.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

15.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

15.12 Incentive Stock Options. If the Option is designated as an Incentive Stock Option:

(a) Participant acknowledges that to the extent the aggregate fair market value of shares (determined as of the time the option with respect to the shares is granted) with respect to which stock options intended to qualify as "incentive stock options" under Section 422 of the Code, including the Option, are exercisable for the first time by Participant during any calendar year exceeds \$100,000 or if for any other reason such stock options do not qualify or cease to qualify for treatment as "incentive stock options" under Section 422 of the Code, such stock options (including the Option) will be treated as non-qualified stock options. Participant further acknowledges that the rule set forth in the preceding sentence will be applied by taking the Option and other stock options into account in the order in which they were granted, as determined under Section 422(d) of the Code. Participant acknowledges that amendments or modifications made to the Option pursuant to the Plan that would cause the Option to become a Non-Qualified Stock Option will not materially or adversely affect Participant's rights under the Option, and that any such amendment or modification shall not require Participant's consent. Participant also acknowledges that if the Option is exercised more than ninety (90) days after Participant's Termination of Service as an Employee, other than by reason of death or Disability, the Option will be taxed as a Non-Qualified Stock Option.

(b) Participant will give prompt written notice to the Company of any disposition or other transfer of any Shares acquired under this Agreement if such disposition or other transfer is made (a) within two (2) years from the Grant Date or (b) within one (1) year after the transfer of such Shares to Participant. Such notice will specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by Participant in such disposition or other transfer.

* * * * *

**FRACTYL HEALTH, INC.
2024 INCENTIVE AWARD PLAN**

STOCK OPTION GRANT NOTICE

Capitalized terms not specifically defined in this Stock Option Grant Notice (the “*Grant Notice*”) have the meanings given to them in the 2024 Incentive Award Plan (as amended from time to time, the “*Plan*”) of Fractyl Health, Inc. (the “*Company*”).

The Company has granted to the participant listed below (“*Participant*”) the stock option described in this Grant Notice (the “*Option*”), subject to the terms and conditions of the Plan and the Stock Option Agreement attached as **Exhibit A** (the “*Agreement*”), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Exercise Price per Share:

Shares Subject to the Option:

Final Expiration Date:

Vesting Commencement Date:

Vesting Schedule:

Type of Option: Non-Qualified Stock Option

By Participant’s signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

FRACTYL HEALTH, INC.

PARTICIPANT

By: _____

Name: _____

Title: _____

STOCK OPTION AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

**ARTICLE XVI.
GENERAL**

16.1 Grant of Option. The Company has granted to Participant the Option effective as of the grant date set forth in the Grant Notice (the “**Grant Date**”).

16.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

**ARTICLE XVII.
PERIOD OF EXERCISABILITY**

17.1 Commencement of Exercisability. The Option will vest and become exercisable according to the vesting schedule in the Grant Notice (the “**Vesting Schedule**”) except that any fraction of a Share as to which the Option would be vested or exercisable will be accumulated and will vest and become exercisable only when a whole Share has accumulated. Notwithstanding anything in the Grant Notice, the Plan or this Agreement to the contrary, unless the Administrator otherwise determines, the Option will immediately expire and be forfeited as to any portion that is not vested and exercisable as of the date Participant ceases to be a non-employee Director for any reason (a “**Termination of Service**”).

17.2 Duration of Exercisability. The Vesting Schedule is cumulative. Any portion of the Option which vests and becomes exercisable will remain vested and exercisable until the Option expires. The Option will be forfeited immediately upon its expiration.

17.3 Expiration of Option. The Option may not be exercised to any extent by anyone after, and will expire on, the first of the following to occur:

(a) The final expiration date in the Grant Notice;

(b) Except as the Administrator may otherwise approve, the expiration of ninety (90) days from the date of Participant’s Termination of Service; and

(c) Except as the Administrator may otherwise approve, the expiration of one (1) year from the date of Participant’s Termination of Service by reason of Participant’s death or Disability.

**ARTICLE XVIII.
EXERCISE OF OPTION**

18.1 Person Eligible to Exercise. During Participant’s lifetime, only Participant may exercise the Option. After Participant’s death, any exercisable portion of the Option may, prior to the time the Option expires, be exercised by Participant’s Designated Beneficiary as provided in the Plan.

18.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised, in whole or in part, according to the procedures in the Plan at any time prior to the time the Option or portion thereof expires, except that the Option may only be exercised for whole Shares.

18.3 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Option as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Option.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Option, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Option. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or exercise of the Option or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the Option to reduce or eliminate Participant's tax liability.

ARTICLE XIX. OTHER PROVISIONS

19.1 Adjustments. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

19.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant (or, if Participant is then deceased, to the person entitled to exercise the Option) at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

19.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

19.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

19.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

19.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Option will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

19.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

19.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

19.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Option, as and when exercised pursuant to the terms hereof.

19.10 Not a Contract of Service. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

19.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

**FRACTYL HEALTH, INC.
2024 INCENTIVE AWARD PLAN**

RESTRICTED STOCK GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Stock Grant Notice (the “*Grant Notice*”) have the meanings given to them in the 2024 Incentive Award Plan (as amended from time to time, the “*Plan*”) of Fractyl Health, Inc. (the “*Company*”).

The Company has granted to the participant listed below (“*Participant*”) the shares of Restricted Stock described in this Grant Notice (the “*Restricted Shares*”), subject to the terms and conditions of the Plan and the Restricted Stock Agreement attached as **Exhibit A** (the “*Agreement*”), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Number of Restricted Shares:

Vesting Commencement Date:

Vesting Schedule:

By Participant’s signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

FRACTYL HEALTH, INC.

PARTICIPANT

By: _____

Name: _____

Title: _____

RESTRICTED STOCK AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

ARTICLE XX. GENERAL

20.1 Issuance of Restricted Shares. The Company will issue the Restricted Shares to the Participant effective as of the grant date set forth in the Grant Notice and will cause (a) a stock certificate or certificates representing the Restricted Shares to be registered in Participant's name or (b) the Restricted Shares to be held in book-entry form. If a stock certificate is issued, the certificate will be delivered to, and held in accordance with this Agreement by, the Company or its authorized representatives and will bear the restrictive legends required by this Agreement. If the Restricted Shares are held in book-entry form, then the book-entry will indicate that the Restricted Shares are subject to the restrictions of this Agreement.

20.2 Incorporation of Terms of Plan. The Restricted Shares are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

ARTICLE XXI. VESTING, FORFEITURE AND ESCROW

21.1 Vesting. The Restricted Shares will become vested Shares (the "*Vested Shares*") according to the vesting schedule in the Grant Notice except that any fraction of a Share that would otherwise become a Vested Share will be accumulated and will become a Vested Share only when a whole Vested Share has accumulated.

21.2 Forfeiture. In the event of Participant's Termination of Service for any reason, Participant will immediately and automatically forfeit to the Company any Shares that are not Vested Shares (the "*Unvested Shares*") at the time of Participant's Termination of Service, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Upon forfeiture of Unvested Shares, the Company will become the legal and beneficial owner of the Unvested Shares and all related interests and Participant will have no further rights with respect to the Unvested Shares.

21.3 Escrow.

(a) Unvested Shares will be held by the Company or its authorized representatives until (i) they are forfeited, (ii) they become Vested Shares or (iii) this Agreement is no longer in effect. By accepting this Award, Participant appoints the Company and its authorized representatives as Participant's attorney(s)-in-fact to take all actions necessary to effect any transfer of forfeited Unvested Shares (and Retained Distributions (as defined below), if any, paid on such forfeited Unvested Shares) to the Company as may be required pursuant to the Plan or this Agreement and to execute such representations or other documents or assurances as the Company or such representatives deem necessary or advisable in connection with any such transfer. The Company, or its authorized representative, will not be liable for any good faith act or omission with respect to the holding in escrow or transfer of the Restricted Shares.

(b) All cash dividends and other distributions made or declared with respect to Unvested Shares (“**Retained Distributions**”) will be held by the Company until the time (if ever) when the Unvested Shares to which such Retained Distributions relate become Vested Shares. The Company will establish a separate Retained Distribution bookkeeping account (“**Retained Distribution Account**”) for each Unvested Share with respect to which Retained Distributions have been made or declared in cash and credit the Retained Distribution Account (without interest) on the date of payment with the amount of such cash made or declared with respect to the Unvested Share. Retained Distributions (including any Retained Distribution Account balance) will immediately and automatically be forfeited upon forfeiture of the Unvested Share with respect to which the Retained Distributions were paid or declared.

(c) As soon as reasonably practicable following the date on which an Unvested Share becomes a Vested Share, the Company will (i) cause the certificate (or a new certificate without the legend required by this Agreement, if Participant so requests) representing the Share to be delivered to Participant or, if the Share is held in book-entry form, cause the notations indicating the Share is subject to the restrictions of this Agreement to be removed and (ii) pay to Participant the Retained Distributions relating to the Share.

21.4 Rights as Stockholder. Except as otherwise provided in this Agreement or the Plan, upon issuance of the Restricted Shares by the Company, Participant will have all the rights of a stockholder with respect to the Restricted Shares, including the right to vote the Restricted Shares and to receive dividends or other distributions paid or made with respect to the Restricted Shares.

ARTICLE XXII. TAXATION AND TAX WITHHOLDING

22.1 Representation. Participant represents to the Company that Participant has reviewed with Participant’s own tax advisors the tax consequences of the Restricted Shares and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

22.2 Section 83(b) Election. If Participant makes an election under Section 83(b) of the Code with respect to the Restricted Shares, Participant will deliver a copy of the election to the Company promptly after filing the election with the Internal Revenue Service.

22.3 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant’s failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the Restricted Shares as Participant’s election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise deliverable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the Restricted Shares, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the Restricted Shares. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the Restricted Shares or the subsequent sale of the Restricted Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure this Award to reduce or eliminate Participant’s tax liability.

**ARTICLE XXIII.
RESTRICTIVE LEGENDS AND TRANSFERABILITY**

23.1 Legends. Any certificate representing a Restricted Share will bear the following legend until the Restricted Share becomes a Vested Share:

THE SHARES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO FORFEITURE IN FAVOR OF THE COMPANY AND MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF A RESTRICTED STOCK AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

23.2 Transferability. The Restricted Shares and any Retained Distributions are subject to the restrictions on transfer in the Plan and may not be sold, assigned or transferred in any manner unless and until they become Vested Shares. Any attempted transfer or disposition of Unvested Shares or related Retained Distributions prior to the time the Unvested Shares become Vested Shares will be null and void. The Company will not be required to (a) transfer on its books any Restricted Share that has been sold or otherwise transferred in violation of this Agreement or (b) treat as owner of such Restricted Share or accord the right to vote or pay dividends to any purchaser or other transferee to whom such Restricted Share has been so transferred. The Company may issue appropriate “stop transfer” instructions to its transfer agent, if any, or make appropriate notations to the same effect in its records.

**ARTICLE XXIV.
OTHER PROVISIONS**

24.1 Adjustments. Participant acknowledges that the Restricted Shares are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

24.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company’s Secretary at the Company’s principal office or the Secretary’s then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant’s last known mailing address, email address or facsimile number in the Company’s personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

24.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

24.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

24.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in this Agreement or the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

24.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement and the Restricted Shares will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

24.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

24.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

24.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Award.

24.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

24.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

**FRACTYL HEALTH, INC.
2024 INCENTIVE AWARD PLAN**

RESTRICTED STOCK UNIT GRANT NOTICE

Capitalized terms not specifically defined in this Restricted Stock Unit Grant Notice (the “**Grant Notice**”) have the meanings given to them in the 2024 Incentive Award Plan (as amended from time to time, the “**Plan**”) of Fractyl Health, Inc. (the “**Company**”).

The Company has granted to the participant listed below (“**Participant**”) the Restricted Stock Units described in this Grant Notice (the “**RSUs**”), subject to the terms and conditions of the Plan and the Restricted Stock Unit Agreement attached as **Exhibit A** (the “**Agreement**”), both of which are incorporated into this Grant Notice by reference.

Participant:

Grant Date:

Number of RSUs:

Vesting Commencement Date:

Vesting Schedule:

By Participant’s signature below, Participant agrees to be bound by the terms of this Grant Notice, the Plan and the Agreement. Participant has reviewed the Plan, this Grant Notice and the Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Agreement.

FRACTYL HEALTH, INC.

PARTICIPANT

By: _____

Name: _____

Title: _____

RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

**ARTICLE XXV.
GENERAL****25.1 Award of RSUs and Dividend Equivalents.**

(a) The Company has granted the RSUs to Participant effective as of the grant date set forth in the Grant Notice (the “**Grant Date**”). Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement. Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the RSUs have vested.

(b) The Company hereby grants to Participant, with respect to each RSU, a Dividend Equivalent for ordinary cash dividends paid to substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable RSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a “**Dividend Equivalent Account**”) for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.

25.2 Incorporation of Terms of Plan. The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.

25.3 Unsecured Promise. The RSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company’s general assets.

**ARTICLE XXVI.
VESTING; FORFEITURE AND SETTLEMENT**

26.1 Vesting; Forfeiture. The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that would otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant’s Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the RSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account) relates.

26.2 Settlement.

(a) RSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company’s option as soon as administratively practicable after the vesting of the applicable RSU, but in no event more than sixty (60) days after the RSU’s vesting date. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Laws until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If an RSU is paid in cash, the amount of cash paid with respect to the RSU will equal the Fair Market Value of a Share on the day immediately preceding the payment date. If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equal the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

**ARTICLE XXVII.
TAXATION AND TAX WITHHOLDING**

27.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

27.2 Tax Withholding.

(a) The Company has the right and option, but not the obligation, to treat Participant's failure to provide timely payment in accordance with the Plan of any withholding tax arising in connection with the RSUs or Dividend Equivalents as Participant's election to satisfy all or any portion of the withholding tax by requesting the Company retain Shares otherwise issuable under the Award.

(b) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs and the Dividend Equivalents, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs or Dividend Equivalents. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting or payment of the RSUs or the Dividend Equivalents or the subsequent sale of Shares. The Company and the Subsidiaries do not commit and are under no obligation to structure the RSUs or Dividend Equivalents to reduce or eliminate Participant's tax liability.

**ARTICLE XXVIII.
OTHER PROVISIONS**

28.1 Adjustments. Participant acknowledges that the RSUs, the Shares subject to the RSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.

28.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.

28.3 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

28.4 Conformity to Securities Laws. Participant acknowledges that the Plan, the Grant Notice and this Agreement are intended to conform to the extent necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

28.5 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

28.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the RSUs and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

28.7 Entire Agreement. The Plan, the Grant Notice and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

28.8 Agreement Severable. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

28.9 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a general unsecured creditor with respect to the RSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.

28.10 Not a Contract of Employment. Nothing in the Plan, the Grant Notice or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

28.11 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

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FRACTYL HEALTH, INC.
2024 EMPLOYEE STOCK PURCHASE PLAN

ARTICLE I.
PURPOSE

The purpose of this Plan is to assist Eligible Employees of the Company and its Designated Subsidiaries in acquiring a stock ownership interest in the Company.

The Plan consists of two components: (i) the Section 423 Component and (ii) the Non-Section 423 Component. The Section 423 Component is intended to qualify as an “employee stock purchase plan” under Section 423 of the Code and shall be administered, interpreted and construed in a manner consistent with the requirements of Section 423 of the Code. The Non-Section 423 Component authorizes the grant of rights which need not qualify as rights granted pursuant to an “employee stock purchase plan” under Section 423 of the Code. Rights granted under the Non-Section 423 Component shall be granted pursuant to separate Offerings containing such sub-plans, appendices, rules or procedures as may be adopted by the Administrator and designed to achieve tax, securities laws or other objectives for Eligible Employees and Designated Subsidiaries but shall not be intended to qualify as an “employee stock purchase plan” under Section 423 of the Code. Except as otherwise determined by the Administrator or provided herein, the Non-Section 423 Component will operate and be administered in the same manner as the Section 423 Component. Offerings intended to be made under the Non-Section 423 Component will be designated as such by the Administrator at or prior to the time of such Offering.

For purposes of this Plan, the Administrator may designate separate Offerings under the Plan in which Eligible Employees will participate. The terms of these Offerings need not be identical, even if the dates of the applicable Offering Period(s) in each such Offering are identical, provided that the terms of participation are the same within each separate Offering under the Section 423 Component (as determined under Section 423 of the Code). Solely by way of example and without limiting the foregoing, the Company could, but shall not be required to, provide for simultaneous Offerings under the Section 423 Component and the Non-Section 423 Component of the Plan.

ARTICLE II.
DEFINITIONS AND CONSTRUCTION

Wherever the following terms are used in the Plan they shall have the meanings specified below, unless the context clearly indicates otherwise.

2.1 “**Administrator**” means the entity that conducts the general administration of the Plan as provided in Article XI.

2.2 “**Agent**” means the brokerage firm, bank or other financial institution, entity or person(s), if any, engaged, retained, appointed or authorized to act as the agent of the Company or an Employee with regard to the Plan.

2.3 “**Applicable Law**” means the requirements relating to the administration of equity incentive plans under U.S. federal and state securities, tax and other applicable laws, rules and regulations, the applicable rules of any stock exchange or quotation system on which Shares are listed or quoted and the applicable laws and rules of any foreign country or other jurisdiction where rights under this Plan are granted.

2.4 “**Board**” means the Board of Directors of the Company.

2.5 “**Code**” means the U.S. Internal Revenue Code of 1986, as amended, and the regulations issued thereunder.

2.6 “**Common Stock**” means the common stock of the Company and such other securities of the Company that may be substituted therefore.

2.7 “**Company**” means Fractyl Health, Inc., a Delaware corporation, or any successor.

2.8 “**Compensation**” of an Eligible Employee means, unless otherwise determined by the Administrator, the gross base compensation or wages received by such Eligible Employee as compensation for services to the Company or any Designated Subsidiary, excluding overtime payments, sales commissions, incentive compensation, bonuses, expense reimbursements, income received in connection with any compensatory equity awards, fringe benefits and other special payments.

2.9 “**Designated Beneficiary**” means the beneficiary or beneficiaries the Participant designates, in a manner the Administrator determines, to receive amounts due or exercise the Participant’s rights if the Participant dies or becomes incapacitated. Without a Participant’s effective designation, “Designated Beneficiary” will mean the Participant’s estate.

2.10 “**Designated Subsidiary**” means any Subsidiary designated by the Administrator in accordance with Section 11.2(b), such designation to specify whether such participation is in the Section 423 Component or Non-Section 423 Component. A Designated Subsidiary may participate in either the Section 423 Component or Non-Section 423 Component, but not both; provided that a Subsidiary that, for U.S. tax purposes, is disregarded from the Company or any Subsidiary that participates in the Section 423 Component shall automatically constitute a Designated Subsidiary that participates in the Section 423 Component.

2.11 “**Effective Date**” means the Pricing Date, provided that the Board has adopted the Plan prior to or on such date.

2.12 “**Eligible Employee**” means:

(a) an Employee who does not, immediately after any rights under this Plan are granted, own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of Shares and other securities of the Company, a Parent or a Subsidiary (as determined under Section 423(b)(3) of the Code). For purposes of the foregoing, the rules of Section 424(d) of the Code with regard to the attribution of stock ownership shall apply in determining the stock ownership of an individual, and stock that an Employee may purchase under outstanding options shall be treated as stock owned by the Employee.

(b) Notwithstanding the foregoing, the Administrator may provide in an Offering Document that an Employee shall not be eligible to participate in an Offering Period under the Section 423 Component if: (i) such Employee is a highly compensated employee within the meaning of Section 423(b)(4)(D) of the Code; (ii) such Employee has not met a service requirement designated by the Administrator pursuant to Section 423(b)(4)(A) of the Code (which service requirement may not exceed two years); (iii) such Employee’s customary employment is for twenty hours per week or less; (iv) such Employee’s customary employment is for less than five months in any calendar year; and/or (v) such Employee is a citizen or resident of a foreign jurisdiction and the grant of a right to purchase Shares under the Plan to such Employee would be prohibited under the laws of such foreign jurisdiction or the grant of a right to purchase Shares under the Plan to such Employee in compliance with the laws of such foreign jurisdiction would cause the Plan to violate the requirements of Section 423 of the Code, as determined by

the Administrator in its sole discretion; provided, that any exclusion in clauses (i), (ii), (iii), (iv) or (v) shall be applied in an identical manner under each Offering Period to all Employees, in accordance with Treasury Regulation Section 1.423-2(e).

(c) Further notwithstanding the foregoing, with respect to the Non-Section 423 Component, the first sentence in this definition shall apply in determining who is an “Eligible Employee,” except (i) the Administrator may limit eligibility further within the Company or a Designated Subsidiary so as to only designate certain Employees of the Company or a Designated Subsidiary as Eligible Employees, and (ii) to the extent the restrictions in the first sentence in this definition are not consistent with applicable local laws, the applicable local laws shall control.

2.13 “**Employee**” means any individual who renders services to the Company or any Designated Subsidiary in the status of an employee, and, with respect to the Section 423 Component, a person who is an employee of the Company or any Designated Subsidiary within the meaning of Section 3401(c) of the Code. For purposes of an individual’s participation in, or other rights under the Plan, all determinations by the Company shall be final, binding and conclusive, notwithstanding that any court of law or governmental agency subsequently makes a contrary determination. For purposes of the Plan, the employment relationship shall be treated as continuing intact while the individual is on sick leave or other leave of absence approved by the Company or Designated Subsidiary and meeting the requirements of Treasury Regulation Section 1.421-1(h)(2). Where the period of leave exceeds three (3) months and the individual’s right to reemployment is not guaranteed either by statute or by contract, the employment relationship shall be deemed to have terminated on the first day immediately following such three (3)-month period.

2.14 “**Enrollment Date**” means the first Trading Day of each Offering Period.

2.15 “**Fair Market Value**” means, as of any date, the value of Shares determined as follows: (i) if the Shares are listed on any established stock exchange, its Fair Market Value will be the closing sales price for such Shares as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; (ii) if the Shares are not traded on a stock exchange but are quoted on a national market or other quotation system, the closing sales price on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; or (iii) without an established market for the Shares, the Administrator will determine the Fair Market Value in its discretion.

2.16 “**Non-Section 423 Component**” means those Offerings under the Plan, together with the sub-plans, appendices, rules or procedures, if any, adopted by the Administrator as a part of this Plan, in each case, pursuant to which rights to purchase Shares during an Offering Period may be granted to Eligible Employees that need not satisfy the requirements for rights to purchase Shares granted pursuant to an “employee stock purchase plan” that are set forth under Section 423 of the Code.

2.17 “**Offering**” means an offer by the Company under the Plan to Eligible Employees of a right to purchase Shares that may be exercised during an Offering Period as further described in Article IV hereof. Unless otherwise specified by the Administrator, each Offering to the Eligible Employees of the Company or a Designated Subsidiary shall be deemed a separate Offering, even if the dates and other terms of the applicable Offering Periods of each such Offering are identical, and the provisions of the Plan will separately apply to each Offering. To the extent permitted by Treas. Reg. § 1.423-2(a)(1), the terms of each separate Offering under the Section 423 Component need not be identical, provided that the terms of the Section 423 Component and an Offering thereunder together satisfy Treas. Reg. § 1.423-2(a)(2) and (a)(3).

2.18 “**Offering Document**” has the meaning given to such term in Section 4.1.

2.19 “**Offering Period**” has the meaning given to such term in Section 4.1.

2.20 “**Parent**” means any corporation, other than the Company, in an unbroken chain of corporations ending with the Company if, at the time of the determination, each of the corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

2.21 “**Participant**” means any Eligible Employee who has executed a subscription agreement and been granted rights to purchase Shares pursuant to the Plan.

2.22 “**Payday**” means the regular and recurring established day for payment of Compensation to an Employee of the Company or any Designated Subsidiary.

2.23 “**Plan**” means this 2024 Employee Stock Purchase Plan, including both the Section 423 Component and Non-Section 423 Component and any other sub-plans or appendices hereto, as amended from time to time.

2.24 “**Pricing Date**” means the date upon which the Company’s Registration Statement on Form S-1 filed with the Securities and Exchange Commission relating to the underwritten public offering of shares of Common Stock becomes effective.

2.25 “**Purchase Date**” means the last Trading Day of each Purchase Period or such other date as determined by the Administrator and set forth in the Offering Document.

2.26 “**Purchase Period**” shall refer to one or more periods within an Offering Period, as designated in the applicable Offering Document; provided, however, that, in the event no Purchase Period is designated by the Administrator in the applicable Offering Document, the Purchase Period for each Offering Period covered by such Offering Document shall be the same as the applicable Offering Period.

2.27 “**Purchase Price**” means the purchase price designated by the Administrator in the applicable Offering Document (which purchase price, for purposes of the Section 423 Component, shall not be less than 85% of the Fair Market Value of a Share on the Enrollment Date or on the Purchase Date, whichever is lower); provided, however, that, in the event no purchase price is designated by the Administrator in the applicable Offering Document, the purchase price for the Offering Periods covered by such Offering Document shall be 85% of the Fair Market Value of a Share on the Enrollment Date or on the Purchase Date, whichever is lower; provided, further, that the Purchase Price may be adjusted by the Administrator pursuant to Article VIII and shall not be less than the par value of a Share.

2.28 “**Section 423 Component**” means those Offerings under the Plan, together with the sub-plans, appendices, rules or procedures, if any, adopted by the Administrator as a part of this Plan or any Offering(s), in each case, pursuant to which rights to purchase Shares during an Offering Period may be granted to Eligible Employees that are intended to satisfy the requirements for rights to purchase Shares granted pursuant to an “employee stock purchase plan” that are set forth under Section 423 of the Code.

2.29 “**Securities Act**” means the U.S. Securities Act of 1933, as amended.

2.30 “**Share**” means a share of Common Stock.

2.31 “**Subsidiary**” means any corporation, other than the Company, in an unbroken chain of corporations beginning with the Company if, at the time of the determination, each of the corporations other than the last corporation in an unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain; provided, however, that a limited liability company or partnership may be treated as a Subsidiary to the extent either (a) such entity is treated as a disregarded entity under Treasury Regulation Section 301.7701-3(a) by reason of the Company or any other Subsidiary that is a corporation being the sole owner of such entity, or (b) such entity elects to be classified as a corporation under Treasury Regulation Section 301.7701-3(a) and such entity would otherwise qualify as a Subsidiary. In addition, with respect to the Non-Section 423 Component, Subsidiary shall include any corporate or non-corporate entity in which the Company has a direct or indirect equity interest or significant business relationship.

2.32 “**Trading Day**” means a day on which national stock exchanges in the United States are open for trading.

2.33 “**Treas. Reg.**” means U.S. Department of the Treasury regulations.

ARTICLE III. SHARES SUBJECT TO THE PLAN

3.1 Number of Shares. Subject to Article VIII, the aggregate number of Shares that may be issued pursuant to rights granted under the Plan shall be 487,070 Shares. In addition to the foregoing, subject to Article VIII, on the first day of each calendar year beginning on January 1, 2025 and ending on and including January 1, 2034, the number of Shares available for issuance under the Plan shall be increased by that number of Shares equal to the lesser of (a) 1% of the aggregate number of Shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of Shares as determined by the Board. If any right granted under the Plan shall for any reason terminate without having been exercised, the Shares not purchased under such right shall again become available for issuance under the Plan. Notwithstanding anything in this Section 3.1 to the contrary, the number of Shares that may be issued or transferred pursuant to the rights granted under the Section 423 Component of the Plan shall not exceed an aggregate of 6,575,470 Shares, subject to Article VIII.

3.2 Shares Distributed. Any Shares distributed pursuant to the Plan may consist, in whole or in part, of authorized and unissued Shares, treasury shares or Shares purchased on the open market.

ARTICLE IV. OFFERING PERIODS; OFFERING DOCUMENTS; PURCHASE DATES

4.1 Offering Periods. The Administrator may from time to time grant or provide for the grant of rights to purchase Shares under the Plan to Eligible Employees during one or more periods (each, an “**Offering Period**”) selected by the Administrator. The terms and conditions applicable to each Offering Period shall be set forth in an “**Offering Document**” adopted by the Administrator, which Offering Document shall be in such form and shall contain such terms and conditions as the Administrator shall deem appropriate and shall be incorporated by reference into and made part of the Plan and shall be attached hereto as part of the Plan. The Administrator shall establish in each Offering Document one or more Purchase Periods during such Offering Period during which rights granted under the Plan shall be exercised and purchases of Shares carried out during such Offering Period in accordance with such Offering Document and the Plan. The provisions of separate Offerings or Offering Periods under the Plan may be partially or wholly concurrent and need not be identical.

4.2 Offering Documents. Each Offering Document with respect to an Offering Period shall specify (through incorporation of the provisions of this Plan by reference or otherwise):

(a) the length of the Offering Period, which period shall not exceed twenty-seven months;

(b) the length of the Purchase Period(s) within the Offering Period;

(c) the maximum number of Shares that may be purchased by any Eligible Employee during such Offering Period, which, in the absence of a contrary designation by the Administrator, shall be 100,000 Shares (and which, for the Section 423 Component Offering Periods, shall be subject to the limitations described in Section 5.5 below);

(d) in connection with each Offering Period that contains more than one Purchase Period, the maximum aggregate number of Shares which may be purchased by any Eligible Employee during each Purchase Period, which, in the absence of a contrary designation by the Administrator, shall be 100,000 Shares (and which, for the Section 423 Component Offering Periods, shall be subject to the limitations described in Section 5.5 below); and

(e) such other provisions as the Administrator determines are appropriate, subject to the Plan.

ARTICLE V. ELIGIBILITY AND PARTICIPATION

5.1 Eligibility. Any Eligible Employee who shall be employed by the Company or a Designated Subsidiary on a given Enrollment Date for an Offering Period shall be eligible to participate in the Plan during such Offering Period, subject to the requirements of this Article V and, for the Section 423 Component, the limitations imposed by Section 423(b) of the Code.

5.2 Enrollment in Plan.

(a) Except as otherwise set forth in an Offering Document or determined by the Administrator, an Eligible Employee may become a Participant in the Plan for an Offering Period by delivering a subscription agreement to the Company by such time prior to the Enrollment Date for such Offering Period (or such other date specified in the Offering Document) designated by the Administrator and in such form as the Company provides.

(b) Except as otherwise determined by the Administrator, each subscription agreement shall designate a whole percentage of such Eligible Employee's Compensation to be withheld by the Company or the Designated Subsidiary employing such Eligible Employee on each Payday during the Offering Period as payroll deductions under the Plan. The percentage of Compensation designated by an Eligible Employee may not be less than 1% and may not be more than the maximum percentage specified by the Administrator in the applicable Offering Document (which percentage shall be 15% in the absence of any such designation) as payroll deductions. The payroll deductions made for each Participant shall be credited to an account for such Participant under the Plan and shall be deposited with the general funds of the Company.

(c) A Participant may increase or decrease the percentage of Compensation designated in his or her subscription agreement, subject to the limits of this Section 5.2, or may suspend his or her payroll deductions, at any time during an Offering Period; provided, however, that the Administrator may

limit the number of changes a Participant may make to his or her payroll deduction elections during each Offering Period in the applicable Offering Document (and in the absence of any specific designation by the Administrator, a Participant shall be allowed to decrease (but not increase) or suspend his or her payroll deduction elections one time during each Offering Period). Any such change or suspension of payroll deductions shall be effective with the first full payroll period following five business days after the Company's receipt of the new subscription agreement (or such shorter or longer period as may be specified by the Administrator in the applicable Offering Document). In the event a Participant suspends his or her payroll deductions during an Offering Period, such Participant's cumulative unapplied payroll deductions prior to the suspension (if any) shall remain in his or her account and shall be applied to the purchase of Shares on the next occurring Purchase Date and shall not be paid to such Participant unless he or she withdraws from participation in the Plan pursuant to Article VII.

(d) Except as otherwise set forth in an Offering Document or as otherwise determined by the Administrator, a Participant may participate in the Plan only by means of payroll deduction and may not make contributions by lump sum payment for any Offering Period.

5.3 Payroll Deductions. Except as otherwise provided in the applicable Offering Document or determined by the Administrator, payroll deductions for a Participant shall commence on the first Payday following the Enrollment Date and shall end on the last Payday in the Offering Period to which the Participant's authorization is applicable, unless sooner terminated by the Participant as provided in Article VII or suspended by the Participant or the Administrator as provided in Section 5.2 and Section 5.6, respectively. Notwithstanding any other provisions of the Plan to the contrary, in any non-U.S. jurisdiction where participation in the Plan through payroll deductions is prohibited, the Administrator may provide that an Eligible Employee may elect to participate through contributions to the Participant's account under the Plan in a form acceptable to the Administrator in lieu of or in addition to payroll deductions; provided, however, that, for any Offering under the Section 423 Component, the Administrator shall take into consideration any limitations under Section 423 of the Code when applying an alternative method of contribution.

5.4 Effect of Enrollment. A Participant's completion of a subscription agreement will enroll such Participant in the Plan for each subsequent Offering Period on the terms contained therein until the Participant either submits a new subscription agreement, withdraws from participation under the Plan as provided in Article VII or otherwise becomes ineligible to participate in the Plan.

5.5 Limitation on Purchase of Shares. An Eligible Employee may be granted rights under the Section 423 Component only if such rights, together with any other rights granted to such Eligible Employee under "employee stock purchase plans" of the Company, any Parent or any Subsidiary, as specified by Section 423(b)(8) of the Code, do not permit such employee's rights to purchase stock of the Company or any Parent or Subsidiary to accrue at a rate that exceeds \$25,000 of the fair market value of such stock (determined as of the first day of the Offering Period during which such rights are granted) for each calendar year in which such rights are outstanding at any time. This limitation shall be applied in accordance with Section 423(b)(8) of the Code.

5.6 Suspension of Payroll Deductions. Notwithstanding the foregoing, to the extent necessary to comply with Section 423(b)(8) of the Code and Section 5.5 (with respect to the Section 423 Component) or the other limitations set forth in this Plan, a Participant's payroll deductions may be suspended by the Administrator at any time during an Offering Period. The balance of the amount credited to the account of each Participant that has not been applied to the purchase of Shares by reason of Section 423(b)(8) of the Code, Section 5.5 or the other limitations set forth in this Plan shall be paid to such Participant in one lump sum in cash as soon as reasonably practicable, but not more than 30 days, after the Purchase Date.

5.7 Foreign Employees. In order to facilitate participation in the Plan, the Administrator may provide for such special terms, rules and procedures applicable to Participants who are citizens or residents of a foreign jurisdiction, or who are employed by a Designated Subsidiary outside of the United States, as the Administrator may consider necessary or appropriate to accommodate differences in local law, tax policy or custom. Except as permitted by Section 423 of the Code, with respect to the Section 423 Component, such special terms may not be more favorable than the terms of rights granted under the Section 423 Component to Eligible Employees who are residents of the United States. Such special terms may be set forth in an addendum to the Plan in the form of an appendix or sub-plan (which appendix or sub-plan may be designed to govern Offerings under the Section 423 Component or the Non-Section 423 Component, as determined by the Administrator). To the extent that the terms and conditions set forth in an appendix or sub-plan conflict with any provisions of the Plan, the provisions of the appendix or sub-plan shall govern. The adoption of any such appendix or sub-plan shall be pursuant to Section 11.2(g). Without limiting the foregoing, the Administrator is specifically authorized to adopt rules and procedures, with respect to Participants who are foreign nationals or employed in non-U.S. jurisdictions, regarding the exclusion of particular Subsidiaries from participation in the Plan, eligibility to participate, the definition of Compensation, handling of payroll deductions or other contributions by Participants, payment of interest, conversion of local currency, data privacy security, payroll tax, withholding procedures, establishment of bank or trust accounts to hold payroll deductions or contributions.

5.8 Leave of Absence. During leaves of absence approved by the Company meeting the requirements of Treasury Regulation Section 1.421-1(h)(2) under the Code, unless otherwise set forth in the terms of an Offering Document, a Participant may continue participation in the Plan by making cash payments to the Company on his or her normal Payday equal to the Participant's authorized payroll deduction.

ARTICLE VI. GRANT AND EXERCISE OF RIGHTS

6.1 Grant of Rights. On the Enrollment Date of each Offering Period, each Eligible Employee participating in such Offering Period shall be granted a right to purchase the maximum number of Shares specified under Section 4.2, subject to the limits in Section 5.5, and shall have the right to buy, on each Purchase Date during such Offering Period (at the applicable Purchase Price), such number of whole Shares as is determined by dividing (a) such Participant's payroll deductions accumulated prior to such Purchase Date and retained in the Participant's account as of the Purchase Date, by (b) the applicable Purchase Price (rounded down to the nearest Share). The right shall expire on the earliest of: (x) the last Purchase Date of the Offering Period, (y) the last day of the Offering Period, and (z) the date on which the Participant withdraws in accordance with Section 7.1 or Section 7.3.

6.2 Exercise of Rights. On each Purchase Date, each Participant's accumulated payroll deductions and any other additional payments specifically provided for in the applicable Offering Document will be applied to the purchase of whole Shares, up to the maximum number of Shares permitted pursuant to the terms of the Plan and the applicable Offering Document, at the Purchase Price. No fractional Shares shall be issued upon the exercise of rights granted under the Plan, unless the Offering Document specifically provides otherwise. Any cash in lieu of fractional Shares remaining after the purchase of whole Shares upon exercise of a purchase right will be credited to a Participant's account and carried forward and applied toward the purchase of whole Shares for the next following Purchase Period, unless the Administrator provides that such amounts should be returned to the Participant in one lump sum payment in a subsequent payroll check. Shares issued pursuant to the Plan may be evidenced in such manner as the Administrator may determine and may be issued in certificated form or issued pursuant to book-entry procedures.

6.3 Pro Rata Allocation of Shares. If the Administrator determines that, on a given Purchase Date, the number of Shares with respect to which rights are to be exercised may exceed (a) the number of Shares that were available for issuance under the Plan on the Enrollment Date of the applicable Offering Period, or (b) the number of Shares available for issuance under the Plan on such Purchase Date, the Administrator may in its sole discretion provide that the Company shall make a pro rata allocation of the Shares available for purchase on such Enrollment Date or Purchase Date, as applicable, in as uniform a manner as shall be practicable and as it shall determine in its sole discretion to be equitable among all Participants for whom rights to purchase Shares are to be exercised pursuant to this Article VI on such Purchase Date, and shall either (i) continue all Offering Periods then in effect, or (ii) terminate any or all Offering Periods then in effect pursuant to Article IX. The Company may make pro rata allocation of the Shares available on the Enrollment Date of any applicable Offering Period pursuant to the preceding sentence, notwithstanding any authorization of additional Shares for issuance under the Plan by the Company's stockholders subsequent to such Enrollment Date. The balance of the amount credited to the account of each Participant that has not been applied to the purchase of Shares shall be paid to such Participant without interest in one lump sum in cash as soon as reasonably practicable after the Purchase Date, or such earlier date as determined by the Administrator.

6.4 Withholding. At the time a Participant's rights under the Plan are exercised, in whole or in part, or at the time some or all of the Shares issued under the Plan is disposed of, the Participant must make adequate provision for the Company's federal, state, or other tax withholding obligations, if any, that arise upon the exercise of the right or the disposition of the Shares. At any time, the Company may, but shall not be obligated to, withhold from the Participant's compensation or Shares received pursuant to the Plan the amount necessary for the Company to meet applicable withholding obligations, including any withholding required to make available to the Company any tax deductions or benefits attributable to sale or early disposition of Shares by the Participant.

6.5 Conditions to Issuance of 6.6 Shares. The Company shall not be required to issue or deliver any certificate or certificates for, or make any book entries evidencing, Shares purchased upon the exercise of rights under the Plan prior to fulfillment of all of the following conditions: (a) the admission of such Shares to listing on all stock exchanges, if any, on which the Shares are then listed; (b) the completion of any registration or other qualification of such Shares under any state or federal law or under the rulings or regulations of the Securities and Exchange Commission or any other governmental regulatory body, that the Administrator shall, in its absolute discretion, deem necessary or advisable; (c) the obtaining of any approval or other clearance from any state or federal governmental agency that the Administrator shall, in its absolute discretion, determine to be necessary or advisable; (d) the payment to the Company of all amounts that it is required to withhold under federal, state or local law upon exercise of the rights, if any; and (e) the lapse of such reasonable period of time following the exercise of the rights as the Administrator may from time to time establish for reasons of administrative convenience.

ARTICLE VII. WITHDRAWAL; CESSATION OF ELIGIBILITY

7.1 Withdrawal. A Participant may withdraw all but not less than all of the payroll deductions credited to his or her account and not yet used to exercise his or her rights under the Plan at any time by giving written notice to the Company in a form acceptable to the Company no later than one week prior to the end of the then-applicable Purchase Period (or such shorter or longer period as may be specified by the Administrator in the applicable Offering Document). All of the Participant's payroll deductions credited to his or her account during such Purchase Period and not yet used to exercise rights under the Plan shall be paid to such Participant as soon as reasonably practicable after receipt of notice of withdrawal and such Participant's rights for the Offering Period shall be automatically terminated, and no further payroll deductions for the purchase of Shares shall be made for such Offering Period. If a Participant withdraws

from an Offering Period, payroll deductions shall not resume at the beginning of any subsequent Offering Period unless the Participant is an Eligible Employee and timely delivers to the Company a new subscription agreement by the applicable enrollment deadline for any such subsequent Offering Period, as determined by the Administrator.

7.2 Future Participation. A Participant's withdrawal from an Offering Period shall not have any effect upon his or her eligibility to participate in any similar plan that may hereafter be adopted by the Company or a Designated Subsidiary or in any subsequent Offering Period that commences after the termination of the Offering Period from which the Participant withdraws.

7.3 Cessation of Eligibility. Upon a Participant's ceasing to be an Eligible Employee for any reason, he or she shall be deemed to have elected to withdraw from the Plan pursuant to this Article VII and the payroll deductions credited to such Participant's account during the then-current Purchase Period shall be paid to such Participant or, in the case of his or her death, to the person or persons entitled thereto under Section 12.4, as soon as reasonably practicable, and such Participant's rights for the Offering Period shall be automatically terminated. If a Participant transfers employment from the Company or any Designated Subsidiary participating in the Section 423 Component to any Designated Subsidiary participating in the Non-Section 423 Component, such transfer shall not be treated as a termination of employment under the Plan, but the Participant shall immediately cease to participate in the Section 423 Component; however, any contributions made for the then-current Purchase Period in which such transfer occurs shall be transferred to the Non-Section 423 Component, and such Participant shall immediately join the then-current Offering under the Non-Section 423 Component upon the same terms and conditions in effect for the Participant's participation in the Section 423 Component, except for such modifications otherwise applicable for Participants in such Offering. A Participant who transfers employment from any Designated Subsidiary participating in the Non-Section 423 Component to the Company or any Designated Subsidiary participating in the Section 423 Component shall not be treated as terminating the Participant's employment under the Plan and shall remain a Participant in the Non-Section 423 Component until the earlier of (i) the end of the current Offering Period under the Non-Section 423 Component or (ii) the Enrollment Date of the first Offering Period in which the Participant is eligible to participate following such transfer. Notwithstanding the foregoing, the Administrator may establish different rules to govern transfers of employment between entities participating in the Section 423 Component and the Non-Section 423 Component, consistent with the applicable requirements of Section 423 of the Code or other Applicable Law.

ARTICLE VIII. ADJUSTMENTS UPON CHANGES IN SHARES

8.1 Changes in Capitalization. Subject to Section 8.3, in the event that the Administrator determines that any dividend or other distribution (whether in the form of cash, Shares, other securities, or other property), change in control, reorganization, merger, amalgamation, consolidation, combination, repurchase, redemption, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Shares or other securities of the Company, issuance of warrants or other rights to purchase Shares or other securities of the Company, or other similar corporate transaction or event, as determined by the Administrator, affects the Shares such that an adjustment is determined by the Administrator to be appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any outstanding purchase rights under the Plan, the Administrator shall make equitable adjustments, if any, to reflect such change with respect to (a) the aggregate number and type of Shares (or other securities or property) that may be issued under the Plan (including, but not limited to, adjustments of the limitations in Section 3.1 and the limitations established in each Offering Document pursuant to Section 4.2 on the maximum number of Shares that may be purchased); (b) the class(es) and

number of Shares and price per Share subject to outstanding rights; and (c) the Purchase Price with respect to any outstanding rights.

8.2 Other Adjustments. Subject to Section 8.3, in the event of any transaction or event described in Section 8.1 or any unusual or nonrecurring transactions or events affecting the Company, any affiliate of the Company, or the financial statements of the Company or any affiliate, or of changes in Applicable Law or accounting principles, the Administrator, in its discretion, and on such terms and conditions as it deems appropriate, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to prevent the dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any right under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(a) To provide for either (i) termination of any outstanding right in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such right had such right been currently exercisable or (ii) the replacement of such outstanding right with other rights or property selected by the Administrator in its sole discretion;

(b) To provide that the outstanding rights under the Plan shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar rights covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices;

(c) To make adjustments in the number and type of Shares (or other securities or property) subject to outstanding rights under the Plan and/or in the terms and conditions of outstanding rights and rights that may be granted in the future;

(d) To provide that Participants' accumulated payroll deductions may be used to purchase Shares prior to the next occurring Purchase Date on such date as the Administrator determines in its sole discretion and the Participants' rights under the ongoing Offering Period(s) shall be terminated; and

(e) To provide that all outstanding rights shall terminate without being exercised.

8.3 No Adjustment Under Certain Circumstances. Unless determined otherwise by the Administrator, no adjustment or action described in this Article VIII or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Section 423 Component of the Plan to fail to satisfy the requirements of Section 423 of the Code.

8.4 No Other Rights. Except as expressly provided in the Plan, no Participant shall have any rights by reason of any subdivision or consolidation of shares of stock of any class, the payment of any dividend, any increase or decrease in the number of shares of stock of any class or any dissolution, liquidation, merger, or consolidation of the Company or any other corporation. Except as expressly provided in the Plan or pursuant to action of the Administrator under the Plan, no issuance by the Company of shares of stock of any class, or securities convertible into shares of stock of any class, shall affect, and no adjustment by reason thereof shall be made with respect to, the number of Shares subject to outstanding rights under the Plan or the Purchase Price with respect to any outstanding rights.

**ARTICLE IX.
AMENDMENT, MODIFICATION AND TERMINATION**

9.1 Amendment, Modification and Termination. The Administrator may amend, suspend or terminate the Plan at any time and from time to time; provided, however, that approval of the Company's stockholders shall be required to amend the Plan to: (a) increase the aggregate number, or change the type, of shares that may be sold pursuant to rights under the Plan under Section 3.1 (other than an adjustment as provided by Article VIII) or (b) change the corporations or classes of corporations whose employees may be granted rights under the Plan.

9.2 Certain Changes to Plan. Without stockholder consent and without regard to whether any Participant rights may be considered to have been adversely affected (and, with respect to the Section 423 Component of the Plan, to the extent permitted by Section 423 of the Code), the Administrator shall be entitled to change or terminate the Offering Periods, limit the frequency and/or number of changes in the amount withheld from Compensation during an Offering Period, establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars, permit payroll withholding in excess of the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of payroll withholding elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Shares for each Participant properly correspond with amounts withheld from the Participant's Compensation, and establish such other limitations or procedures as the Administrator determines in its sole discretion to be advisable that are consistent with the Plan.

9.3 Actions In the Event of Unfavorable Financial Accounting Consequences. In the event the Administrator determines that the ongoing operation of the Plan may result in unfavorable financial accounting consequences, the Administrator may, in its discretion and, to the extent necessary or desirable, modify or amend the Plan to reduce or eliminate such accounting consequence including, but not limited to:

(a) altering the Purchase Price for any Offering Period, including an Offering Period underway at the time of the change in Purchase Price;

(b) shortening any Offering Period so that the Offering Period ends on a new Purchase Date, including an Offering Period underway at the time of the Administrator action; and

(c) allocating Shares.

Such modifications or amendments shall not require stockholder approval or if the Administrator so determines, the consent of any Participant.

9.4 Payments Upon Termination of Plan. Upon termination of the Plan, the balance in each Participant's Plan account shall be refunded as soon as practicable after such termination, without any interest thereon, or the Offering Period may be shortened so that the purchase of Shares occurs prior to the termination of the Plan.

**ARTICLE X.
TERM OF PLAN**

The Plan shall become effective on the Effective Date. The effectiveness of the Section 423 Component of the Plan shall be subject to approval of the Plan by the Company's stockholders within twelve months following the date the Plan is first approved by the Board. No right may be granted under

the Section 423 Component of the Plan prior to such stockholder approval. The Plan shall remain in effect until terminated under Section 9.1. No rights may be granted under the Plan during any period of suspension of the Plan or after termination of the Plan.

ARTICLE XI. ADMINISTRATION

11.1 Administrator. Unless otherwise determined by the Board, the Administrator of the Plan shall be the Compensation Committee of the Board (or another committee or a subcommittee of the Board to which the Board delegates administration of the Plan). The Board may at any time vest in the Board any authority or duties for administration of the Plan. The Administrator may delegate administrative tasks under the Plan to the services of an Agent or Employees to assist in the administration of the Plan, including establishing and maintaining an individual securities account under the Plan for each Participant.

11.2 Authority of Administrator. The Administrator shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(a) To determine when and how rights to purchase Shares shall be granted and the provisions of each offering of such rights (which need not be identical).

(b) To designate from time to time which Subsidiaries of the Company shall be Designated Subsidiaries, which designation may be made without the approval of the stockholders of the Company.

(c) To impose a mandatory holding period pursuant to which Participants may not dispose of or transfer Shares purchased under the Plan for a period of time determined by the Administrator in its discretion.

(d) To construe and interpret the Plan and rights granted under it, and to establish, amend and revoke rules and regulations for its administration. The Administrator, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, in a manner and to the extent it shall deem necessary or expedient to make the Plan fully effective.

(e) To amend, suspend or terminate the Plan as provided in Article IX.

(f) Generally, to exercise such powers and to perform such acts as the Administrator deems necessary or expedient to promote the best interests of the Company and its Subsidiaries and to carry out the intent that the Plan be treated as an "employee stock purchase plan" within the meaning of Section 423 of the Code for the Section 423 Component.

(g) The Administrator may adopt sub-plans applicable to particular Designated Subsidiaries or locations, which sub-plans may be designed to be outside the scope of Section 423 of the Code. The rules of such sub-plans may take precedence over other provisions of this Plan, with the exception of Section 3.1 hereof, but unless otherwise superseded by the terms of such sub-plan, the provisions of this Plan shall govern the operation of such sub-plan.

11.3 Decisions Binding. The Administrator's interpretation of the Plan, any rights granted pursuant to the Plan, any subscription agreement and all decisions and determinations by the Administrator with respect to the Plan are final, binding, and conclusive on all parties.

**ARTICLE XII.
MISCELLANEOUS**

12.1 Restriction upon Assignment. A right granted under the Plan shall not be transferable other than by will or the Applicable Laws of descent and distribution, and is exercisable during the Participant's lifetime only by the Participant. Except as provided in Section 12.4 hereof, a right under the Plan may not be exercised to any extent except by the Participant. The Company shall not recognize and shall be under no duty to recognize any assignment or alienation of the Participant's interest in the Plan, the Participant's rights under the Plan or any rights thereunder.

12.2 Rights as a Stockholder. With respect to Shares subject to a right granted under the Plan, no Participant or Designated Beneficiary shall be deemed to be a stockholder of the Company, and no Participant or Designated Beneficiary shall have any of the rights or privileges of a stockholder, until such Shares have been issued to the Participant or the Designated Beneficiary following exercise of the Participant's rights under the Plan. No adjustments shall be made for dividends (ordinary or extraordinary, whether in cash securities, or other property) or distribution or other rights for which the record date occurs prior to the date of such issuance, except as otherwise expressly provided herein or as determined by the Administrator.

12.3 Interest. No interest shall accrue on the payroll deductions or contributions of a Participant under the Plan.

12.4 Designation of Beneficiary.

(a) A Participant may, in the manner determined by the Administrator, file a written designation of a beneficiary who is to receive any Shares and/or cash, if any, from the Participant's account under the Plan in the event of such Participant's death subsequent to a Purchase Date on which the Participant's rights are exercised but prior to delivery to such Participant of such Shares and cash. In addition, a Participant may file a written designation of a beneficiary who is to receive any cash from the Participant's account under the Plan in the event of such Participant's death prior to exercise of the Participant's rights under the Plan. If the Participant is married and resides in a community property state, a designation of a person other than the Participant's spouse as his or her beneficiary shall not be effective without the prior written consent of the Participant's spouse.

(b) Such designation of beneficiary may be changed by the Participant at any time by written notice to the Company. In the event of the death of a Participant and in the absence of a beneficiary validly designated under the Plan who is living at the time of such Participant's death, the Company shall deliver such Shares and/or cash to the executor or administrator of the estate of the Participant, or if no such executor or administrator has been appointed (to the knowledge of the Company), the Company, in its discretion, may deliver such Shares and/or cash to the spouse or to any one or more dependents or relatives of the Participant, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.

12.5 Notices. All notices or other communications by a Participant to the Company under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by the Company at the location, or by the person, designated by the Company for the receipt thereof.

12.6 Equal Rights and Privileges. Subject to Section 5.7, all Eligible Employees will have equal rights and privileges under the Section 423 Component so that the Section 423 Component of this Plan qualifies as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Subject to Section 5.7, any provision of the Section 423 Component that is inconsistent with Section 423 of the Code

will, without further act or amendment by the Company, the Board or the Administrator, be reformed to comply with the equal rights and privileges requirement of Section 423 of the Code. Eligible Employees participating in the Non-Section 423 Component need not have the same rights and privileges as other Eligible Employees participating in the Non-Section 423 Component or as Eligible Employees participating in the Section 423 Component.

12.7 Use of Funds. All payroll deductions received or held by the Company under the Plan may be used by the Company for any corporate purpose, and the Company shall not be obligated to segregate such payroll deductions.

12.8 Reports. Statements of account shall be given to Participants at least annually, which statements shall set forth the amounts of payroll deductions, the Purchase Price, the number of Shares purchased and the remaining cash balance, if any.

12.9 No Employment Rights. Nothing in the Plan shall be construed to give any person (including any Eligible Employee or Participant) the right to remain in the employ or service of the Company or any Parent or Subsidiary or affect the right of the Company or any Parent or Subsidiary to terminate the employment or service of any person (including any Eligible Employee or Participant) at any time, with or without cause.

12.10 Notice of Disposition of Shares. Each Participant shall give prompt notice to the Company of any disposition or other transfer of any Shares purchased upon exercise of a right under the Section 423 Component of the Plan if such disposition or transfer is made: (a) within two years from the Enrollment Date of the Offering Period in which the Shares were purchased or (b) within one year after the Purchase Date on which such Shares were purchased. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.

12.11 Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, other employee or agent of the Company or any Subsidiary will be liable to any Participant, former Participant, Designated Beneficiary or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Offering Period, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in his or her capacity as an Administrator, director, officer, other employee or agent of the Company or any Subsidiary. The Company will indemnify and hold harmless each director, officer, other employee and agent of the Company or any Subsidiary that has been or will be granted or delegated any duty or power relating to the Plan's administration or interpretation, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Administrator's approval) arising from any act or omission concerning this Plan unless arising from such person's own fraud or bad faith.

12.12 Data Privacy. As a condition for participation in the Plan, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this section by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing the Participant's participation in the Plan. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant's name, address and telephone number; birthdate; social security number, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and participation details, to implement, manage and administer the Plan and any Offering Period(s) (the "**Data**"). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant's participation in the Plan and any Offering Period(s), and the Company and its Subsidiaries and affiliates may transfer the Data

to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. By participating in any Offering Period under the Plan, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or withdraw the consents in this Section 12.12 in writing, without cost, by contacting the local human resources representative. If the Participant refuses or withdraws the consents in this Section 12.12, and the Company may cancel Participant's ability to participate in the Plan or any Offering Period(s). For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

12.13 Severability. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

12.14 Titles and Headings. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.

12.15 Conformity to Securities Laws. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Laws. Notwithstanding anything herein to the contrary, the Plan and all Offering Periods will be administered only in conformance with Applicable Laws. To the extent Applicable Laws permit, the Plan and all Offering Periods will be deemed amended as necessary to conform to Applicable Laws.

12.16 Relationship to Other Benefits. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary except as expressly provided in writing in such other plan or an agreement thereunder.

12.17 Governing Law. The Plan and any agreements hereunder shall be administered, interpreted and enforced in accordance with the laws of the State of Delaware, disregarding any state's choice of law principles requiring the application of a jurisdiction's laws other than the State of Delaware.

12.18 Electronic Forms. To the extent permitted by Applicable Law and in the discretion of the Administrator, an Eligible Employee may submit any form or notice as set forth herein by means of an electronic form approved by the Administrator. Before the commencement of an Offering Period, the Administrator shall prescribe the time limits within which any such electronic form shall be submitted to the Administrator with respect to such Offering Period in order to be a valid election.

12.19 Section 409A. The Section 423 Component of the Plan and the rights to purchase Shares granted pursuant to Offerings thereunder are intended to be exempt from the application of Section 409A of the Code and the U.S. Department of Treasury Regulations and other interpretive guidance issued thereunder (collectively, "**Section 409A**"). Neither the Non-Section 423 Component nor any right to purchase Shares granted pursuant to an Offering thereunder is intended to constitute or provide for

“nonqualified deferred compensation” within the meaning of Section 409A. Notwithstanding any provision of the Plan to the contrary, if the Administrator determines that any right to purchase Shares granted under the Plan may be or become subject to Section 409A or that any provision of the Plan may cause a right to purchase Shares granted under the Plan to be or become subject to Section 409A, the Administrator may adopt such amendments to the Plan and/or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions as the Administrator determines are necessary or appropriate to avoid the imposition of taxes under Section 409A, either through compliance with the requirements of Section 409A or with an available exemption therefrom.

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FRACTYL HEALTH, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the “**Board**”) of Fractyl Health, Inc. (the “**Company**”) shall receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this “**Program**”). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any subsidiary of the Company (each, a “**Non-Employee Director**”) who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. This Program shall become effective on the date of the Company’s initial public offering of common stock (the “**Effective Date**”), subject to the closing of such offering.

I. CASH COMPENSATION

A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of \$43,500 for service on the Board.

B. Additional Annual Retainers. In addition, each Non-Employee Director shall receive the following annual retainers:

1. *Chair of the Board or Lead Independent Director*. A Non-Employee Director serving as Chair of the Board or Lead Independent Director shall receive an additional annual retainer of \$35,000 for such service.

2. *Audit Committee*. A Non-Employee Director serving as Chair of the Audit Committee shall receive an additional annual retainer of \$20,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Audit Committee shall receive an additional annual retainer of \$10,000 for such service.

3. *Compensation Committee*. A Non-Employee Director serving as Chair of the Compensation Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Compensation Committee shall receive an additional annual retainer of \$7,500 for such service.

4. *Nominating and Corporate Governance Committee*. A Non-Employee Director serving as Chair of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$5,000 for such service.

C. Payment of Retainers. The retainers described in Sections I(A) and (B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

II. EQUITY COMPENSATION

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2024 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "**Equity Plan**") and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement. For the avoidance of doubt, the share numbers in Sections II(A) and II(B) shall be subject to adjustment as provided in the Equity Plan.

A. Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall receive an option to purchase 45,000 shares of the Company's common stock on the date of such initial election or appointment. The awards described in this Section II(A) shall be referred to as "**Initial Awards**." No Non-Employee Director shall be granted more than one Initial Award.

B. Subsequent Awards. A Non-Employee Director who (i) has been serving as a Non-Employee Director on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall receive an option to purchase 22,500 shares of the Company's common stock on the date of such annual meeting. The awards described in this Section II(B) shall be referred to as "**Subsequent Awards**." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

C. Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section II(A) above, but to the extent that they are otherwise entitled, will receive, after termination of employment with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section II(B) above.

D. Terms of Awards Granted to Non-Employee Directors

1. *Exercise Price.* The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of the Company's common stock on the date the option is granted.

2. *Vesting.* Each Initial Award shall vest and become exercisable in equal installments on each of the first three anniversaries of the date of grant, such that the Initial Award shall be fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service as a Non-Employee Director through each such vesting date. Each Subsequent Award shall vest and become exercisable in a single installment on the earlier of the date of the next annual meeting of shareholders or the first anniversary of the date of grant, subject to the Non-Employee Director continuing in service on the Board as a Non-Employee Director through such vesting date. Unless the Board otherwise determines, any portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All of a Non-Employee Director's outstanding Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term.* The maximum term of each stock option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

* * * * *

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated August 22, 2023 (except for Note 17, as to which the date is January 26, 2024), in the Registration Statement (Form S-1 No. 333-276046) and related Prospectus of Fractyl Health, Inc. for the registration of shares of its common stock.

/s/ Ernst & Young LLP

Boston, Massachusetts
January 28, 2024

Calculation of Filing Fee Tables

Form S-1
(Form Type)

FRACTYL HEALTH, INC.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price ⁽¹⁾	Fee Rate	Amount of Registration Fee ⁽²⁾
Fees to be Paid	Equity	Common Stock, par value \$0.00001 per share ⁽³⁾	457(o)	—	\$16.00	\$134,933,312	0.00014760	\$19,916.16
		Total Offering Amount			—	\$134,933,312	—	\$19,916.16
		Total Fees Previously Paid			—	—	—	\$14,760.15
		Total Fee Offsets			—	—	—	—
		Net Fee Due			—	—	—	\$5,156.01

- (1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").
- (2) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price.
- (3) Includes up to an additional 15% of the aggregate offering price to cover a 30-day option granted to the underwriters to purchase additional shares of our common stock to cover over-allotments, if any.