UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-41942

Fractyl Health, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-3553477**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3 Van de Graaff Drive, Suite 200 Burlington, MA	**01803**
(Address of principal executive offices)	**(Zip Code)**

(781) 902-8800
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	GUTS	The Nasdaq Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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 check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 31, 2025, the number of shares of the registrant's common stock outstanding was approximately 137,044,440.

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 subsidiaries.

The unaudited condensed consolidated financial statements include the accounts of Fractyl Health, Inc. Our unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. Our fiscal year ends on December 31 of each year. Our most recent fiscal year ended on December 31, 2024.

Certain monetary amounts, percentages and other figures included in this Quarterly Report on Form 10-Q have been subject to rounding adjustments. Percentage amounts included in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q may vary from those obtained by performing the same calculations using the figures in our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. Certain other amounts that appear in this Quarterly Report on Form 10-Q may not sum due to rounding.

TRADEMARKS AND TRADENAMES

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy (including our Strategic Reprioritization, as defined herein), prospective products or product candidates, plans regarding or status of clinical trials or studies and their design, our plans for readouts of interim or final results, product approvals, communications with or submissions to the U.S. Food and Drug Administration (the "FDA"), 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, the anticipated use of or impact of the net proceeds from the August 2025 Offering and the September 2025 Offering, and the timing of any of the foregoing 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 Quarterly Report on Form 10-Q 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, certifications and approvals, including final regulatory approval certifications 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, certified 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;
- the status, breadth and strength of our intellectual property portfolio and its ability to protect our innovations;
- our ability to obtain patent coverage for our products;
- our ability to successfully defend litigation and other similar complaints and to establish and maintain intellectual property rights covering our products;
- developments and projections relating to our competitors and our industry;
- our expectations related to the use of proceeds from our financing activities;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

- our ability to continue as a going concern;
- 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, 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 Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions, described in *Part II. Item 1A. Risk Factors* and elsewhere in this Quarterly Report on Form 10-Q. 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, 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 Quarterly Report on Form 10-Q, 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.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in *Part II, Item 1A. Risk Factors*. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business 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 from 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;
- We require substantial additional capital or must implement other business strategies to execute our operating plan and continue to operate as a going concern. 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;
- 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;
- 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;
- 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 may not be able to submit investigational device exemptions ("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;
- We may experience delays, interruptions or additional costs in obtaining and maintaining government regulatory approvals, licenses, certifications or reimbursements as a result of federal government shutdowns, reduced staffing or funding lapses. Such delays or disruptions could adversely affect our ability to develop, commercialize or market our product candidates, or to receive payments or reimbursements in a timely manner.
- We may not be able to submit investigational new drug applications ("INDs") or IND amendments with the FDA, clinical trial applications ("CTAs") or comparable documents with regulatory bodies 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;
- We are substantially dependent on the success of our lead product candidate, Revita®, and our lead product candidate RJVA-001 in the Rejuva® platform. 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 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;
- Additional time may be required to develop and obtain regulatory approval or certification for our Rejuva gene therapy candidates because we expect them to be regulated as a combination product;

- We cannot be certain that our Rejuva gene therapy candidates will successfully complete preclinical and clinical studies, or that they will not cause significant adverse events or toxicities. 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 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. If we are unable to demonstrate the safety and efficacy of Revita for repeat use, it could have a material adverse effect on the clinical utility and commercial adoption of the device;
- 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 substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations ("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;
- 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;
- We contract with third parties for the manufacture and supply 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;
- If we or our suppliers fail to comply with the FDA's quality system and/or good manufacturing practice regulations, this could impair our ability to market our products in a cost-effective and timely manner;
- 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;
- 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; and
- 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.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Fractyl Health, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except for share and per share information)
(unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 77,657	$ 67,464
Inventory	—	73
Prepaid expenses and other current assets	2,046	4,226
Total current assets	79,703	71,763
Restricted cash, long-term	4,255	4,255
Property and equipment, net	2,683	2,979
Right-of-use lease assets, operating	27,239	28,414
Other long-term assets	392	666
Total assets	$ 114,272	$ 108,077
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,261	$ 3,240
Accrued expenses and other current liabilities	12,354	11,579
Operating lease liabilities, current	5,067	4,956
Total current liabilities	18,682	19,775
Notes payable, long-term	30,770	30,162
Operating lease liabilities, long-term	26,347	27,382
Warrant liabilities, long-term	40,898	1,336
Other long-term liabilities	753	998
Total liabilities	117,450	79,653
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized, no shares issued or outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock, $0.00001 par value; 300,000,000 shares authorized as of September 30, 2025 and December 31, 2024, 132,216,275 shares issued and outstanding at September 30, 2025; 48,755,451 shares issued and outstanding at December 31, 2024	1	—
Additional paid-in capital	509,358	443,734
Accumulated deficit	(512,537)	(415,310)
Total stockholders' equity (deficit)	(3,178)	28,424
Total liabilities and stockholders' equity (deficit)	$ 114,272	$ 108,077

See accompanying notes to condensed consolidated financial statements (unaudited).

Fractyl Health, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share information)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	$ —	$ 14	$ —	$ 90
Cost of goods sold	—	7	—	50
Gross profit	—	7	—	40
Operating expenses:				
Research and development	17,457	19,004	58,043	50,190
Selling, general and administrative	5,237	4,797	15,489	18,171
Total operating expenses	22,694	23,801	73,532	68,361
Loss from operations	(22,694)	(23,794)	(73,532)	(68,321)
Other income (expense), net:				
Interest income, net	166	947	895	3,420
Change in fair value of notes payable	(1,868)	(2,610)	(3,824)	3,772
Change in fair value of warrant liabilities	(21,201)	2,293	(20,724)	17,442
Other expense, net	(6)	(9)	(42)	(37)
Total other income (expense), net	(22,909)	621	(23,695)	24,597
Net loss and comprehensive loss	(45,603)	(23,173)	(97,227)	(43,724)
Accretion of dividends on convertible preferred stock	—	—	—	(1,737)
Net loss attributable to common stockholders	$ (45,603)	$ (23,173)	$ (97,227)	$ (45,461)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (0.48)	$ (1.79)	$ (1.09)
Weighted-average number of common shares outstanding, basic and diluted	64,652,953	47,973,951	54,243,512	41,892,347

See accompanying notes to condensed consolidated financial statements (unaudited).

Fractyl Health, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except for share information)
(Unaudited)

	Series A, B, C-1, C-2, D, E and F Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2024	—	$ —	48,755,451	$ —	$ 443,734	$ (415,310)	$ 28,424
Exercise of common stock options	—	—	164,770	—	280	—	280
Share-based compensation expense	—	—	—	—	1,406	—	1,406
Net loss	—	—	—	—	—	(23,735)	(23,735)
Balance at March 31, 2025	**—**	**$ —**	**48,920,221**	**$ —**	**$ 445,420**	**$ (439,045)**	**$ 6,375**
Issuance of common stock in connection with at-the-market offering, net of issuance costs of $188	—	—	997,404	—	1,517	—	1,517
Exercise of common stock options	—	—	166	—	—	—	—
Share-based compensation expense	—	—	—	—	1,785	—	1,785
Net loss	—	—	—	—	—	(27,889)	(27,889)
Balance at June 30, 2025	**—**	**$ —**	**49,917,791**	**$ —**	**$ 448,722**	**$ (466,934)**	**$ (18,212)**
Issuance of common stock from RSU vesting	—	—	22,500	—	—	—	—
Issuance of common stock in connection with at-the-market offering, net of issuance costs of $17	—	—	371,223	—	552	—	552
Issuance of common stock in August 2025 public offering, net of underwriting discounts, commissions and offering costs of $1,731	—	—	21,904,761	—	2,431	—	2,431
Issuance of common stock in September 2025 offering, net of underwriting discounts, commissions and offering costs of $3,984	—	—	60,000,000	1	56,015	—	56,016
Share-based compensation expense	—	—	—	—	1,638	—	1,638
Net loss	—	—	—	—	—	(45,603)	(45,603)
Balance at September 30, 2025	**—**	**$ —**	**132,216,275**	**$ 1**	**$ 509,358**	**$ (512,537)**	**$ (3,178)**

	Series A, B, C-1, C-2, D, E and F Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2023	77,994,156	$ 287,330	2,105,815	$ —	$ 21,554	$ (346,616)	$ (325,062)
Issuance of common stock in initial public offering, net of underwriting discounts, commissions and offering costs of $11,223	—	—	7,433,332	—	100,277	—	100,277
Conversion of convertible preferred stock into common stock upon initial public offering	(77,994,156)	(287,330)	36,343,909	—	287,330	—	287,330
Conversion of 2022 Convertible Notes into common stock upon initial public offering	—	—	1,841,321	—	19,150	—	19,150
Reclassification of warrant liability to equity upon initial public offering	—	—	—	—	425	—	425
Exercise of common stock warrants	—	—	38,544	—	—	—	—
Exercise of common stock options	—	—	133,987	—	163	—	163
Share-based compensation expense	—	—	—	—	5,217	—	5,217
Net loss	—	—	—	—	—	(3,322)	(3,322)
Balance at March 31, 2024	—	$ —	**47,896,908**	$ —	$ 434,116	$ (349,938)	$ 84,178
Exercise of common stock options	—	—	16,327	—	16	—	16
Share-based compensation expense	—	—	—	—	3,790	—	3,790
Net loss	—	—	—	—	—	(17,229)	(17,229)
Balance at June 30, 2024	—	$ —	**47,913,235**	$ —	$ 437,922	$ (367,167)	$ 70,755
Exercise of common stock options	—	—	135,561	—	220	—	220
Issuance of common stock from restricted stock units vesting	—	—	40,829	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,520	—	2,520
Net loss	—	—	—	—	—	(23,173)	(23,173)
Balance at September 30, 2024	—	$ —	**48,089,625**	$ —	$ 440,662	$ (390,340)	$ 50,322

See accompanying notes to condensed consolidated financial statements (unaudited).

Fractyl Health, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (97,227)	$ (43,724)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	850	454
Non-cash interest expense	227	275
Non-cash operating lease expense	1,174	1,496
Loss on disposal of fixed assets	—	1
Stock-based compensation expense	4,829	11,527
Change in fair value of warrant liabilities	20,724	(17,442)
Change in fair value of notes payable, non-cash	608	(5,685)
Changes in operating assets and liabilities:		
Accounts receivable	—	22
Inventory	73	—
Prepaid expenses and other current assets	2,180	(885)
Accounts payable	(1,984)	1,181
Accrued expenses and other current liabilities	583	3,036
Operating lease liabilities	(923)	1,374
Other long-term assets and liabilities	(106)	(117)
Net cash used in operating activities	(68,992)	(48,487)
Cash flows from investing activities:		
Purchases of property and equipment	(554)	(1,532)
Net cash used in investing activities	(554)	(1,532)
Cash flows from financing activities:		
Proceeds from initial public offering, net of underwriting discounts and commissions	—	103,695
Payments related to initial public offering costs	—	(2,854)
Issuance of common stock in connection with at-the-market offering, net of issuance costs	2,069	—
Issuance of common stock and warrants in the August 2025 public offering, net of underwriting commissions and offering costs	21,328	—
Issuance of common stock in the September 2025 offering, net of underwriting commissions and offering costs	56,400	—
Proceeds from exercise of stock options	280	399
Principal payments on finance lease obligations	(338)	(81)
Net cash provided by financing activities	79,739	101,159
Net increase in cash, cash equivalents and restricted cash	10,193	51,140
Cash, cash equivalents and restricted cash at beginning of period	71,719	37,779
Cash, cash equivalents and restricted cash at end of period	$ 81,912	$ 88,919
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,216	$ 1,992
Payment for operating leases within operating activities	$ 3,917	$ 1,749
Non-cash investing and financing activities:		
Fair value of warrant liabilities recognized in connection with August 2025 public offering	$ 18,838	$ —
Offering costs included in accounts payable and accrued expenses	$ 444	$ —
Conversion of convertible preferred stock into common stock upon initial public offering	$ —	$ 287,330
Conversion of 2022 Convertible Notes into common stock upon initial public offering	$ —	$ 19,150
Reclassification of warrant liability to equity upon initial public offering	$ —	$ 425
Finance lease right-of-use asset obtained in exchange for lease liability	$ —	$ 1,401
Reclassification of deferred offering costs to additional paid-in capital	$ —	$ 3,418
Purchases of property and equipment included in accounts payable	$ —	$ 32

See accompanying notes to condensed consolidated financial statements (unaudited).

Fractyl Health, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Nature of the Business

Fractyl Health, Inc. (the "Company" or "Fractyl") was incorporated on August 30, 2010 under the name MedCatalyst, Inc. The Company then 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 pioneering pattern-breaking treatments for metabolic diseases, including obesity and type 2 diabetes ("T2D"). Despite advances in treatment over the last 50 years, obesity and T2D continue to be principal and rapidly growing drivers of morbidity and mortality in the 21st century. The Company believes the unmet need has shifted from short term weight loss and glucose control to durable metabolic health solutions without daily or weekly pharmacotherapy. 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 disease.

Revita

The Revita DMR System ("Revita") is based on the Company's insights surrounding the potential role of the gut in obesity. Revita is designed to remodel the duodenal lining via hydrothermal ablation (i.e. duodenal mucosal resurfacing) to reverse damage to intestinal nutrient sensing and signaling mechanisms caused by chronic high-fat and high-sugar diets that are a root cause of metabolic disease. In the U.S., Revita is for investigational use only. Revita has U.S. FDA Breakthrough Device designation in weight maintenance for people with obesity who discontinue glucagon-like peptide-1 ("GLP-1") based drugs. The Company is evaluating Revita in the REMAIN-1 weight maintenance program, which is designed to evaluate Revita's potential to sustain weight loss following GLP-1 discontinuation. The REMAIN program includes three distinct patient cohorts that are conducted under a single IDE: the REVEAL-1 Cohort, the REMAIN-1 Midpoint Cohort, and the REMAIN-1 Pivotal Cohort, designed to collectively establish the clinical and regulatory foundation for Revita in weight maintenance.

- REVEAL-1 Cohort (n=22) is an open-label study in individuals with obesity who have lost at least 15% of their total body weight on a GLP-1 medication and who either need or choose to discontinue GLP-1 therapy.
- REMAIN-1 Midpoint Cohort (n=45) is a randomized, double-blind, sham-controlled pilot study to assess the potential of Revita to maintain weight loss after GLP-1 discontinuation.
- REMAIN-1 Pivotal Cohort (n=315) is a randomized, double-blind, sham-controlled pivotal study to evaluate the safety and efficacy of Revita in maintaining weight loss.

Pursuant to the Company's Strategic Reprioritization, Fractyl has paused additional investment in the REVITALIZE-1 clinical study of Revita for T2D and the Germany Real-World Registry study. The Company continues to follow existing participants in both studies per protocol and will report clinical, health economic, and patient-relevant outcomes from the Germany Real-World Registry study on an ongoing basis.

Rejuva

Rejuva is the Company's novel, locally administered, adeno-associated virus ("AAV") delivered pancreatic gene therapy platform. Rejuva leverages advanced delivery systems and proprietary screening methods to identify and develop metabolically active gene therapy candidates targeting the pancreas. Rejuva is designed to enable long term remission of T2D and obesity by durably reprogramming pancreatic islet cells to endogenously produce metabolic hormones. The Company has a key near-term goal of advancing the lead product candidate in the platform, RJVA-001, which is targeting patients with inadequately controlled T2D, into first-in-human studies, subject to regulatory approval. RJVA-001 targets GLP-1 biology with the goal of achieving durable, well-tolerated, glycemic improvements from a single intervention.

The Company's second candidate from the Rejuva platform, RJVA-002, is a dual GIP/GLP-1 gene therapy and is currently in preclinical development. RJVA-002 expands the Rejuva platform into obesity, targeting dual incretin biology with the goal of achieving durable, well-tolerated, weight loss from a single intervention.

The Company believes Revita and Rejuva, if approved by relevant regulatory bodies, have the potential to revolutionize treatment across the spectrum of obesity and T2D, 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.

Initial Public Offering

On February 6, 2024, the Company completed its IPO, pursuant to which it issued and sold 7,333,333 shares of its common stock at a price to the public of $15.00 per share, resulting in net proceeds of approximately $98.9 million, after deducting underwriting discounts and commissions as well as related offering expenses.

On March 5, 2024, the Company issued an additional 99,999 shares of its common stock pursuant to the partial exercise of the underwriters' option to purchase additional shares at the IPO public price of $15.00 per share, resulting in additional net proceeds of approximately $1.4 million, after deducting underwriting discounts and commissions.

S-3 Registration Statement

On March 3, 2025, the Company filed a Registration Statement on Form S-3 with the U.S. Securities and Exchange Commission ("SEC"), which was subsequently amended on March 13, 2025 (as amended, the "S-3 Registration Statement"). The S-3 Registration Statement became effective on March 18, 2025. It contains a base prospectus, which covers the offering, issuance and sale of up to $300.0 million in the aggregate of the securities from time to time in one or more offerings.

At-The-Market Offering

Concurrently with the filing of the S-3 Registration Statement, the Company filed a sales agreement prospectus supplement under an at-the-market offering (the "ATM Offering") covering the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $100.0 million of the Company's common stock that may be offered, issued and sold from time to time. During the nine months ended September 30, 2025, the Company issued and sold 1,368,627 shares of its common stock under the ATM Offering at a weighted average price of $1.66 per share, resulting in net proceeds of approximately $2.1 million, after deducting underwriting discounts and commissions as well as related offering expenses. In October 2025, the Company issued and sold an additional 3,333,333 shares of its common stock under the ATM Offering at a weighted average price of $1.47 per share, resulting in net proceeds of approximately $4.8 million, after deducting underwriting discounts and commissions.

August 2025 Offering

On August 6, 2025, the Company entered into an underwriting agreement with Ladenburg Thalmann & Co. Inc. ("Ladenburg"), pursuant to which it issued and sold 19,047,619 shares of its common stock, accompanied by warrants to purchase up to 19,047,619 shares of our common stock (the "Tranche A Warrants") and warrants to purchase 19,047,619 shares of our common stock (the "Tranche B Warrants"), at a combined offering price of $1.05 per share. As part of the underwriting agreement, the Company also granted Ladenburg a 30-day option to purchase up to an additional 2,857,142 shares of the Company's common stock, along with associated Tranche A Warrants and Tranche B Warrants, at the combined public offering price of $1.05 per share. On August 6, 2025, Ladenburg exercised the option to purchase additional shares of the Company's common stock, along with associated Tranche A Warrants and Tranche B Warrants, in full. The securities were issued pursuant to the S-3 Registration Statement and a related prospectus supplement filed with the SEC (the "August 2025 Offering").

The August 2025 Offering closed on August 7, 2025, from which the Company received approximately $20.7 million of net proceeds, after deducting underwriting discounts and commissions as well as estimated offering expenses, excluding any potential future proceeds from the exercise of the Tranche A Warrants and Tranche B Warrants. See Note 6—"Warrant Liabilities" for more details on the Tranche A Warrants and Tranche B Warrants.

September 2025 Offering

On September 26, 2025, the Company entered into an underwriting agreement with BofA Securities, Inc. and Evercore Group L.L.C., as representatives of several underwriters, pursuant to which it issued and sold 60,000,000 shares

of its common stock, at a price to the public of $1.00 per share. The securities were issued pursuant to the S-3 Registration Statement and a related prospectus supplement filed with the SEC (the "September 2025 Offering").

The September 2025 Offering closed on September 29, 2025, from which the Company received approximately $56.0 million, after deducting underwriting discounts and commissions as well as estimated offering expenses.

Liquidity

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 (the "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 a history of operating losses and had an accumulated deficit of $512.5 million as of September 30, 2025. Management expects continuing operating losses in the future. The Company has financed its operations to date primarily through its equity and debt financings. Based on its current business plans, the Company believes that its available cash and cash equivalents of $77.7 million as of September 30, 2025, combined with subsequent proceeds received to date from common stock issued under the ATM Offering and warrant exercises (see Note 6—"Warrant Liabilities"), will be sufficient to fund the Company's operating plan into early 2027. The Company's forecast of its cash needs is subject to significant assumptions, which could change, and management could use its available capital resources sooner than it currently anticipates. In addition, without additional financing, management projects that it may not be able to comply with the minimum liquidity covenant related to the Company's 2023 Notes by the end of 2026. Given the inherent risk and uncertainty of future cash flow estimates as well as the minimum liquidity covenant requirement, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for at least one year after the date that these financial statements are issued. The accompanying unaudited interim condensed 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 unaudited interim condensed 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.

The Company plans to alleviate the substantial doubt about its ability to continue as a going concern by seeking additional funds through equity or debt financings or through collaboration or licensing transactions or other sources. The Company may be unable to obtain equity or debt financings or enter into collaboration or licensing transactions and, if necessary, the Company will be required to implement cost reduction strategies which could curtail or delay its current operating plans.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"), for interim

financial reporting and as required by Regulation S-X, Rule 10-01. The unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. 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 three and nine months ended September 30, 2025 and 2024. The results of operations for the interim periods are not necessarily indicative of results to be expected for the year ending December 31, 2025, any other interim periods, or any future year or period. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2024 and notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 3, 2025. The accompanying unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. 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 condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates relied upon in preparing these condensed consolidated financial statements include, but are not limited to, the fair value of common stock warrants, the fair value of notes payable, the fair value of stock-based awards, the incremental borrowing rate for lease accounting, estimates of future cash flows used in the assessment of our ability to continue as a going concern, 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.

Leases

The Company has entered into operating leases for office and laboratory spaces and finance leases for certain laboratory equipment, which are accounted for in accordance with ASC 842, *Leases*.

The Company determines whether an arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement at inception. Operating leases are included in right-of-use lease assets ("ROU assets") and current and long-term lease liabilities on the Company's condensed consolidated balance sheets. Lease expenses for operating leases are recognized on a straight-line basis over the lease term as an operating expense. Assets subject to finance leases are included in property and equipment, net, on the Company's condensed consolidated balance sheets. Current and long-term portion of the related lease liabilities of the finance leases are included in accrued expenses and other current liabilities and other long-term liabilities, respectively, on the Company's condensed consolidated balance sheets. Lease expenses for finance leases consist of depreciation of the assets, which is recognized on a straight-line basis over the useful life of the assets as an operating expense, and interest expense using the effective interest method over the lease term.

Warrant Liabilities

The Company classifies warrants to purchase shares of its common stock as liabilities on its consolidated balance sheets as such warrants may result in delivery of a variable number of shares or delivery of a settlement amount that is not solely indexed to the Company's own stock. 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 expected volatility assumption is based on a blend of historical volatilities of the Company's share price and those of its publicly traded peer companies. 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. The expected dividend yield for the common stock warrants is 0% 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 6—"Warrant Liabilities".

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 is 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 recognized using an accelerated attribution method. Upon final determination of the performance conditions achieved, the compensation costs are adjusted to reflect those awards that ultimately vest. 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 condensed 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 considers the fair value of its common stock to be equal to the closing price of its common stock traded on the Nasdaq Global Market. Due to the limited company-specific historical and implied volatility information available to the Company, the expected stock volatility used in the option pricing model was 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.

Recently Adopted Accounting Pronouncements

The Company has not adopted any accounting pronouncements during the nine months ended September 30, 2025.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). The ASU focuses on the rate reconciliation and income taxes paid. ASU 2023-09 requires the Company to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. ASU 2023-09 is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the potential impact of adopting this ASU on its consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU No. 2024-03, Disaggregation of Income Statement Expenses ("ASU 2024-03"), which is intended to provide more detailed and disaggregated information about significant expense categories, such as purchases of inventory, employee compensation, depreciation and amortization and selling expenses. This new standard, including related updates, is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted, and the amendments may be applied either prospectively or retrospectively. The Company is currently assessing the impact ASU 2024-03 will have on its consolidated financial statements, including its footnote 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 September 30, 2025			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	$ 7,701	$ —	$ —	$ 7,701
	$ 7,701	$ —	$ —	$ 7,701
Liabilities:				
Warrant liabilities, long-term	$ —	$ —	$ 40,898	$ 40,898
Notes payable, long-term	—	—	30,770	30,770
	$ —	$ —	$ 71,668	$ 71,668

	Fair Value measurements as of December 31, 2024			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	$ 38,295	$ —	$ —	$ 38,295
	$ 38,295	$ —	$ —	$ 38,295
Liabilities:				
Warrant liabilities, long-term	$ —	$ —	$ 1,336	$ 1,336
Notes payable, long-term	—	—	30,162	30,162
	$ —	$ —	$ 31,498	$ 31,498

During the nine months ended September 30, 2025 and 2024, there were no transfers between Level 1, Level 2 and Level 3 measurements.

See Note 5—"Notes Payable" for the discussion of the fair value methodology of the notes payable and a rollforward of the fair value. See Note 6—"Warrant Liabilities" for the discussion of the fair value methodology of the stock warrants and a rollforward of the fair value.

4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	September 30, 2025	December 31, 2024
Payroll and payroll-related expenses	$ 4,384	$ 4,184
Research and development expenses	5,919	5,750
Professional fees and consulting services	1,544	814
Other current liabilities	507	831
	$ 12,354	$ 11,579

5. Notes Payable

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 $20.1 million (the "2022 Convertible Notes"). On July 11, 2023, the Company 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. Following these amendments, $20.9 million in aggregate principal under the 2022 Convertible Notes remained outstanding and accrued interest at the rate of 10% per year until they were 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 condensed consolidated balance sheet.

Upon the closing of the IPO on February 6, 2024, all of the outstanding principal plus accrued interest under the 2022 Convertible Notes were converted into 1,841,321 shares of the Company's common stock at a conversion price of $12.00 per share. The 2022 Convertible Notes were marked to market to its fair value as of the time of the conversion before being reclassified to equity.

2023 Notes

On September 7, 2023, the Company entered into a credit agreement (the "Credit Agreement") with certain lenders (the "2023 Lenders") that provided for term loans up to aggregate principal amount of $45.0 million (the "Applicable Commitments") in two tranches (the "2023 Notes"). The first tranche with a principal amount of $30.0 million was extended on September 7, 2023. The second tranche with a principal amount of $15.0 million would have been extended upon the Company's achievement of certain operating and funding milestones as defined in the Credit Agreement, by July 31, 2024. Under the Credit Agreement, a further principal amount of $20.0 million may be extended to the Company, subject to the 2023 Lenders' prior written consent in their sole discretion. Due to a shift in business strategy to include the weight maintenance study, the Company decided not to pursue the milestones required to access the second tranche. As a result, the second tranche was not extended.

The outstanding balances of 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 was 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. Under the terms of the Credit Agreement, the first principal payment date may be extended to September 30, 2027, at the Company's option, if certain financing milestones as defined in the Credit Agreement are achieved on or prior to September 30, 2026. During 2024, the Company achieved the defined milestones and elected to extend the first principal payment date to September 30, 2027. In addition, upon any principal payment, the Company is required to make an additional payment to the 2023 Lenders of a 6.0% fee (the "Exit Fee") over the principal and accrued PIK interest paid. The aggregate Exit Fee of the 2023 Notes should be equal to 6.0% of the total Applicable Commitments 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 the issuance of the first tranche 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 condensed consolidated balance sheet.

The Company elected to apply the fair value option to the 2023 Notes in accordance with ASC 825, *Financial Instruments*. Accordingly, the 2023 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 condensed consolidated statements of operations and comprehensive loss. The fair value was estimated using a discounted cash flow model by discounting projected future cash flows associated with the 2023 Notes to their present value. The discount rate used in the model is based on observable market yields for similarly rated instruments, adjusted for any specific risks inherent in the 2023 Notes. Accrued interest on the 2023 Notes is incorporated into the determination of the fair value of the 2023 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 2023 Notes:

(in thousands)	**Fair Value**
Balance as of December 31, 2024	$ 30,162
Increase in fair value	3,824
Payment of interest	(3,216)
Balance as of September 30, 2025	$ 30,770

The Credit Agreement contains a minimum liquidity covenant that requires the Company to maintain a minimum $10.0 million balance in cash and/or certain permitted cash equivalent investments, subject to certain exceptions. In

addition, the Credit Agreement contains a 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, 2025, the Company was in compliance with the financial covenants and other terms of the arrangement.

6. 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. In January 2024, the 2014 Warrant was amended to extend the expiration date to the earlier of (i) the date that is 30 calendar days after the closing of the Company's IPO and (ii) July 31, 2024. Upon the closing of the Company's IPO on February 6, 2024, the amended expiration date of the 2014 Warrant was determined to be March 7, 2024.

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 income (expense) in the condensed consolidated statements of operations and comprehensive loss. Upon the closing of the IPO on February 6, 2024, the warrant to purchase 118,483 shares of the Company's Series B Convertible Preferred Stock was converted to a warrant to purchase 55,211 shares of the Company's common stock. Accordingly, the 2014 Warrant was remeasured upon the closing of the IPO and marked to market to its fair value before being reclassified to equity.

The 2014 Warrant was fully cashless exercised on the amended expiration date of March 7, 2024, as a result of which a total of 38,544 shares of common stock were issued to the warrant holder.

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 $20.9 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 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, 2025.

The fair value of the July 2023 Warrants at issuance was $9.9 million and was recorded as part of the warrant liabilities on the condensed 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 income (expense) in the condensed consolidated statements of operations and comprehensive loss.

Prior to the Company's IPO in February 2024, 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. After the completion of its IPO, the fair value of the July 2023 Warrants was determined using the Black-Scholes valuation model with the following assumptions:

	September 30, 2025
Risk-free interest rate	4.0%
Expected term (in years)	7.8
Expected volatility	61%
Expected dividend yield	0%

The following table provides a rollforward of the fair value of the July 2023 Warrants:

(in thousands)	Fair Value
Balance as of December 31, 2024	$ 1,169
Decrease in fair value	(457)
Balance as of September 30, 2025	$ 712

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 $4.2 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 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, 2025.

The fair value of the September 2023 Warrants at issuance was $2.6 million and was recorded as part of the warrant liabilities on the condensed 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 income (expense) in the condensed consolidated statements of operations and comprehensive loss.

Prior to the Company's IPO in February 2024, 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. After the completion of its IPO, the fair value of the September 2023 Warrants was determined using the Black-Scholes valuation model with the following assumptions:

	September 30, 2025
Risk-free interest rate	4.0%
Expected term (in years)	7.9
Expected volatility	60%
Expected dividend yield	0%

The following table provides a rollforward of the fair value of the September 2023 Warrants:

(in thousands)	Fair Value
Balance as of December 31, 2024	$ 167
Decrease in fair value	(66)
Balance as of September 30, 2025	$ 101

August 2025 Warrants

On August 7, 2025, the Company issued Tranche A Warrants and Tranche B Warrants to purchase 21,904,761 shares of the Company's common stock, respectively, in connection with the August 2025 Offering (see Note 1—"Nature of the Business"). The Tranche A Warrants were immediately exercisable and the Tranche B Warrants were only exercisable upon receipt of required stockholder approval, which approval was received on October 3, 2025. See details of each set of warrants below.

August 2025 Tranche A Warrants ("Tranche A Warrants")

Each Tranche A Warrant has an exercise price of $1.05 per share, subject to certain adjustments. The Tranche A Warrants are exercisable at any time on or after August 7, 2025 and will expire on August 7, 2027. The Tranche A

Warrants are callable at the Company's option following the release of 3-month randomized midpoint clinical data from the ongoing REMAIN-1 study, which data was published on September 26, 2025, subject to satisfaction of certain conditions including that the average trading price of the stock exceeds $1.37 per share for 15 consecutive trading days and a minimum daily trading volume threshold.

The fair value of the Tranche A Warrants at issuance was $7.9 million and was recorded as part of the warrant liabilities on the condensed consolidated balance sheet. The Company will remeasure the fair value at the end of each reporting period, with any adjustments being recorded as a component of other income (expense) in the condensed consolidated statements of operations and comprehensive loss.

Tranche A Warrants fair value was determined using the Monte-Carlo simulation model with the following key assumptions, which was based on significant inputs that are not observable in the market and represented a Level 3 measurement. See Note 2—"Summary of Significant Accounting Policies" for a discussion of the assumptions and estimates used in the fair value measurement.

	August 7, 2025	September 30, 2025
Risk-free interest rate	3.7%	3.6%
Expected term (in years)	2.0	1.9
Expected volatility	110%	105%
Expected dividend yield	0%	0%

The following table provides a rollforward of the fair value of the Tranche A Warrants:

	Fair Value
Fair value at issuance date of August 7, 2025	$ 7,886
Increase in fair value	6,571
Balance as of September 30, 2025	$ 14,457

Subsequent to September 30, 2025, certain holders exercised Tranche A Warrants at an exercise price of $1.05 per share resulting in the issuance of 1,290,618 shares of the company's common stock for net proceeds of $1.3 million, after deducting underwriting discounts and commissions.

August 2025 Tranche B Warrants ("Tranche B Warrants")

Each Tranche B Warrant has an exercise price per share of our common stock equal to $1.05, subject to certain adjustments. The Tranche B Warrants are exercisable upon receipt of stockholder approval as may be required by the applicable rules and regulations of The Nasdaq Global Market which approval was obtained at the Special Meeting of Stockholders and the Tranche B Warrants became exercisable on October 3, 2025. The Tranche B Warrants will expire on October 3, 2030, which is the date that is five years from the date that stockholder approval (the "Tranche B Warrant Stockholder Approval") was received.

The fair value of the Tranche B Warrants at issuance was $11.0 million and was recorded as part of the warrant liabilities on the condensed consolidated balance sheet. The Company will remeasure the fair value at the end of each reporting period, with any adjustments being recorded as a component of other income (expense) in the condensed consolidated statements of operations and comprehensive loss.

Tranche B Warrants fair value was determined using the Black-Scholes valuation model with the following key assumptions, which was based on significant inputs that are not observable in the market and represented a Level 3 measurement. See Note 2—"Summary of Significant Accounting Policies" for a discussion of the assumptions and estimates used in the fair value measurement.

	August 7, 2025	September 30, 2025
Risk-free interest rate	3.8%	3.7%
Expected term (in years)	5.2	5.0
Expected volatility	85%	80%
Expected dividend yield	0%	0%

The following table provides a rollforward of the fair value of the Tranche B Warrants:

	Fair Value
Fair value at issuance date of August 7, 2025	$ 10,952
Increase in fair value	14,676
Balance as of September 30, 2025	$ 25,628

Subsequent to September 30, 2025, certain holders exercised Tranche B Warrants at an exercise price of $1.05 per share resulting in the issuance of 204,214 shares of the company's common stock for net proceeds of $0.2 million, after deducting underwriting discounts and commissions.

7. Commitments and Contingencies

Leases

The following table summarizes the future minimum lease payments for operating and finance leases as of September 30, 2025:

(in thousands)	
2025 (Remaining)	$ 1,475
2026	5,979
2027	5,817
2028	5,735
2029	5,907
Thereafter	28,860
Total future minimum lease payments	53,773

Please see Note 7—"Leases" in the Notes to Consolidated Financial Statements included in Item 8 of the Company's Annual Report on Form 10-K for the year ended December 31, 2024 for further discussion of the Company's material lease agreements.

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 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 condensed consolidated financial statements as of September 30, 2025 and December 31, 2024.

8. Preferred and Common Stock

Preferred Stock

On January 26, 2024, the Company's Board approved an Amended and Restated Certificate of Incorporation, authorizing the Company to issue 10,000,000 shares of undesignated preferred stock at $0.00001 par value per share. There were no shares of such preferred stock outstanding as of September 30, 2025.

Common Stock

As of December 31, 2023, the Company's then effective certificate of incorporation, as amended and restated, authorized the Company to issue 107,000,000 shares of $0.00001 par value common stock. On January 26, 2024, the Company's Board approved an Amended and Restated Certificate of Incorporation, authorizing the Company to issue 300,000,000 shares of common stock at $0.00001 par value per share.

9. Stock-Based Compensation

2011 Stock Incentive Plan

The Company's 2011 Stock Incentive Plan, as amended, (the "2011 Plan") provided for the Company to grant restricted stock, restricted stock units, incentive stock options and nonqualified stock options with respect to shares of common stock to employees, officers, directors, consultants and advisors of the Company. Incentive stock options could only be granted to employees. The 2011 Plan is administered by the Board, or at the discretion of the Board, by a committee of the Board. The exercise prices, vesting schedules and other restrictions of awards were determined at the discretion of the Board or by a committee of the Board if so delegated, except that the exercise price per share of stock options could not be less than 100% of the fair market value of a share of common stock on the date of grant and the term of stock option could not be greater than ten years. Upon the effective date of the 2024 Incentive Award Plan, as discussed below, the Company ceased granting equity awards under the 2011 Plan.

2024 Incentive Award Plan

On January 26, 2024, the Company's Board adopted the 2024 Incentive Award Plan (the "2024 Plan"), which became effective on February 1, 2024. The 2024 Plan provides for the grant of restricted stock, restricted stock units, incentive stock options, nonqualified stock options, stock appreciation rights and other stock or cash-based awards with respect to shares of common stock to employees, officers, directors, consultants and advisors of the Company. The 2024 Plan is administered by the Board, or at the discretion of the Board, by a committee of the Board. The exercise prices, vesting schedules and other restrictions on awards are determined at the discretion of the Board or by a committee of the Board if so delegated, except that the term of any stock option may not be greater than ten years. The number of shares of the Company's common stock initially reserved for issuance under the 2024 Plan was 4,298,825 shares plus the number of shares subject to awards outstanding under the 2011 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company on or after the effective date of the 2024 Plan. In addition, the number of shares of common stock available for issuance under the 2024 Plan is subject to an annual increase on the first day of each calendar year beginning on January 1, 2025 and ending on and including January 1, 2034 equal to the lesser of (i) 5% of the aggregate number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Common Stock as determined by the Board. There were 3,703,185 and 2,275,046 shares available for future grant under the 2024 Plan as of September 30, 2025 and December 31, 2024, respectively.

2024 Employee Stock Purchase Plan

On January 26, 2024, the Company's Board adopted the 2024 Employee Stock Purchase Plan (the "2024 ESPP Plan"), which became effective on February 1, 2024. The number of shares of the Company's common stock initially reserved for issuance under the 2024 ESPP Plan was 487,070 shares, which is eligible for an annual increase on the first day of each calendar year beginning on January 1, 2025 and ending on and including January 1, 2034 equal to the lesser of

(i) 1% of the shares of Common Stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Common Stock as determined by the Board. The Company has not issued any shares under the 2024 ESPP Plan since it became effective. There were 974,624 and 487,070 shares available for future grant under the 2024 ESPP Plan as of September 30, 2025 and December 31, 2024, respectively.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense related to ESPP, stock options and restricted stock units in the following expense categories within its condensed consolidated statements of operations and comprehensive loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2025	2024	2025	2024
Research and development	$ 855	$ 1,716	$ 2,283	$ 5,271
Selling, general and administrative	783	804	2,546	6,256
	$ 1,638	$ 2,520	$ 4,829	$ 11,527

During the nine months ended September 30, 2025, the Company granted to its employees, directors and consultants stock options to purchase a total of 2,401,486 shares of common stock.

10. 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:

	Three And Nine Months Ended September 30,	
	2025	2024
Outstanding stock options	11,170,521	10,727,247
Outstanding restricted stock units	—	586,180
Common stock warrants	43,971,138	161,616
Total	55,141,659	11,475,043

The table presented above does not include the number of shares that may be issued upon exercises of the common 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.

11. Segment Information

The Company has identified one operating and reportable segment. The Company defines its operating segments based on internally reported financial information that is regularly reviewed by the Chief Operating Decision Maker (“CODM”) to analyze financial performance, make decisions, and allocate resources. The Company's Chief Executive Officer is the CODM.

The Company's CODM views specific categories within research and development expenses and selling, general and administrative expenses in total as significant given the direct correlation between cash burn and profitability as a pre-commercial company. The following table reconciles reported revenues to net loss under the significant expense principle for the three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Nine months ended September 30,	
(in thousands)	2025	2024	2025	2024
Revenue	$ —	$ 14	$ —	$ 90
Less:				
Cost of goods sold	—	7	—	50
Research and development:				
Revita direct program expenses	7,183	7,770	22,118	18,282
Rejuva direct program expenses	2,315	2,272	10,193	4,507
Indirect expenses	1,826	1,780	5,679	6,239
Personnel-related expenses	6,133	7,182	20,053	21,162
Total research and development expenses	17,457	19,004	58,043	50,190
Selling, general and administrative	5,237	4,797	15,489	18,171
Total other income (expense), net	(22,909)	621	(23,695)	24,597
Segment net loss	$ (45,603)	$ (23,173)	$ (97,227)	$ (43,724)

12. Subsequent Event

In October 2025, the Company issued and sold 3,333,333 shares of its common stock at a weighted average price of $1.47 per share under the ATM Offering, as further described in Note 1—“Nature of the Business”, for aggregate net proceeds of approximately $4.8 million after sales agent’s commission and other expenses.

Item 2. 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 our unaudited condensed consolidated financial statements and related notes and other information included elsewhere in this Quarterly Report on Form 10-Q. 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, assumptions, and other important factors. 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 Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q and the section titled "Forward-Looking Statements" included elsewhere herein. 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 pioneering pattern-breaking treatments for metabolic diseases, including obesity and type 2 diabetes ("T2D"). We are focused on developing durable disease-modifying therapies that are designed to provide long-term maintenance of metabolic health without requiring lifetime treatment. Our therapeutic approach targets the organ-level root causes of obesity and T2D and is intended to move beyond chronic, symptom-focused disease management.

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, securing related intellectual property rights and conducting discovery, research and development activities for our product candidates.

Revita

The Revita DMR System ("Revita") is approved in Europe under a Conformitè Europëenne ("CE mark") and has received reimbursement authorization through NUB in Germany for the treatment of T2D. In the first half of 2023, we initiated a limited commercial pilot in a single center in Dusseldorf, Germany. This pilot has since been paused, pursuant to the strategic reprioritization we announced on January 31, 2025 ("Strategic Reprioritization").

We have also paused additional investment in the REVITALIZE-1 clinical study of Revita in T2D and the Germany Real-World Registry study. We are continuing to follow existing participants in both studies per protocol and will report clinical, health economic, and patient-relevant outcomes from the Germany Real-World Registry study on an ongoing basis.

We are evaluating Revita in the REMAIN weight maintenance program, which is designed to include three distinct patient cohorts:

REVEAL-1 Cohort (n=22): an open-label study in individuals with obesity who have lost at least 15% of their total body weight on a GLP-1 medication and who either need or choose to discontinue GLP-1 therapy. After stopping the GLP-1 drug, participants receive Revita treatment in an open-label setting and take part in a structured diet and lifestyle program. REVEAL-1 is designed to provide early, real-world insights on how Revita performs after GLP-1 discontinuation.

REMAIN-1 Midpoint Cohort (n=45): a randomized, double-blind, sham-controlled pilot study to assess the potential of Revita to maintain weight loss after GLP-1 discontinuation. Participants are individuals with obesity who have not yet taken GLP-1 drugs, are initiated on tirzepatide at the time of enrollment, and treated with the drug to achieve at least 15% total body weight loss. Participants then discontinue tirzepatide and are randomized to undergo either Revita or a sham procedure with a 2:1 treatment allocation. The key efficacy endpoint is total body weight change in Revita versus sham at 3 months. The randomized Midpoint Cohort serves as an important early randomized readout to assess Revita's potential to maintain weight loss after GLP-1 discontinuation.

REMAIN-1 Pivotal Cohort (n=315): a randomized, double-blind, sham-controlled pivotal study to evaluate the safety and efficacy of Revita in maintaining weight loss. The first co-primary endpoint is defined as the percent of total body weight regain from the time of tirzepatide discontinuation in Revita versus sham patients through 6-month follow up. The primary objective is to demonstrate a benefit of Revita versus sham for weight maintenance after GLP-1

discontinuation. The second co-primary endpoint evaluates a responder rate among the Revita treated participants at 1 year to demonstrate the durability of the Revita procedure for weight maintenance after discontinuation of a GLP-1 based therapy. The responder rate is defined as the percentage of participants who received the Revita procedure who maintain at least 5% total body weight loss from pre-tirzepatide (week -21) to week 52.

We have completed enrollment of the REVEAL-1 Cohort, REMAIN-1 Midpoint Cohort and REMAIN-1 Pivotal Cohort.

Rejuva

We are also developing Rejuva, a gene therapy platform which is designed to enable long-term remission of T2D and obesity by durably reprogramming pancreatic islet cells to endogenously produce metabolic hormones.

The lead product candidate from this platform, RJVA-001, is being advanced for patients with inadequately controlled T2D. RJVA-001 is designed to express GLP-1 locally in pancreatic beta cells using nutrient-responsive control, in a single intervention, potentially enabling physiologic hormone secretion without the high circulating levels that contribute to side effects seen with systemic GLP-1 drugs. We have submitted the first Clinical Trial Application ("CTA") module for RJVA-001 in T2D to regulators, and if the CTA is authorized, the Company expects to dose the first patients with RJVA-001 and report preliminary data in 2026.

The Company's second candidate from the Rejuva platform, RJVA-002, is a dual GIP/GLP-1 gene therapy and is currently in preclinical development. RJVA-002 expands the Rejuva platform into obesity, targeting dual incretin biology with the goal of achieving durable, well-tolerated, weight loss from a single intervention.

We do not have any products approved for sale in the United States. To date, we have financed our operations primarily through the proceeds from sales of our equity and debt financings.

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 nine months ended September 30, 2025 and 2024, we incurred net losses of $97.2 million and $43.7 million, respectively. As of September 30, 2025, we had an accumulated deficit of $512.5 million. As discussed further in *Liquidity and Capital Resources—Funding Requirements and Going Concern*, substantial doubt exists about our ability to continue as a going concern. 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.

Recent Developments

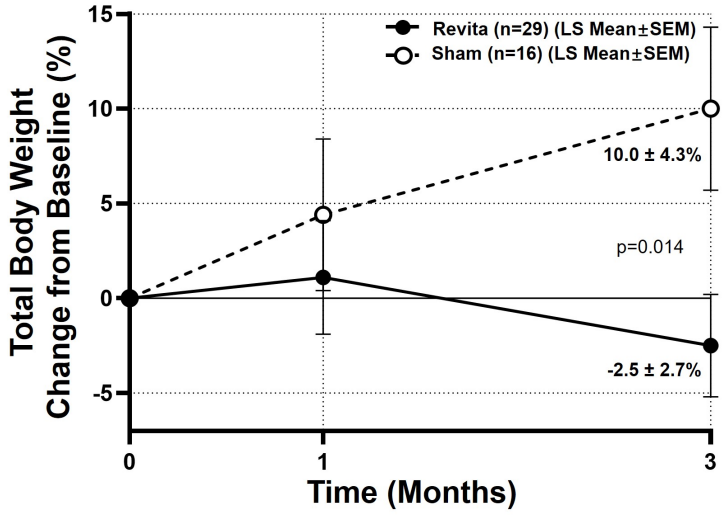
Revita - Ongoing REMAIN Weight Maintenance Program

REVEAL-1 Cohort: we anticipate presenting 6-month data for the REVEAL-1 Cohort in the fourth quarter of 2025, and 1-year data in the second quarter of 2026.

REMAIN-1 Midpoint Cohort: on September 26, 2025, we announced positive results from the randomized REMAIN-1 Midpoint Cohort (n=45), demonstrating Revita's potential to sustain weight loss after discontinuation of GLP-1 treatment. Enrollment for this cohort had been previously completed, and as of September 26, 2025, all participants had been treated. The study met its 3-month efficacy endpoint with strong statistical significance (p=0.014), delivering 2.5% further weight loss with Revita (n=29) even after stopping tirzepatide, versus 10% weight regain in sham-treated patients (n=16) (Figure 1). These results are clinically and statistically significant and provide randomized, blinded evidence that drug-free, durable weight maintenance is possible. No Revita-related SAEs or Grade II+ AEs were observed. Side effects were infrequent, mild, and transient, consistent with prior Revita clinical study experience. We anticipate presenting 6-month randomized data from this cohort in the first quarter of 2026.

3-Month Post-Procedure Total Body Weight Change from Baseline (%)

Figure 1: Percent Total Body Weight Change by Month



REMAIN-1 Pivotal Cohort: we have completed enrollment of the REMAIN-1 Pivotal Cohort. As of October 31, 2025, randomization was complete in 194 participants and the procedure was well-tolerated, with no unanticipated or device/procedure related serious adverse effects reported. No new safety concerns were observed. We expect to complete randomization of 315 participants to Revita versus sham in early 2026, with 6-month topline primary

endpoint data anticipated in the second half of 2026. We anticipate potentially submitting a Premarket Approval ("PMA") application with the FDA in the second half of 2026.

Rejuva

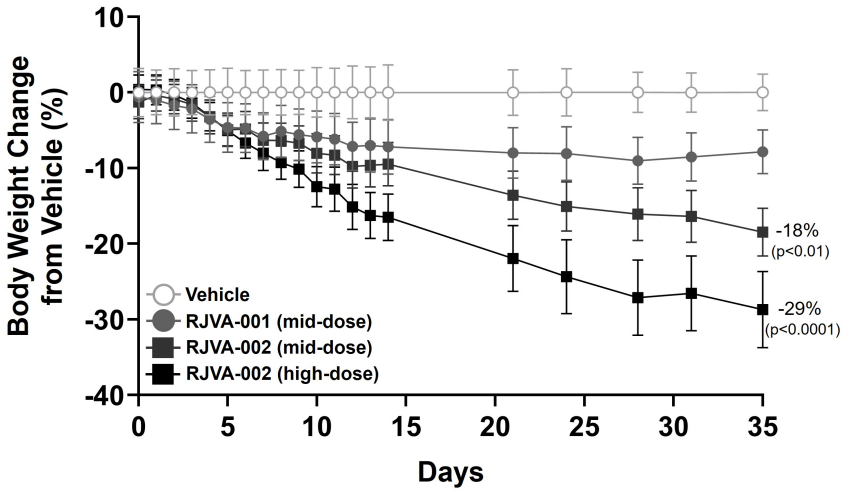
RJVA-001: in the first quarter of 2025, we achieved alignment with European authorities on a patient population and study design for our lead candidate RJVA-001 first-in-human study. In June 2025, we announced the submission of the first module of the CTA in Europe for RJVA-001. In early November 2025, the Company completed preclinical chemistry, manufacturing, and controls activities and lot release for its RJVA-001 drug product.

Pending regulatory authorization, we expect to dose the first patients with RJVA-001 and report preliminary data in 2026. We believe Rejuva could be a potentially first-in-class, smart, durable gene therapy designed to reprogram the pancreas to provide improved metabolic control.

The upcoming Phase 1/2 first in human study is designed to be an open-label, multicenter, single ascending dose study evaluating the safety, tolerability, and preliminary efficacy of RJVA-001 in adults with inadequately controlled T2D despite use of multiple glucose-lowering agents, including GLP-1 receptor agonists. Participants will undergo a standardized medication run-in and GLP-1 washout before receiving RJVA-001 delivered via endoscopic ultrasound-guided intrapancreatic infusion. The preliminary study design comprises three escalating dose cohorts (up to 3 participants each) which will be followed by an optional expansion cohort of up to 10 additional participants treated at the selected optimal dose. Participants will be monitored for 12 months for safety, glucose control, immune response, and GLP-1 expression, and enrolled in a long-term follow-up study for up to 5 years. Primary endpoints include safety and tolerability. Secondary endpoints include change in HbA1c, fasting plasma glucose, and time-in-range as measured by continuous glucose monitoring. Exploratory endpoints assess beta-cell function, metabolic biomarkers, cardiovascular risk markers, and transgene expression.

RJVA-002: on October 7, 2025, we announced potent new preclinical data from RJVA-002, the second candidate from our Rejuva platform, at the 2025 Cell & Gene Meeting on the Mesa. The new data expand the potential of the Rejuva platform from the durable treatment of T2D to obesity. In this ongoing preclinical study, male mice engineered to express a humanized GIP receptor (Biocytogen) were fed a 60% high-fat diet ("HFD") to induce obesity and were then randomized into one of four treatment cohorts: vehicle control, RJVA-001 mid-dose, RJVA-002 mid-dose, and RJVA-002 high-dose (n=7 per group). All mice were continued on HFD for the duration of the study. Treatment with RJVA-002 resulted in a robust, dose-dependent reduction in body weight compared to vehicle control (Figure 2). By day 35, mice in mid- and high-dose cohorts had lost a mean of 18% ($p<0.01$) and 29% ($p<0.0001$) of their body weight after a single dose of RJVA-002, respectively (Figure 2). Results from this ongoing study at longer time points and with associated metabolic measurements will be presented at an upcoming scientific congress.

Figure 2: Percent Body Weight Change Over Time



Board of Directors Update

On August 29, 2025 and effective as of September 2, 2025 (the "Effective Date"), the Board appointed Christopher Thompson, M.D. as a Class I director, with a term expiring at our 2028 annual meeting of stockholders and until his successor is duly elected and qualified or until his earlier resignation or removal. Additionally on August 29, 2025 and effective as of the Effective Date, the Board appointed Ian Sheffield as a Class II director, with a term expiring at our 2026 annual meeting of stockholders and until his successor is duly elected and qualified or until his earlier resignation or removal. Mr. Sheffield was also appointed to the audit committee of the Board, effective as of the Effective Date.

Additionally, on August 31, 2025, Amy W. Schulman tendered her resignation as a Class I director and as a member of the Board's Nominating and Corporate Governance Committee, effective as of the Effective Date. Ms. Schulman's resignation was not the result of any dispute or disagreement with the Company or the Board on any matter relating to the Company's operations, policies or practices.

Intellectual Property Update

As of September 30, 2025, we have built a patent portfolio that includes 33 issued U.S. patents and approximately 45 pending U.S. applications, together with numerous foreign counterparts. We intend to continue seeking patent protection in the United States and internationally for our technologies.

Germany Real-World Registry Study

In 2023, we initiated the Germany Real-World Registry study, a prospective, post-market, clinical follow-up study to evaluate the Revita procedure in patients with inadequately controlled T2D. Participants' per-protocol target entry criteria included a baseline Hemoglobin A1c ("HbA1c") between 7–10% (inclusive), BMI ≤45 kg/m^2, and treatment with at least one glucose-lowering agent ("GLA").

As of October 31, 2025, the first 30 participants with 1 year of follow-up had, at baseline, a mean age of 60 years, a mean weight of 102 kg (225 lbs; BMI 33 kg/m²), and a mean HbA1c of 8.8%, despite being on up to three GLAs.

After a single Revita procedure, these 30 participants achieved a mean total body weight loss of 8.0% with weight decreasing from 102 kg to 94 kg at 3 months, a result that was sustained throughout 1 year post-procedure (94 kg) (Table 1, Figure 3). Notably, 28 of 30 participants lost weight, 20 of 30 participants experienced at least a 5% weight reduction, and 12 of 30 participants saw weight reductions of 10% or more. In parallel, mean HbA1c decreased by 1.0% at 3 months, from 8.8% at baseline to 7.7%, and this improvement was sustained throughout 1 year post-procedure (7.9%) (Table 1) with 83% (25/30) of participants on stable or reduced GLAs. In this cohort, weight loss and glucose improvements began as early as one month after the Revita procedure and were sustained through 1 year of follow-up (Table 1).

Table 1. Germany Real-World Registry Study Weight and Blood Sugar Data Post-Revita Procedure (n=30)

Endpoint	**Baseline**	**3 Months**	**6 Months**	**1 Year**
Weight (kg)	102 ± 3.4	94 ± 3.3	94 ± 3.3	94 ± 3.3
HbA1c (%)	8.8 ± 0.2	7.7 ± 0.4	7.9 ± 0.3	7.9 ± 0.2

Mean ± standard error of the mean ("SEM") values shown. Fractyl Health internal data.

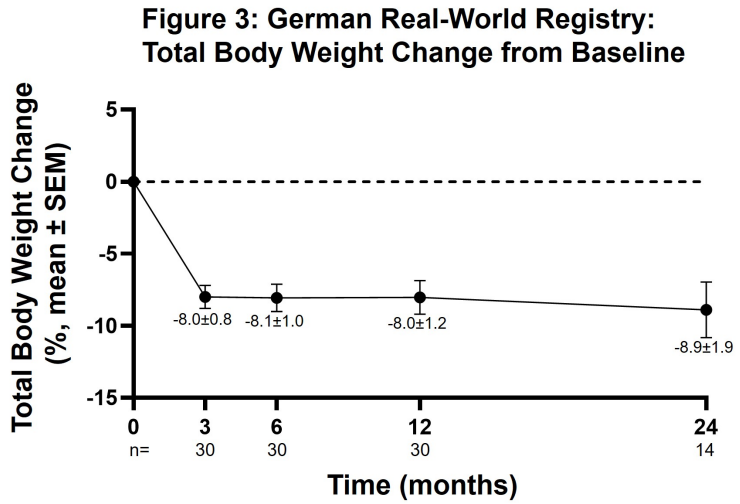
Of these 30 participants, 14 have now been followed for 2 years post-procedure. These 14 participants had a mean age of 62 years, mean weight of 104 kg (229 lbs; BMI 34 kg/m²), and a mean HbA1c of 9.1%, despite being on up to three GLAs. These 14 participants achieved a mean weight loss of 7.9% at 1 year with weight decreasing from 104 kg to 95 kg, an improvement that was maintained through 2 years post-procedure (94 kg) (Table 2). Mean HbA1c reduced by 1.2% at 1 year, from 9.1% at baseline to 7.8%, and this improvement was sustained throughout 2 years post procedure (7.4%) (Table 2), with 86% (12/14) of participants on stable or reduced GLAs.

Table 2. Germany Real-World Registry Study Weight and Blood Sugar Data Post-Revita Procedure (n=14)

Endpoint	Baseline	3 Months	6 Months	1 Year	2 Years
Weight (kg)	104 ± 5.7	96 ± 5.5	96 ± 5.3	95 ± 5.3	94 ± 5.3
HbA1c (%)	9.1 ± 0.4	8.1 ± 0.7	8.2 ± 0.5	7.8 ± 0.3	7.4 ± 0.3

Mean ± SEM values shown. Fractyl Health internal data.

Figure 3. Germany Real-World Registry Study: Total Body Weight Change from Baseline



Medication use was recorded at baseline and each follow-up visit. Changes were categorized as initiation or discontinuation of any GLA or anti-obesity medication class. In this Germany Real-World Registry study, treatment adjustments reflected routine clinical management and were not protocol-mandated. At baseline, patients were on up to 3 GLAs prior to treatment with Revita with inadequately controlled T2D.40% of participants were already receiving a glucagon-like peptide-1 receptor agonist ("GLP-1RA") for glucose control and remained inadequately controlled despite treatment. During follow-up, 14 of 30 (47%) participants remained on stable GLAs through their last follow-up period, 11 of 30 (37%) participants decreased the number of GLAs from baseline, and only 5 of 30 (17%) participants increased the number of GLAs from baseline. Analyses of weight and HbA1c were stratified by the change in the number of GLAs from baseline to account for the potential confounding effects of concomitant pharmacotherapy.

When stratifying for medication adjustments post-baseline, participants who were on either stable or reduced medications (n=25) had similar effects on weight and HbA1c at 1 year and 2 years post-procedure compared to the entire cohort. Those participants on stable or reduced medications had a mean weight reduction of 8.4±1.3% and 8.8±2.2% compared to 8.0±1.2% and 8.9±1.9% for the entire cohort (Figure 3) at 1 year and 2 years post-procedure, respectively. Likewise, participants on stable or reduced medications had a mean HbA1c reduction of 0.9±0.3% and 1.7±0.4% compared to 0.8±0.3% and 1.7±0.4% for the entire cohort at 1 year and 2 years post-procedure, respectively. Thus, the sustained improvement in weight and HbA1c observed after Revita occurred despite a substantial reduction in average GLA use and cannot be attributed to new medication use during the Germany Real-World Registry study follow up period.

Patient-reported outcomes ("PROs") revealed that Revita was valued by patients and improved T2D management. At 1 year and 2 years post-procedure, 97% and 93% of participants, respectively, reported that they would undergo the

Revita procedure again, and 100% and 93% of participants, respectively, would recommend the procedure to a family member or friend (n=30 at 1 year; n=14 at 2 years post-procedure). Revita received a mean score of 9.8±0.1 and 10±0.0 (1-10 scale, 10 highest) for its ability to improve T2D management. Revita's ability to improve quality of life was scored a mean of 9.6±0.2 and 10±0.0 by Germany Real-World Registry study participants at 1 and 2 years post-procedure, respectively.

No device- or procedure-related serious adverse events have been reported to date.

Collectively, these findings highlight the potential of a single Revita treatment to deliver durable weight maintenance, glucose improvement, and reduction in medication utilization without significant adverse events in a real-world setting out to 2 years post-procedure. Parallel PROs demonstrate durable patient-perceived value and improvement in T2D management.

Components of our Condensed Consolidated Results of Operations

There have been no material changes to the components of our results of operations described in *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* of our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 3, 2025 (our "Annual Report"), except as stated below.

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)	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Direct program-specific expenses:				
Revita	$ 7,183	$ 7,770	$ 22,118	$ 18,282
Rejuva	2,315	2,272	10,193	4,507
Total direct program-specific expenses	9,498	10,042	32,311	22,789
Indirect expenses	1,826	1,780	5,679	6,239
Personnel-related expenses (including stock-based compensation)	6,133	7,182	20,053	21,162
Total research and development expenses	$ 17,457	$ 19,004	$ 58,043	$ 50,190

Critical Accounting Policies and Significant Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of unaudited condensed 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 condensed 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.

Our significant accounting policies are described in more detail in Note 2 to our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q as well as Note 2 to our audited financial statements as of and for the year ended December 31, 2024 included in our Annual Report. Our critical accounting estimates related to warrant liabilities, as described below, have been updated from what we disclosed in the "Critical Accounting Policies and Significant Estimates" section of the Management's Discussion and Analysis of Financial Condition and Results of Operation in our Annual Report. For a complete discussion of our updated critical accounting estimates related to warrant liabilities, see Note 2 to our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of three months ended September 30, 2025 and 2024

The following table summarizes our condensed consolidated results of operations for the three months ended September 30, 2025 and 2024.

(in thousands)	Three Months Ended September 30, 2025	2024	Change Amount	%
Revenue	$ —	$ 14	$ (14)	(100.0%)
Cost of goods sold	—	7	(7)	(100.0%)
Gross profit	—	7	(7)	(100.0%)
Operating expenses:				
Research and development	17,457	19,004	(1,547)	(8.1%)
Selling, general and administrative	5,237	4,797	440	9.2%
Total operating expenses	22,694	23,801	(1,107)	(4.7%)
Loss from operations	(22,694)	(23,794)	1,100	(4.6%)
Other income (expense), net	(22,909)	621	(23,530)	(3,789.0%)
Net loss and comprehensive loss	$ (45,603)	$ (23,173)	$ (22,430)	96.8%

Revenue and Cost of Goods Sold

Revenue and cost of goods sold during the three months ended September 30, 2024 was related to our pilot commercial launch in Germany. As part of the Strategic Reprioritization, we paused our commercial efforts in Germany in the first quarter of 2025.

Research and Development Expenses

Research and development expenses decreased by $1.5 million, or 8.1%, during the three months ended September 30, 2025, as compared to the three months ended September 30, 2024, primarily due to reduced spending on the REVITALIZE-1 study as a result of our Strategic Reprioritization and a decrease in stock-based compensation expense.

Revita-related expenses decreased by $0.6 million primarily due to a $0.1 million decrease in clinical related expenses and a $0.5 million decrease in collaborative medical research expenditures. Decreases in clinical related expenses were primarily driven by reduced expenses from the REVITALIZE-1 study as a result of our Strategic Reprioritization, partially offset by the positive progress made in our REMAIN-1 study. Rejuva-related expenditures were comparable to those incurred in the same period in 2024. In addition, stock-based compensation expenses decreased by $0.9 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $0.4 million, or 9.2%, during the three months ended September 30, 2025 as compared to the three months ended September 30, 2024, primarily attributable to professional service fees incurred related to the issuance of the warrants in connection with the August 2025 Offering. See the “Liquidity and Capital Resources” section below for details about the August 2025 Offering and its associated warrants.

Other Income (Expense), Net

Other expense, net, of $22.9 million during the three months ended September 30, 2025 was primarily attributable to a $21.2 million loss from the change in fair value of warrant liabilities and a $1.9 million loss from the change in fair value of the 2023 Notes, partially offset by $0.2 million of net interest income. Other income, net, of $0.6 million during the three months ended September 30, 2024 was primarily attributable to a $2.3 million gain from the change in fair value of warrant liabilities and $0.9 million of net interest income, partially offset by a $2.6 million loss from the change in fair value of the 2023 Notes.

Change in fair value of warrant liabilities was mainly a result of the fluctuation of the value of the underlying shares of our common stock. Change in fair value of the 2023 Notes were primarily driven by a combination of interest on the notes payable and the fluctuation of market interest rates.

Comparison of nine months ended September 30, 2025 and 2024

The following table summarizes our condensed consolidated results of operations for the nine months ended September 30, 2025 and 2024.

(in thousands)	Nine Months Ended September 30, 2025	2024	Change Amount	%
Revenue	$ —	$ 90	$ (90)	(100.0%)
Cost of goods sold	—	50	(50)	(100.0%)
Gross profit	—	40	(40)	(100.0%)
Operating expenses:				
Research and development	58,043	50,190	7,853	15.6%
Selling, general and administrative	15,489	18,171	(2,682)	(14.8%)
Total operating expenses	73,532	68,361	5,171	7.6%
Loss from operations	(73,532)	(68,321)	(5,211)	7.6%
Other income (expense), net	(23,695)	24,597	(48,292)	(196.3%)
Net loss and comprehensive loss	$ (97,227)	$ (43,724)	$ (53,503)	122.4%

Revenue and Cost of Goods Sold

Revenue and cost of goods sold during the nine months ended September 30, 2024 was related to our pilot commercial launch in Germany. As part of the Strategic Reprioritization, we paused our commercial efforts in Germany in the first quarter of 2025.

Research and Development Expenses

Research and development expenses increased by $7.9 million, or 15.6%, during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, primarily due to the advancements made in our Revita and Rejuva programs.

Revita-related expenses increased by $3.8 million primarily due to a $5.0 million increase in clinical related expenses, partially offset by a $1.2 million decrease in collaborative medical research expenditures. Increases in clinical expenses were primarily driven by the positive progress made in our REMAIN-1 study, partially offset by reduced expenses from the REVITALIZE-1 study as a result of our Strategic Reprioritization. Rejuva-related expenditures increased by $5.7 million due to continued development in our Rejuva gene therapy program.

Salaries, bonuses and other compensatory benefits increased by $1.9 million primarily due to severance expenses related to the Strategic Reprioritization as well as our effort to bring certain clinical and scientific resources in house.

The increases above were partially offset by a $3.0 million decrease in stock-based compensation and a $0.7 million decrease in our allocated facility expenses primarily due to the expenses incurred when we moved into our new office and laboratory space in Burlington, MA in the first quarter of 2024.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $2.7 million, or 14.8%, during the nine months ended September 30, 2025, as compared to the nine months ended September 30, 2024, primarily due to a $3.7 million decrease in stock-based compensation, partially offset by a $0.3 million increase in personnel-related expenses, including salaries, bonuses and other compensatory benefits, as a result of the expansion of our general and administrative workforce to support our operation as a public company. In the third quarter of 2025, we also incurred $0.5 million professional service fees related to the issuance of the warrants in connection with the August 2025 Offering. See the “Liquidity and Capital Resources” section below for details about the August 2025 Offering and its associated warrants.

Other Income (Expense), Net

Other expense, net, of $23.7 million during the nine months ended September 30, 2025 was primarily attributable to a $20.7 million loss from the change in fair value of warrant liabilities and a $3.8 million loss from the change in fair value of the 2023 Notes, partially offset by $0.9 million of net interest income. Other income, net, of $24.6 million during the nine months ended September 30, 2024 was primarily attributable to a $17.4 million gain from the change in fair value of warrant liabilities, a $8.0 million gain from the change in fair value of the 2022 Convertible Notes and $3.4 million net interest income, partially offset by a $4.2 million loss from the change in fair value of the 2023 Notes.

Changes in fair value of warrant liabilities and changes in fair value of the 2022 Convertible Notes were mainly a result of the fluctuation of the value of the underlying shares of our common stock. Changes in fair value of the 2023 Notes were primarily driven by a combination of interest on the notes payable and the fluctuation of market interest rates.

Liquidity and Capital Resources

We manage our cash and capital structure to maintain our 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.

Loan and Security Agreements

2023 Notes

On September 7, 2023, we entered into a credit agreement, as amended from time to time (the "Credit Agreement"), with Symbiotic Capital Opportunities Holding, L.P. and Catalio Structured Opportunities AIV I LP (the "2023 Lenders") that provided for term loans up to an aggregate principal amount of $45.0 million (the "2023 Notes") 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, would have been extended upon our achievement of certain operating and funding milestones as defined in the Credit Agreement, by July 31, 2024. The Credit Agreement also provides for a third tranche with an uncommitted principal amount of $20.0 million that may be extended to us, subject to the 2023 Lenders' prior written consent in their sole discretion. Due to a shift in business strategy expansion to include the weight maintenance study, we decided not to pursue the milestones required to access the second tranche. As a result, the second tranche was not extended.

The Credit Agreement, as amended, contains financial covenants 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. As of September 30, 2025, we were in compliance with the minimum liquidity covenant and other terms of the arrangement.

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. Under the terms of the Credit Agreement, the first principal payment date may be extended to September 30, 2027, at our election, if certain financing milestones as defined in the Credit Agreement are achieved on or prior to September 30, 2026. During 2024, we achieved the defined milestones and elected to extend the first principal payment date to September 30, 2027. In addition, upon any principal payment, we are required to make an additional payment to the 2023 Lenders of 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 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.

As of September 30, 2025, the balance of the 2023 Notes was carried at its fair value of $30.8 million.

S-3 Registration Statement

On March 3, 2025, we filed a Registration Statement on Form S-3 with the U.S. Securities and Exchange Commission ("SEC"), which was subsequently amended on March 13, 2025 (as amended, the "S-3 Registration

Statement"). The S-3 Registration Statement became effective on March 18, 2025. It contains a base prospectus, which covers the offering, issuance and sale of up to $300.0 million in the aggregate of the securities from time to time in one or more offerings.

At-The-Market Offering

Concurrently with the filing of the S-3 Registration Statement, we filed a sales agreement prospectus supplement under an at-the-market offering (the "ATM Offering") covering the offering, issuance and sale by us of up to a maximum aggregate offering price of $100.0 million of our common stock that may be offered, issued and sold from time to time. During the nine months ended September 30, 2025, we issued and sold 1,368,627 shares of our common stock under the ATM Offering at a weighted average price of $1.66 per share resulting in net proceeds of approximately $2.1 million, after deducting underwriting discounts and commissions as well as related offering expenses. In October 2025, we issued and sold an additional 3,333,333 shares of our common stock under the ATM Offering at a weighted average price of $1.47 per share, resulting in net proceeds of approximately $4.8 million, after deducting underwriting discounts and commissions.

August 2025 Offering

On August 6, 2025, we entered into an underwriting agreement with Ladenburg Thalmann & Co. Inc. ("Ladenburg"), in connection with the underwritten offering, issuance and sale by us of 19,047,619 shares of our common stock, warrants to purchase up to 19,047,619 shares of our common stock (the "Tranche A Warrants") and warrants to purchase 19,047,619 shares of our common stock (the "Tranche B Warrants"). The combined offering price for each share of our common stock, accompanying Tranche A Warrant and accompanying Tranche B Warrant was $1.05. The securities were issued pursuant to the S-3 Registration Statement and a related prospectus supplement filed with the SEC (the "August 2025 Offering").

Each Tranche A Warrant has an exercise price per share of common stock equal to $1.05, subject to certain adjustments. The Tranche A Warrants are exercisable at any time on or after August 7, 2025 and will expire on August 7, 2027. The Tranche A Warrants are callable at our option following the release of 3-month randomized midpoint clinical data from the ongoing REMAIN-1 study, which data was published on September 26, 2025, subject to satisfaction of certain conditions including that the average trading price of the stock exceeds $1.37 per share for 15 consecutive trading days and a minimum daily trading volume threshold.

Each Tranche B Warrant has an exercise price per share of common stock equal to $1.05, subject to certain adjustments. The Tranche B Warrants are exercisable upon receipt of the Tranche B Warrant Stockholder Approval, which was obtained at the Special Meeting of Stockholders and the Tranche B Warrants became exercisable on October 3, 2025. The Tranche B Warrants will expire on October 3, 2030, which is the date that is five years from the date of the Tranche B Warrant Stockholder Approval.

In addition, we granted Ladenburg a 30-day option to purchase up to an additional 2,857,142 shares of our common stock, along with associated Tranche A Warrants and Tranche B Warrants, at the combined public offering price of $1.05 per share, less underwriting discounts and commissions. On August 6, 2025, Ladenburg exercised the option to purchase additional shares of our common stock, along with associated Tranche A Warrants and Tranche B Warrants, in full.

The August 2025 Offering closed on August 7, 2025, from which we received approximately $20.7 million of net proceeds, after deducting underwriting discounts and commissions as well as estimated offering expenses payable by us.

Subsequent to September 30, 2025, certain holders exercised Tranche A Warrants at an exercise price of $1.05 per share resulting in the issuance of 1,290,618 shares of our common stock for net proceeds of $1.3 million, after deducting underwriting discounts and commissions. Certain holders exercised Tranche B Warrants at an exercise price of $1.05 per share resulting in the issuance of 204,214 shares of the our common stock for net proceeds of $0.2 million, after deducting underwriting discounts and commissions.

September 2025 Offering

On September 26, 2025, we entered into an underwriting agreement with BofA Securities, Inc. and Evercore Group L.L.C., as representatives of several underwriters, pursuant to which we issued and sold 60,000,000 shares of our

common stock, at a price to the public of $1.00 per share. The securities were issued pursuant to the S-3 Registration Statement and a related prospectus supplement filed with the SEC (the "September 2025 Offering").

The September 2025 Offering closed on September 29, 2025, from which we received approximately $56.0 million of net proceeds, after deducting underwriting discounts and commissions as well as estimated offering expenses.

Funding Requirements and Going Concern

We expect our expenses to increase in connection with our ongoing research and development activities, particularly as we advance our product candidates. 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, we do not have any products approved for sale and have not generated any revenue from any sources, including product sales. Our product candidates, if approved, may not achieve commercial success. In addition, 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, and we will need to obtain additional funds to achieve our business objectives.

Our future success is dependent on our ability to develop product candidates, generate significant revenue, 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 our product candidates, raising additional capital with favorable terms, development by our 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 capital which may not be available to us on favorable terms or not at all.

To date, we have financed our operations primarily through our equity and debt financings. We have a history of operating losses and had an accumulated deficit of $512.5 million as of September 30, 2025. Based on our current business plans, we believe that our available cash and cash equivalents of $77.7 million as of September 30, 2025, combined with subsequent proceeds received to date from common stock issued under the ATM Offering and warrant exercises, will be sufficient to fund our operating expenses and capital expenditure requirements into early 2027, through multiple key clinical and regulatory milestones. Our estimate as to how long we expect our existing cash and cash equivalents will be able to continue to fund our operating expenses and capital expenditure requirement is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. In addition, without additional financing, we may not be able to comply with the minimum liquidity covenant related to our 2023 Notes by the end of 2026. Given the inherent risk and uncertainty of future cash flow estimates as well as the minimum liquidity covenant requirement, we have concluded that substantial doubt exists about our ability to continue as a going concern for at least one year after the date that these financial statements are issued. The accompanying unaudited interim condensed consolidated financial statements in this Quarterly Report on Form 10-Q 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 unaudited interim condensed 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.

We expect to seek additional funds through equity or debt financings or through collaboration or licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into collaboration or licensing transactions and, if necessary, we will be required to implement cost reduction strategies which could curtail or delay our current operating plans.

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. 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 financings 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 additional 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 *Part II. Item 1A. Risk Factors—Risks Related to Financial Condition and Capital Requirements.*

We will require substantial additional capital beyond the proceeds from our IPO, ATMt Offering, August 2025 Offering and September 2025 Offering and subsequent offerings 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

The following table summarizes our sources and uses of cash for each of the periods presented:

(in thousands)	Nine Months Ended September 30, 2025	2024
Net cash used in operating activities	$ (68,992)	$ (48,487)
Net cash used in investing activities	(554)	(1,532)
Net cash provided by financing activities	79,739	101,159
Net increase in cash, cash equivalents and restricted cash	$ 10,193	$ 51,140

Operating Activities

Cash used in operating activities of $69.0 million for the nine months ended September 30, 2025 was primarily driven by spending on our ongoing clinical studies, Rejuva-related research activities, professional services related to our corporate and general administrative activities, as well as personnel-related expenses, including salaries, bonuses, and other compensatory benefits. Cash used in operating activities resulted primarily from our net loss of $97.2 million adjusted for net non-cash expense of $28.4 million, primarily consisting of $20.7 million non-cash loss from the change in fair value of warrant liabilities, $0.6 million non-cash loss from the change in fair value of notes payable, $4.8 million in stock-based compensation, $1.2 million non-cash operating lease expense, $0.9 million depreciation and $0.2 million non-cash interest expense. 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 of $48.5 million for the nine months ended September 30, 2024 was primarily driven by spending on our ongoing clinical studies, Rejuva-related research activities, professional services related to our corporate and general administrative activities, as well as personnel-related expenses, including salaries, bonuses, and other compensatory benefits. Cash used in operating activities resulted primarily from our net loss of $43.7 million adjusted for net non-cash income of $9.4 million, primarily consisting of a $17.4 million gain from change in fair value of warrant liabilities and $5.7 million gain from change in fair value of notes payable (non-cash portion), offset by $11.5 million in stock-based compensation, a $1.5 million non-cash operating lease expense, a $0.5 million depreciation and a $0.3 million non-cash interest expense. Cash used in operating activities was also impacted by changes in working capital and other assets and liabilities of $4.6 million.

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2025 and 2024 were related to the purchase of property and equipment. The decrease in the nine months ended September 30, 2025, as compared with the nine months ended September 30, 2024, was primarily due to our spending on leasehold improvement, office furniture and information technology equipment as we moved into our new office and laboratory space in Burlington, MA in the first quarter of 2024.

Financing Activities

Cash provided by financing activities of $79.7 million for the nine months ended September 30, 2025 was primarily driven by net proceeds of $79.8 million from the issuance of common stock in connection with the August 2025 Offering and the September 2025 Offering and our ATM offering and $0.3 million from stock option exercises, partially offset by $0.3 million of principal payments made on finance lease obligations.

Cash provided by financing activities of $101.2 million for the nine months ended September 30, 2024 was primarily driven by the $103.7 million capital raised from the IPO, net of discounts and commissions, partially offset by $2.9 million payments of public offering costs made to third-party service providers. We also received proceeds of $0.4 million from stock option exercises.

Contractual Obligations and Commitments

We have entered into arrangements that contractually obligate us to make payments that will affect our liquidity and cash flows in future periods.

As of September 30, 2025, our lease commitments reflect payments due for our operating and finance leases. The operating leases include our corporate office and laboratory space in Burlington, MA that will expire in June 2034. The finance leases represent leases of laboratory equipment used in our Rejuva pre-clinical activities. As of September 30, 2025, our future contractual commitments for our leases were $53.8 million, of which $52.8 million were related to our operating leases. For additional information on our leases and timing of future payments, please see Note 7— "Commitments and Contingencies" to the unaudited condensed consolidated financial statements included in this Quarterly Report on this Form 10-Q.

We have also entered into contracts in the normal course of business with various third parties for clinical trials, preclinical research studies, manufacturing, and other services and products for operating purposes. These contracts typically do not contain any minimum purchase commitments and provide for termination upon notice. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation.

Recent Accounting Pronouncements

See Note 2—"Summary of Significant Accounting Policies" to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information.

OBBB Act

On July 4, 2025, the One Big Beautiful Bill ("OBBB") Act, which includes a broad range of tax reform provisions, was signed into law in the United States and we continue to assess its impact. We currently do not expect the OBBB Act to have a material impact on our estimated annual effective tax rate in 2025.

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Act of 2012 ("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 have also elected 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 our IPO; (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 SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to interest rate risk, credit risk, foreign currency risk, and inflation risk. These market risks arise in the normal course of business. There have been no material changes to the information included under *Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk*, in our Annual Report.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not subject to any material legal proceedings.

Item 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below and the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and in Part I. Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain important 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 a 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 received CE mark for Revita in Europe, following its European Certification in 2016, and have received reimbursement authorization through NUB in Germany for the treatment of T2D. 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 lead product candidate Revita, including the ongoing REMAIN-1 pivotal clinical study, and preclinical and clinical studies of our product candidate Rejuva. Pursuant to our Strategic Reprioritization, we paused additional investment in our Revita programs for T2D, which consist of the REVITALIZE-1 study and the Germany Real-World Registry study. We are continuing to follow existing participants in both studies per protocol and will report clinical, health economic, and patient-relevant outcomes from the Germany Real-World Registry study on an ongoing basis. We have not yet demonstrated our ability to successfully complete any pivotal clinical studies, submit a Premarket Approval application ("PMA"), a new drug application, or biologic license application ("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 proceeds from sales of our equity and debt financing. We have incurred a net loss of approximately $97.2 million and $43.7 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of approximately $512.5 million. As noted elsewhere in this Quarterly Report on Form 10-Q, we have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. 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 the REMAIN-1 pivotal clinical study, a randomized, double-blind trial of Revita versus sham in patients who have lost at least 15% total body weight on tirzepatide therapy and wish to discontinue their GLP-1 therapy without weight regain. Pursuant to our Strategic Reprioritization, we paused additional investment in our Revita programs for T2D, which consist of the REVITALIZE-1 study and the Germany Real-World Registry study. We are continuing to follow existing participants in both studies per protocol and will report clinical, health economic, and patient-relevant outcomes from the Germany Real-World Registry study on an ongoing basis. 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 revenue from our pilot commercial launch of Revita in Germany, in which additional investment has been paused. 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.

We require substantial additional capital or must implement other business strategies to execute our operating plan and continue to operate as a going concern. 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. We are incurring additional costs associated with operating as a public company. Accordingly, we will need to obtain additional funding beyond the proceeds from our IPO, ATM Offering, August 2025 Offering and September 2025 Offering in order to maintain our continuing operations in the future.

As of September 30, 2025, we had approximately $77.7 million in cash and cash equivalents, which, combined with subsequent proceeds received to date from common stock issued under the ATM Offering and warrant exercises, will be sufficient to fund our operating expenses and capital expenditure requirements into early 2027, through multiple key clinical and regulatory milestones. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operating expenses and capital expenditure requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. In addition, without additional financing, we may not be able to comply with the minimum liquidity covenant related to our 2023 Notes by the end of 2026. Given the inherent risk and uncertainty of future cash flow estimates as well as the minimum liquidity covenant requirement, we have concluded that substantial doubt exists about our ability to continue as a going concern for at least one year after the date that these financial statements are issued. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited.

We expect to seek additional funds through equity or debt financings or through collaboration or licensing transactions or other sources. We may be unable to obtain equity or debt financings or enter into collaboration or licensing transactions and, if necessary, we will be required to implement additional or new cost reduction strategies which could curtail or delay our current operating plans.

Pursuant to a Strategic Reprioritization, we:

- are prioritizing our REMAIN-1 pivotal study;
- are advancing Rejuva; and
- paused additional investment in our Revita programs for T2D, consisting of the REVITALIZE-1 study and the Germany Real-World Registry study.

As part of the Strategic Reprioritization, we streamlined resources, including a workforce reduction impacting 22 employees, or approximately 17% of our workforce. The Strategic Reprioritization has been substantially implemented.

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;
- our business strategy, including our Strategic Reprioritization;
- 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;
- 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 our existing cash and cash equivalents to fund the ongoing REMAIN-1 pivotal clinical study of Revita; fund the continued preclinical and clinical development of our Rejuva gene therapy candidate RJVA-001; follow the existing participants in the REVITALIZE-1 pivotal clinical study of Revita per protocol; follow the Germany Real-World Registry study participants per protocol; 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. 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 and geopolitical 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 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 financial covenants including 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. We may not be able to maintain the minimum liquidity covenant related to the Credit Agreement without additional financing. 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. See "—We require substantial additional capital or must implement other business strategies to execute our operating plan and continue to operate as a going concern. 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."

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 will be required to obtain further funding 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. 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. Additionally, changing trade policies and geopolitical disputes and other international conflicts have resulted in increased tariffs, sanctions and other measures that restrict international trade, and may materially adversely affect our business, particularly if these measures affect regions where manufacturing and product development activities take place or raw materials are sourced. For example, tensions between the United States and other countries have led to a series of tariffs being imposed by the United States and those countries, as well as other business restrictions. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain. As these tensions continue to rise, more targeted approaches on certain products, industries or companies could significantly impact our development and commercialization efforts. The U.S. government has recently imposed tariffs on certain foreign goods, and some foreign governments have threatened or instituted retaliatory tariffs on certain U.S. goods and have indicated a willingness to impose additional tariffs on U.S. products, which could increase the cost of goods needed to commercialize our products and continue development of our product candidates. Further, such actions by the U.S. could result in other retaliatory actions by those countries which could impact our ability to profitably commercialize our products in those jurisdictions. As a result, our business, operations, and financial condition could be materially harmed.

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 ("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 September 30, 2025, 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, 2024, we had U.S. federal and state net operating loss carryforwards of approximately $260.4 million and $225.9 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 (the "Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security (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, 2024, we had U.S. federal and state research and development tax credit carryforwards of $14.3 million and $5.6 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 our IPO, together with other transactions that have occurred since our inception, may have triggered such an ownership change pursuant to Section 382. We may have experienced or 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 and expect to initiate clinical development of our Rejuva candidate RJVA-001 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.

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 ("FDCA"), or approval of a PMA application, from the FDA, unless an exemption applies. We expect Revita to be subject to the requirement for approval of a PMA application. 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 for weight maintenance and to improve glycemic control.

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 authorized by the FDA. Any delay or failure to obtain necessary marketing authorizations could harm our business. Furthermore, even if we are granted such marketing authorizations, 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 ("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 applications to comparable foreign authorities. A BLA and similar applications must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency (or efficacy) 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 ("EU"), our products must comply with the general safety and performance requirements of the Medical Devices Regulation ("MDR") (Regulation (EU) No 2017/745), which repeals and replaces the Medical Devices Directive (the "MDD"). Compliance with these requirements is a prerequisite to be able to affix the European conformity ("CE" 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 *Part I, Item 1. Business—Government Regulations—Regulation of Medical Devices in the European Union* in our Annual Report for more information.

The CE mark for Revita was applied 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 (" 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 the EU have diverged. Northern Ireland has adopted a hybrid approach as a result of the divergence in accordance with the Northern Ireland Protocol. GB's national legislation remains based on the (EU) MDD as implemented nationally. However, on December 16, 2024, the UK government published an amendment to the UK Medical Devices Regulations to clarify and strengthen the post-market surveillance requirements for medical devices in GB. This amendment will come into force on June 16, 2025. In addition, the Medicines and Healthcare products Regulatory Agency (the "MHRA") launched a consultation between November 14, 2024 and January 5, 2025 on proposals to update the pre-market requirements for medical devices in GB. The MHRA has stated that it will incorporate feedback to this consultation into new UK legislation on pre-market requirements for medical devices in GB. The new legislation is expected to come into force in 2026. Under the UK Medical Devices Regulations, certain medical devices need to be "UKCA" certified by a UK approved body in order to be lawfully placed on the GB market. However, certain medical devices in compliance with: (1) the (EU) MDD can continue to be placed on the GB market until the sooner of certificate expiration or June 30, 2028. or (2) the (EU) MDR can continue to be placed on the GB market until the sooner of certificate expiration or June 30, 2030. Medical devices also need to bear a physical United Kingdom Conformity Assessment (the "UKCA") mark in order to be lawfully placed on the GB market. However, one of the key topics in the MHRA's recent consultation was to obtain feedback on whether to remove the requirement for a medical device and its labelling (i.e., packaging and instructions for use) in GB to bear a physical UKCA mark. Instead of requiring a medical device and its labelling to bear a UKCA mark, manufacturers would be required to assign a unique design identification ("UDI") to medical devices before they are placed on the GB market. If this change is implemented, we may no longer be required to affix the physical UKCA mark to our devices, but we may need to assign and affix a UDI.

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, pure, potent and/or 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 results from clinical studies to meet the level of statistical significance or otherwise demonstrate the evidence 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 submission of a 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 any such 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 and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however 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, or with respect to biological product candidates, that such candidates are safe, pure, and potent for their intended 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 alignment with the FDA or other regulatory authorities as to the design or implementation of our clinical studies;
- delays in or failure to obtain regulatory allowance or approval to commence a clinical study;
- delays in or failure to reach an agreement on acceptable terms with clinical study sites or prospective 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 clinical studies in accordance with the FDA's good clinical practice ("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 ("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 and Australia. 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, regardless of whether such clinical studies were conducted pursuant to an IND or IDE, 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, if the applicable clinical studies were not otherwise subject to an IND or IDE, the FDA will not accept the data as support for an application for regulatory approval unless the study was well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. 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 submit 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 in the United States, if necessary to support for a PMA, 510(k) premarket notification or de novo classification request, a sponsor must, among other things, apply for and obtain institutional review board ("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 submit or obtain approval of such IDEs or comparable documents on the timeline we expect. 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:
- the report of prior investigations or the investigational plan;
- the methods, facilities, and controls used for the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device; or
- 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 an 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 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. In addition, even if we are able to obtain approval of an IDE, such approval does not guarantee that the applicable clinical investigation, even if successful, will eventually lead to FDA approval of the underlying product candidate.

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

While we have submitted a CTA module and plan to submit INDs, CTAs or comparable documents for our Rejuva gene therapy candidates, we may not be able to submit such INDs or comparable documents on the timeline we expect. Moreover, we cannot be sure that submission of an IND or CTA or comparable application will result in the FDA or other comparable foreign regulatory authorities allowing clinical studies to begin, or that, once begun, issues will not arise that suspend or terminate clinical studies. These considerations also apply to clinical studies we may submit as amendments to existing INDs or to a new IND. Any failure to submit INDs, CTAs or other comparable documents, on the timelines we

expect or to obtain regulatory allowances or other authorizations for any proposed studies may prevent us from completing such clinical studies or commercializing our product candidates on a timely basis, if at all.

Delays or disruptions in regulatory, permit or governmental approval processes may impact our business

If federal government funding lapses, and/or if federal agencies are unable to perform their usual duties, such as reviewing regulatory submissions, issuing permits, or performing inspections, our business could be adversely affected. For example, a prolonged federal government shutdown could result in delays in regulatory approvals.

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, serious adverse events 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, adverse events 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 ("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 designations, there can be no guarantee that the designation will benefit the development and regulatory approval process.

The FDA granted Breakthrough Device designation for the Revita DMR System, as an adjunct to diet and exercise, to perform hydrothermal ablation of the duodenal mucosa (the "Revita DMR procedure"), for use in the maintenance of weight loss after discontinuation of GLP-1-based therapy on patients who cannot tolerate long-term GLP-1 therapy and who are not candidates for endoscopic remodeling procedure or bariatric surgery. 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, compared to more conventional procedures and Breakthrough Device designation has no bearing on whether or not the FDA will approve Revita for any indication. 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 ("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, ("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 them 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. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the underlying biologic component application, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with respect to any device component, which may delay the approval of the combination product.

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 ("cGMPs"), or similar foreign requirements, good clinical practice requirements ("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 ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application ("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 transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully 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 *Part I, Item 1. Business—Government Regulation—Regulation of Medical Devices in the European Union* in our Annual Report 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 ("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.

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 policy changes, new leadership, 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 (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, in recent 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. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown or similar constraints on funding or staffing occur, or if renewed global health concerns 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. Their designation process, which is significantly stricter under the MDR, has experienced considerable delays due to the COVID-19 pandemic. Despite a recent increase in designations, the current number of notified bodies designated under the MDR remains significantly lower than the number of notified bodies designated under the previous regime. The current designated notified bodies are therefore facing a backlog of requests as a consequence of which 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 ("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 (“ 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, and our product candidates for Rejuva. 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 and Rejuva. In 2016, Revita was CE marked under the MDD. The certificate was renewed under the MDD on March 8, 2021. We are investing significant efforts and financial resources in the research and development of Revita as well as our Rejuva gene therapy candidates. As part of our Strategic Reprioritization, we are prioritizing our REMAIN-1 pivotal study, advancing Rejuva, and paused additional investment in our Revita programs for T2D, including the REVITALIZE-1 study and the Germany Real-World Registry study. 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, Rejuva 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, Rejuva, or any other product candidate 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/or 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 or Rejuva, if approved, 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 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 . 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 efficacy of Revita for repeat use, it could have a material adverse effect 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 people living with obesity or T2D. To the extent any of the aforementioned groups do not accept Revita as a compelling treatment option for people living with obesity or T2D, 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 PMA application, BLA 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 for people living with obesity or T2D 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 any PMA application or BLA we may submit for our product candidates, the FDA 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 application 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 PMA applications 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 educate 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 obesity or 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 obesity and T2D, 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 obesity and/or T2D may be primary care physicians ("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, obesity and/or 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 obesity and/or

T2D 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, obesity and 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 obesity, 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 gene therapy candidates involve introducing genetic material into a patient's pancreas via endoscopic administration. Gene therapy remains a novel technology, with only a limited number of gene therapies 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 and supply 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, for the device component of the Rejuva product 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 currently manage the final assembly and testing of Revita at our headquarters located in Burlington, Massachusetts, except for the sterilization of the Revita DMR single-use disposable components, including the Revita DMR catheter, and the device component of the Rejuva product, which are 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. Additionally, trade policies and geopolitical disputes and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures affect regions where manufacturing and product development activities take place or raw materials are sourced. See "Risks Related to Our Financial Condition and Capital Requirements—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."

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;
- the misappropriation of our proprietary information, including our trade secrets and know-how; and
- geopolitical or macroeconomic factors.

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 planned contract manufacturing partners for the production of sub-assembly components of Revita, such as the Revita DMR catheter, Revita console and Rejuva catheter. We rely on a third party manufacturer to manufacture and supply cGMP-grade RJVA-001 for our first-in-human clinical trials. 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 others, they will not be able to secure and/or maintain marketing approval for the use of their manufacturing facilities in connection with our product candidates. 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.

Certain Chinese biotechnology companies, CROs and contract development and manufacturing organizations may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could potentially impact services available for our research and development or our ability to secure the materials we need for our drug candidates. For example, the House of Representatives of the prior Congress (the "118th Congress") passed the BIOSECURE Act, which proposed prohibiting U.S. government contracts, grants, and loans to entities that use equipment and services from certain named Chinese biotech companies and certain of their respective subsidiaries and affiliates, and would authorize the U.S. government to include additional Chinese biotechnology companies of concern. This version of the BIOSECURE Act included a grandfathering provision allowing biotechnology equipment and services provided or produced by named biotechnology companies of concern under a contract or agreement entered into before the effective date until January 1, 2032. The BIOSECURE Act did not become law in the 118th Congress. On October 9, 2025, the Senate of the current Congress (the "119th Congress") passed its version of the National Defense Authorization Act ("NDAA") for Fiscal Year 2026, which includes an amendment prohibiting contracting with certain biotechnology providers. While the amendment includes the same general prohibitions around government funding, contracts, and grants to certain biotechnology companies and entities which contract with such companies, there are certain differences from the versions of the BIOSECURE Act proposed by the prior 118th Congress. Rather than explicitly naming the companies of concern, the amendment defines a "biotechnology company of concern" as an entity that is identified on the annual 1260H List of Chinese military companies (the "1260H List") issued by the U.S. Department of Defense, any entity designated as such by the U.S. Government, and certain subsidiaries, parents, affiliates, and successors of the foregoing. In addition, the amendment provides a grandfathering period of five years for entities that are designated by the U.S. Government; however, entities identified on the 1260H List are not eligible for such grandfathering period. The House and Senate of the current Congress will need to reconcile their respective versions of the NDAA and therefore it is possible for the language to further change and be amended, or even for the amendment to be removed from the final reconciled version of the NDAA. If the BIOSECURE Act becomes law, or similar laws or restrictions are passed, they would have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, collaborate with, or otherwise work with certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We do business with companies in China, and it is possible that some of our contractual counterparties could be impacted by the legislation described above. Such counterparties may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such

material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. Such disruption could have adverse effects on the development of our drug candidates.

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 currently known as the Quality System Regulation ("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 ("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 candidates' 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 manufacture and 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 Burlington, 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 REMAIN-1 pivotal clinical study of Revita, and potential future clinical study of RJVA-001. 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 (" 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 purchases 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 (the "ACA"), made a number of substantial changes in the way healthcare is financed by both governmental and private insurers, including: establishing 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; implementing 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 expanding 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 (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." 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, ("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. For example, on August 16, 2022, the Inflation Reduction Act (the "IRA"), was signed into law, which, among other things, contains provisions to lower prescription drug costs. The impact of the IRA on the pharmaceutical industry is likely to be significant. In addition, the current U.S. administration has also issued executive orders that address the pricing of pharmaceuticals in the U.S. and propose a so-called most favored nation pricing policy, which would tie the price of drugs in the U.S. to the lowest price in a group of other countries. On September 30, 2025, the current administration announced the first agreement with a major pharmaceutical company that requires the drug manufacturer to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. While it is unclear whether and how these proposals will be implemented, these policies are likely to have a negative impact on the pharmaceutical industry. Even proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector. 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 One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our product candidates that we may commercialize. 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.

In the EU, similar developments may affect our ability to profitably commercialize our product candidates, if approved or certified. On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA"), amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, certain high-risk medical devices as of 2026, orphan medicinal products as of 2028, and all other medicinal products by 2030. The 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 provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It 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 highest 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 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 (the "EU GDPR"), governs certain collection and other processing activities involving personal data about individuals in the European Economic Area (the "EEA"), and the UK General Data Protection Regulation and UK Data Protection Act 2018 (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 Quarterly Report on Form 10-Q include both the EU GDPR and the UK GDPR. Among other things, the GDPR imposes requirements regarding processing data relating to an identifiable living individual or "personal data", including health and other sensitive data, including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit, as well as regulating cross-border transfers of personal data out of the EEA and the UK. 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 Case law from the Court of Justice of the European Union ("CJEU") states that reliance on the standard contractual clauses - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. In relation to data transfers from the EEA to the United States, the EU-US Data Privacy Framework ("DPF") was approved by the European Commission in July 2023 as an effective EU GDPR data transfer mechanism to U.S. entities self-certified under the DPF. The UK Extension to the DPF followed in October 2023, as an effective UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the European Commission approval of the current EU-US Data Privacy Framework for data transfers to certified entities in the United to be challenged and

international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes; we may have to implement alternative data transfer mechanisms under the GDPR and/or take additional compliance and operational measures.

In addition, we use artificial intelligence, machine learning, and automated decision-making technologies (collectively, "AI Technologies") in our business. The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations. Additionally, existing laws and regulations may be interpreted in ways that would affect the operation of AI Technologies. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or market perception of their requirements may have on our business and may not always be able to anticipate how to respond to these laws or regulations.

It is possible that new laws and regulations will be adopted in the United States and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations. 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.

We are subject to complex and changing laws and regulations, which exposes us to potential liabilities, increased costs and other adverse effects on our business.

We are subject to complex and changing laws, regulations, and executive orders, and compliance with these laws and regulations and executive orders, as well as changing interpretations, policies, and enforcement priorities related to such laws, regulations, and executive orders, is onerous and expensive. Compliance with such laws, regulations, and executive orders can adversely affect our business by increasing our costs, limiting our ability to pursue or offer a product candidate or product, and requiring changes to our business. New and changing laws, regulations, and executive orders can also create uncertainty about how such laws and regulations will be interpreted, prioritized, or applied. Regulatory changes and other actions that materially adversely affect our business may be announced with little or no advance notice we may not be able to effectively mitigate all adverse impacts from such measures. Differing interpretations of such legal obligations and policy changes or changes in enforcement priorities can expose us to significant fines, government investigations, litigation and reputational harm. If we are found to have violated laws, regulations, or executive orders, it could materially adversely affect our business, reputation, results of operations and financial condition.

Damage to our reputation or brand image could adversely affect our sales and results of operations.

Incidents that erode trust or confidence in us could adversely affect our reputation and thereby impact our business, particularly if the incidents result in rapid or significant adverse publicity, protests, litigation, boycotts, governmental inquiries, or other stakeholder responses. This could include incidents regarding our actions or inactions on issues related to corporate social responsibility or environmental, social, and governance ("ESG") matters. Any goals and initiatives that we establish on ESG matters, including with respect to sustainability and diversity, equity, and inclusion topics, are subject to risk. We cannot guarantee that we will achieve and goals and initiatives that may from time to time set. Any failure, or perceived failure, by us to achieve such goals and initiatives could adversely affect our reputation. Further, stakeholder expectations regarding ESG matters continue to evolve and are not uniform, and our pursuit of our goals and initiatives could adversely impact our reputation due to such differing expectations and opinions regarding such goals and initiatives. In turn, damage to our reputation or brand image could, among other things, adversely impact our relationships with third

parties, our business opportunities, our ability to attract and retain talent sufficient to meet business needs, and results of operations. Any of the foregoing can be further exacerbated by changes to laws, regulation, standards and executive orders. See "—We are subject to complex and changing laws and regulations, which exposes us to potential liabilities, increased costs and other adverse effects on our business."

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 (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 (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.

Moreover, geo-political actions in the U.S. and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the U.S. and foreign government actions related to Russia's conflict with Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. For example, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the U.S. without consent or compensation. 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. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other IP rights may not be effective or sufficient to prevent them from competing.

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.

On June 1, 2023, the European Union Patent Package (the "EU Patent Package"), regulations were implemented with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (the "UPC"), for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We decided to opt out our European patents from the UPC, and doing so may preclude us from realizing the benefits of the UPC.

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. We may also need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. The failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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 have a small market development team. In order to commercialize any product candidates, if approved, we must build marketing, sales, reimbursement and market access, 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 and Treasurer, 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, including as we realign our business in accordance with the Strategic Reprioritization, 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.

As part of the Strategic Reprioritization, we streamlined resources, including a workforce reduction impacting 22 employees. In light of this workforce reduction, we may find it difficult to maintain valuable aspects of our culture, to prevent a negative effect on employee morale or attrition beyond our planned workforce reduction, and to attract competent personnel who are willing to embrace our culture in the future.

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, recruit, integrate, motivate 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, including our Strategic Reprioritization, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2025, we have 101 full-time employees, including 73 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we are 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, retaining 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 Ownership of Our Common Stock

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 may 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 *Part II. Item 1A. Risk Factors* and elsewhere in this Quarterly Report on Form 10-Q, 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, geopolitical, 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 *Part II. Item 1A. Risk Factors*, could have a dramatic and adverse impact on the market price of our common stock.

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 is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. 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.

As of September 30, 2025, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates owned approximately 51% of our voting stock, including securities currently exercisable or convertible into voting stock. Therefore, these stockholders may be able to exert control over us through this ownership position and 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.

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 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.

As of September 30, 2025, we had outstanding a total of 132,216,275 shares of our common stock. All shares of our common stock that were sold in our IPO are freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the "Securities Act"), unless held by our "affiliates" as defined in Rule 144 under the Securities Act. Subject to applicable securities law restrictions, the shares previously subject to lock-up agreements in connection with our IPO are now able to be sold in the public market. We have filed a registration statement on Form S-8 under the Securities Act to register 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. Accordingly, shares registered under the registration statement on Form S-8 will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and subject, in the case of affiliates, to volume, manner of sale and other limitations under Rule 144.

The holders of approximately 38,518,563 shares of our common stock as of the effective date of our IPO, which was approximately 29% of our outstanding shares as of September 30, 2025 have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares (including additional shares of our common acquired by such holders after the IPO, subject to the terms of our fifth amended and restated investors' rights agreement) or to include such shares in registration statements that we may file for ourselves or our other stockholders. Once we register the offer and sale of shares for the holders of registration rights, these shares will be able to be sold in the public market.

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 *Part I. Item 2. 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 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 so that not all members of our board of directors (the "Board") are elected at one time;

- permit only the Board to establish the number of directors and fill vacancies on our 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 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 (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 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 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 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 (including those caused or exacerbated by climate change) 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:

- 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 our Annual Reports on Form 10-K and our other 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 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 IPO.

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 being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced *Part I. Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations* disclosure in this Quarterly Report on Form 10-Q and scaled 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 ("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 are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (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, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this Quarterly Report on Form 10-Q 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 are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are a low revenue 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;
- 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;
- limitations or adverse findings regarding our ability to do business in some jurisdictions; and
- On July 4, 2025, the OBBB Act, which includes a broad range of tax reform provisions, was signed into law in the United States and we continue to assess its impact.

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, including tariffs;
- 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. 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 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. On July 4, 2025, the OBBB Act, which includes a broad range of tax reform provisions, was signed into law in the United States and we continue to assess its impact. We currently do not expect the OBBB Act to have a material impact on our estimated annual effective tax rate in 2025. We are unable to predict which, if any, additional U.S. tax reform proposals will be enacted into law, and what effects the OBBB Act or any other enacted legislation might have on our tax liabilities.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

None.

Purchases of equity securities by the issuer and affiliated purchasers

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) Disclosure in lieu of reporting on a Current Report on Form 8-K.

None.

(b) Material changes to the procedures by which security holders may recommend nominees to the Board.

None.

(c) Insider Trading Arrangements and Policies.

During the three months ended September 30, 2025, Harith Rajagopalan, Chief Executive Officer and Director, adopted a Rule 10b5-1 trading arrangement on August 29, 2025 that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 483,885 shares of the Company's common stock until June 26, 2026.

Other than described above, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed/ Furnished Herewith**
3.1	Amended and Restated Certificate of Incorporation of Fractyl Health, Inc.	8-K	001-41942	3.1	2/6/2024	
3.2	Amended and Restated Bylaws of Fractyl Health, Inc.	8-K	001-41942	3.2	2/6/2024	
4.1	Specimen Stock Certificate evidencing the shares of common stock.	S-1	333-276046	4.1	12/14/2023	
4.2	Fifth Amended and Restated Investors' Rights Agreement, dated June 9, 2021, by and among Fractyl Health, Inc. and certain of its stockholders.	S-1	333-276046	4.2	12/14/2023	
4.3	Warrant Agency Agreement.	8-K	001-41942	4.1	8/7/2025	
4.4	Form of Tranche A Warrant.	8-K	001-41942	4.2	8/7/2025	
4.5	Form of Tranche B Warrant.	8-K	001-41942	4.3	8/7/2025	
10.1	Form of Voting Agreement by and among the Company and its directors, its officers and Mithril, dated August 6, 2025	8-K	001-41942	10.1	8/7/2025	
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					*

101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents	*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	*

* Filed herewith

** Furnished herewith

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Fractyl Health, Inc.

Date: November 12, 2025

By: /s/ Harith Rajagopalan

Harith Rajagopalan, M.D., Ph.D.
Co-Founder, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 12, 2025

By: /s/ Lisa A. Davidson

Lisa A. Davidson
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, Harith Rajagopalan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Fractyl Health, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2025

By: /s/ Harith Rajagopalan

Harith Rajagopalan, M.D., Ph.D.
Co-Founder, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Lisa Davidson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Fractyl Health, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a)All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2025

By: /s/ Lisa A. Davidson

Lisa A. Davidson
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION

PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Harith Rajagopalan, Chief Executive Officer of Fractyl Health, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2025, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2025

By: /s/ Harith Rajagopalan

Harith Rajagopalan, M.D., Ph.D.
Co-Founder, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION

PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Lisa A. Davidson, Chief Financial Officer of Fractyl Health, Inc. (the "Company"), hereby certifies that, to the best of her knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2025, to which this Certification is attached as Exhibit 32.2 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2025

By: /s/ Lisa A. Davidson

Lisa A. Davidson
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)