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, 2026

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 November 2, 2026, the number of shares of the registrant's common stock outstanding was 13,264,926.

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 (“U.S. GAAP”). Our fiscal year ends on December 31 of each year. Our most recent fiscal year ended on December 31, 2025.

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, 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 offerings of our securities, 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 authorizations, 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 authorized, approved, certified or cleared for commercial use;
- the implementation of our business model and our strategic plans for our business, product candidates and technology;
- the potential benefits of our sharpened strategic focus and strategic reprioritization adopted on October 21, 2026 (the "Reprioritization"), including the workforce reduction and its anticipated impact on our expenditures and financial runway;
- our expected quarterly operating cash spending and cash runway;
- our exploration of strategic alternatives for Rejuva and the potential benefits thereof;
- our commercialization, marketing and manufacturing capabilities and strategy, as well as our product development strategy;
- the pricing and reimbursement of our product candidates, if authorized, 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, capital expenditure requirements, and to satisfy the minimum liquidity covenant under our credit agreement;
- 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 Jumpstart Our Business Startups Act of 2012 ("JOBS Act");
- our ability to maintain compliance with the continued listing standards of the Nasdaq Global Market;
- the impact of adverse macroeconomic conditions, geopolitical events, and potential future public health crises, including epidemics and pandemics; and
- other forward-looking statements, risks and uncertainties, including those listed in *Part I, Item 1A, "Risk Factors"* of our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, filed with the Securities and Exchange Commission (the "SEC") on March 24, 2026 ("Annual Report") and in *Part II, Item 1A, "Risk Factors"* of this Quarterly Report on Form 10-Q.

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 the Risk Factors in our Annual Report 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.

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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, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 31,515	$ 81,540
Prepaid expenses and other current assets	2,819	6,036
Total current assets	34,334	87,576
Restricted cash, long-term	4,255	4,255
Property and equipment, net	1,686	2,407
Right-of-use lease assets, operating	25,518	26,827
Other long-term assets	132	337
Total assets	$ 65,925	$ 121,402
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,725	$ 1,574
Accrued expenses and other current liabilities	9,988	11,651
Notes payable, current	413	—
Operating lease liabilities, current	5,219	5,104
Total current liabilities	17,345	18,329
Notes payable, long-term	29,234	30,586
Operating lease liabilities, long-term	24,667	25,956
Warrant liabilities, long-term	7,340	36,410
Other long-term liabilities	555	663
Total liabilities	79,141	111,944
Stockholders' equity (deficit):		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.00001 par value; 300,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 13,264,987 and 12,781,004 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	573,518	565,722
Accumulated deficit	(586,734)	(556,264)
Total stockholders' equity (deficit)	(13,216)	9,458
Total liabilities and stockholders' equity (deficit)	$ 65,925	$ 121,402

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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 12,454	$ 17,457	$ 41,864	$ 58,043
Selling, general and administrative	6,195	5,237	16,701	15,489
Total operating expenses	18,649	22,694	58,565	73,532
Loss from operations	(18,649)	(22,694)	(58,565)	(73,532)
Other income (expense), net:				
Interest income, net	297	166	1,321	895
Change in fair value of notes payable	(284)	(1,868)	(2,276)	(3,824)
Change in fair value of warrant liabilities	4,499	(21,201)	29,070	(20,724)
Other expense, net	(13)	(6)	(20)	(42)
Total other income (expense), net	4,499	(22,909)	28,095	(23,695)
Net loss and comprehensive loss	$ (14,150)	$ (45,603)	$ (30,470)	$ (97,227)
Net loss per share, basic and diluted	$ (1.07)	$ (8.46)	$ (2.30)	$ (21.51)
Weighted-average number of common shares outstanding, basic and diluted	13,250,080	5,387,747	13,226,323	4,520,293

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2025	**12,781,004**	**$ —**	**$ 565,722**	**$ (556,264)**	**$ 9,458**
Exercise of pre-funded warrants	403,598	—	—	—	—
Stock-based compensation expense	—	—	2,531	—	2,531
Issuance of common stock under employee stock purchase plan	36,145	—	170	—	170
Net income	—	—	—	9,218	9,218
Balance at March 31, 2026	**13,220,747**	**$ —**	**$ 568,423**	**$ (547,046)**	**$ 21,377**
Stock-based compensation expense	—	—	2,496	—	2,496
Net loss	—	—	—	(25,538)	(25,538)
Balance at June 30, 2026	**13,220,747**	**$ —**	**$ 570,919**	**$ (572,584)**	**$ (1,665)**
Stock-based compensation expense	—	—	2,386	—	2,386
Issuance of common stock under employee stock purchase plan	44,240	—	213	—	213
Net loss	—	—	—	(14,150)	(14,150)
Balance at September 30, 2026	**13,264,987**	**$ —**	**$ 573,518**	**$ (586,734)**	**$ (13,216)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance at December 31, 2024	**4,062,954**	**$ —**	**$ 443,734**	**$ (415,310)**	**$ 28,424**
Exercise of common stock options	13,731	—	280	—	280
Stock-based compensation expense	—	—	1,406	—	1,406
Net loss	—	—	—	(23,735)	(23,735)
Balance at March 31, 2025	**4,076,685**	**$ —**	**$ 445,420**	**$ (439,045)**	**$ 6,375**
Issuance of common stock in connection with at-the-market offering, net of issuance costs of $188	83,117	—	1,517	—	1,517
Exercise of common stock options	14	—	—	—	—
Stock-based compensation expense	—	—	1,785	—	1,785
Net loss	—	—	—	(27,889)	(27,889)
Balance at June 30, 2025	**4,159,816**	**$ —**	**$ 448,722**	**$ (466,934)**	**$ (18,212)**
Issuance of common stock from RSU vesting	1,875	—	—	—	—
Issuance of common stock in connection with at-the-market offering, net of issuance costs of $17	30,935	—	552	—	552
Issuance of common stock in August 2025 public offering, net of underwriting discounts, commissions and offering costs of $1,731	1,825,397	—	2,431	—	2,431
Issuance of common stock in September 2025 offering, net of underwriting discounts, commissions and offering costs of $3,984	5,000,000	—	56,016	—	56,016
Stock-based compensation expense	—	—	1,638	—	1,638
Net loss	—	—	—	(45,603)	(45,603)
Balance at September 30, 2025	**11,018,023**	**$ —**	**$ 509,359**	**$ (512,537)**	**$ (3,178)**

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,	
	2026	**2025**
Cash Flows from operating activities:		
Net loss	$ (30,470)	$ (97,227)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	835	850
Non-cash interest expense	184	227
Non-cash operating lease expense	1,308	1,174
Stock-based compensation expense	7,413	4,829
Change in fair value of warrant liabilities	(29,070)	20,724
Change in fair value of notes payable, non-cash	(939)	608
Changes in operating assets and liabilities:		
Inventory	—	73
Prepaid expenses and other current assets	(841)	2,180
Accounts payable	136	(1,984)
Accrued expenses and other current liabilities	(1,431)	583
Operating lease liabilities	(1,173)	(923)
Other long-term assets and liabilities	(38)	(106)
Net cash used in operating activities	(54,086)	(68,992)
Cash flows from investing activities:		
Purchases of property and equipment	—	(554)
Net cash used in investing activities	—	(554)
Cash flows from financing activities:		
Exercises of common stock warrants	4,058	—
Proceeds from issuance of common stock under employee stock purchase plan	383	—
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
Principal payments on finance lease obligations	(380)	(338)
Net cash provided by financing activities	4,061	79,739
Net increase (decrease) in cash, cash equivalents and restricted cash	(50,025)	10,193
Cash, cash equivalents and restricted cash at beginning of period	85,795	71,719
Cash, cash equivalents and restricted cash at end of period	$ 35,770	$ 81,912
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,215	$ 3,216
Payment for operating leases within operating activities	$ 4,034	$ 3,917
Non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 114	$ —
Fair value of warrant liabilities recognized in connection with August 2025 public offering	$ —	$ 18,838
Offering costs included in accrued expenses	$ —	$ 444

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

1. Nature of the Business

Fractyl Health, Inc. (the "Company" or "Fractyl") was incorporated in Delaware 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 clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes ("T2D"). The Company's lead product candidate, Revita®, is an endoscopic procedural therapy in pivotal development for post-GLP-1 weight maintenance.

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 has received favorable FDA feedback on its De Novo classification request for Revita and anticipates submitting a potential De Novo marketing application in the late fourth quarter of 2026, followed by topline one-year data from the REMAIN-1 Pivotal Cohort in the first quarter of 2027. The Company is evaluating Revita in the REMAIN-1 weight maintenance program, which is designed to evaluate Revita's potential to maintain weight loss following GLP-1 based therapy discontinuation. The REMAIN-1 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.

- The 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 based therapy.
- The 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 based therapy discontinuation.
- The 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.

The REMAIN-1 study was initiated in the third quarter of 2024. The Company completed enrollment of the REMAIN-1 Pivotal Cohort in July 2025 and completed randomization of the REMAIN-1 Pivotal Cohort in February 2026. The Company anticipates submitting a planned De Novo marketing application in post-GLP-1 weight maintenance in the late fourth quarter of 2026.

On October 16, 2026, the Company reported topline six-month results from the REMAIN-1 Pivotal Cohort, a 308-participant (mITT population), multicenter, randomized, double-blind, sham-controlled study of Revita for weight maintenance in adults with obesity following discontinuation of GLP-1 therapy. REMAIN-1 met its pre-specified six-month co-primary endpoint of weight loss retention, as patients treated with a single Revita procedure demonstrated a highly statistically significant reduction in weight regain compared to sham (p=0.0023). Topline one-year data from the REMAIN-1 Pivotal Cohort, including the second co-primary endpoint, is anticipated in the first quarter of 2027.

Pursuant to the Company's strategic reprioritization adopted in January 2025, 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

The Company was developing Rejuva, a novel, locally administered, adeno-associated virus delivered pancreatic gene therapy platform. Rejuva was designed to enable long-term remission of T2D and obesity by durably reprogramming pancreatic islet cells to endogenously produce metabolic hormones. Rejuva leveraged advanced delivery systems and proprietary screening methods to identify and develop metabolically active gene therapy candidates targeting the pancreas. The lead candidate from the Rejuva platform, RJVA-001, was designed to be delivered to the pancreas via a single endoscopic intervention to enable pancreatic beta cells to express GLP-1 locally via nutrient-responsive control. This gene therapy approach enables physiologic GLP-1 secretion without the high circulating levels that contribute to side effects seen with systemic GLP-1 based drugs. The Company completed key preclinical *in vivo* studies to support a clinical trial application ("CTA") for RJVA-001 and subsequently submitted CTAs for RJVA-001 in T2D to regulators in the EU (Netherlands) and Australia in the second half of 2025, advancing the program toward its anticipated first-in-human study. In April 2026, the Company received CTA authorization in the Netherlands for RJVA-001, enabling initiation of the anticipated Phase 1/2 first-in-human study evaluating RJVA-001 in adults with inadequately controlled T2D. In July 2026, the Company received ethics committee approval in Australia.

The Company was developing RJVA-002, a dual GIP/GLP-1 gene therapy. RJVA-002 expanded the Rejuva platform into obesity, targeting dual incretin biology with the goal of achieving durable, well-tolerated, weight loss from a single intervention.

In connection with the Strategic Reprioritization (see Note 12—"Subsequent Events"), the Company is discontinuing internal development of its Rejuva gene therapy program and is seeking strategic alternatives for the program. There can be no assurance that the Company's review of strategic alternatives for Rejuva will result in any transaction, and the Company does not intend to disclose further developments unless and until it determines that disclosure is appropriate or required.

Nasdaq Minimum Bid Price Notice

On March 13, 2026, the Company received a letter from Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was not in compliance with the minimum bid price requirement of Nasdaq Listing Rule 5450(a)(1) because the closing bid price of the Company's common stock had been below $1.00 per share for 30 consecutive business days. As the Company did not regain compliance with the minimum bid price requirement within the 180-calendar day compliance period set forth by Nasdaq Listing Rule 5810(c)(3)(A), by September 9, 2026, Nasdaq notified the Company by letter dated September 10, 2026, that the Company's securities are subject to delisting from Nasdaq unless the Company timely requests a hearing before a Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel. The hearing request automatically stayed any suspension or delisting of the Company's securities and, as a result, the Company's common stock has continued to be listed and traded on Nasdaq pending the conclusion of the hearings process. Pursuant to Listing Rule 5810(c)(3)(H), in order to regain compliance with the minimum bid price requirement, the closing minimum bid price of the Company's common stock must be at least $1.00 per share for at least 10 consecutive business days and up to 20 consecutive business days, at Nasdaq staff's discretion. On October 2, 2026, the Company effected a 1-for-12 reverse stock split in order to regain compliance with the minimum bid price requirement. See Note 12—"Subsequent Events". There can be no assurance that the Company will be successful in maintaining the listing of its common stock on the Nasdaq Global Market.

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 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 financed its operations to date primarily through its equity and debt financings. The Company has a history of operating losses and had an accumulated deficit of $586.7 million as of September 30, 2026, and management expects continuing operating losses in the future. As of September 30, 2026, the Company had available cash and cash equivalents of $31.5 million. On October 21, 2026, the Company adopted the Reprioritization to sharpen its strategic focus on its Revita program. As part of the Reprioritization, the Company will reduce its workforce by approximately 45% of the Company's current headcount, and the Company is discontinuing internal development of its Rejuva gene therapy program and is seeking strategic alternatives for the program. The reduction in force is expected to be completed during the fourth quarter of 2026. See Note 12—"Subsequent Events" for additional information. Based on its current operating plan and anticipated expense reductions, including the expected cash costs associated with the Reprioritization, management believes its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2027, through multiple key clinical and regulatory milestones. However, these existing cash resources are not expected to be sufficient to fund the Company's current operating plan for at least twelve months from the issuance date of this Quarterly Report on Form 10-Q. As a result, 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 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 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 Credit Agreement, as defined in Note 5—"Notes Payable", contains financial covenants, including a minimum liquidity covenant requiring the Company 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, 2026, the Company was in compliance with the minimum liquidity covenant and other terms of the arrangement. Without additional financing, the Company may not be able to maintain the minimum liquidity covenant by the end of the first quarter of 2027. Management intends to mitigate the conditions and events that raise substantial doubt about the Company's ability to continue as a going concern entity by (i) negotiating other cash equity, debt or strategic financing, (ii) continuing to pursue the necessary regulatory approvals to launch commercially in the U.S. market, (iii) executing cost-cutting measures to manage operating cash spending, including the workforce reduction described above, and (iv) pursuing strategic alternatives for the Rejuva program. However, there can be no assurances that the current plans will generate any liquidity to the Company or be available on terms acceptable to the Company.

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 U.S. GAAP for interim financial reporting and as required by Regulation S-X, Rule 10-01. The unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. 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, 2026 and 2025. The results of operations for the interim periods are not necessarily indicative of results to be expected for the year ending December 31, 2026, 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, 2025 and notes thereto, included in the Company's Annual Report. The accompanying unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements.

Reverse Stock Split

On October 2, 2026, the Company effected a 1-for-12 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split"). See Note 12—"Subsequent Events" for additional information. As a result of the Reverse Stock Split, every 12 shares of the Company's issued and outstanding common stock were automatically combined into one share of common stock. No fractional shares were issued in connection with the Reverse Stock Split. The Reverse Stock Split did not change the par value of the common stock or the number of authorized shares of common stock.

Because the Reverse Stock Split became effective after September 30, 2026, but before the issuance of these condensed consolidated financial statements, all share and per share amounts of common stock, stock options, restricted stock units, warrants, and the related exercise prices, as well as net loss per share, for all periods presented in these condensed consolidated financial statements and the accompanying notes have been retroactively adjusted to reflect the Reverse Stock Split. In addition, an amount equal to the reduction in the aggregate par value of common stock resulting from the Reverse Stock Split was reclassified from common stock to additional paid-in capital for all periods presented.

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 the Company's 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,* ("ASC 842").

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 condensed 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 condensed 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 a Black-Scholes option-pricing model. 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 fair value of the underlying

shares represents the closing price of its common stock traded on the Nasdaq Global Market. 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 of 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. 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 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 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 in the foreseeable future. Forfeitures are accounted for as they occur.

Recently Adopted Accounting Pronouncements

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles Goodwill and Other Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software* ("ASU 2025-06"). The ASU simplifies the guidance around capitalization of software development costs. ASU 2025-06 is effective for annual periods beginning after December 15, 2027, with early adoption permitted. The Company elected to early adopt ASU 2025-06 effective January 1, 2026. The adoption had no material impact on the Company's condensed consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements

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 condensed 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:

(in thousands)	Fair Value measurements as of September 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	$ 20,897	$ —	$ —	$ 20,897
	$ 20,897	$ —	$ —	$ 20,897
Liabilities:				
Notes payable, current	$ —	$ —	$ 413	$ 413
Notes payable, long-term	—	—	29,234	29,234
Warrant liabilities, long-term	—	—	7,340	7,340
	$ —	$ —	$ 36,987	$ 36,987

(in thousands)	Fair Value measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	$ 35,829	$ —	$ —	$ 35,829
	$ 35,829	$ —	$ —	$ 35,829
Liabilities:				
Notes payable, long-term	$ —	$ —	$ 30,586	$ 30,586
Warrant liabilities, long-term	—	—	36,410	36,410
	$ —	$ —	$ 66,996	$ 66,996

During the nine months ended September 30, 2026 and 2025, 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, 2026	December 31, 2025
Payroll and payroll-related expenses	$ 4,403	$ 5,653
Research and development services	4,039	4,316
Professional fees and consulting services	861	721
Other current liabilities	685	961
	$ 9,988	$ 11,651

5. Notes Payable

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 an 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. 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 was originally scheduled to make monthly principal payments in the amount of 1.5% of the aggregate principal amount outstanding, including accrued PIK interest. The Credit Agreement permits a one-year extension of the commencement date to September 30, 2027, at the Company's option if specified financing milestones are achieved by September 30, 2026. In 2024, the Company met these milestones and elected to extend the commencement 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 will 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 are 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, which is a Level 3 fair value measurement and requires judgment to determine at each period end. 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, 2025	$ 30,586
Increase in fair value	2,276
Payment of interest	(3,215)
Balance as of September 30, 2026	$ 29,647

The Company's obligations under the Credit Agreement are collateralized by substantially all of its assets, including its intellectual property, but excluding certain customary and agreed upon assets. 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 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, 2026, the Company was in compliance with the financial covenants and other terms of the arrangement.

6. Warrant Liabilities

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) $215.91 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, 2026.

The fair value of the July 2023 Warrants 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.

The fair value of the July 2023 Warrants was determined using the Black-Scholes valuation model with the following assumptions:

	September 30, 2026
Risk-free interest rate	5.1%
Expected term (in years)	6.8
Expected volatility	82.0%
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, 2025	$ 1,139
Decrease in fair value	(886)
Balance as of September 30, 2026	$ 253

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) $215.91 per share of common 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, 2026.

The fair value of the September 2023 Warrants 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.

The fair value of the September 2023 Warrants was determined using the Black-Scholes valuation model with the following assumptions:

	September 30, 2026
Risk-free interest rate	5.1%
Expected term (in years)	6.9
Expected volatility	82.0%
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, 2025	$ 167
Decrease in fair value	(129)
Balance as of September 30, 2026	$ 38

August 2025 Warrants

On August 6, 2025, the Company entered into an underwriting agreement with Ladenburg Thalmann & Co. Inc. ("Ladenburg"), pursuant to which it issued and sold 1,587,302 shares of its common stock, accompanied by warrants to purchase up to 1,587,302 shares of its common stock (the "Tranche A Warrants") and warrants to purchase 1,587,302 shares of its common stock (the "Tranche B Warrants"), at a combined offering price of $12.60 per share. As part of the underwriting agreement, the Company also granted Ladenburg a 30-day option to purchase up to an additional 238,095 shares of the Company's common stock, along with associated Tranche A Warrants and Tranche B Warrants, at the combined public offering price of $12.60 per share. Concurrent with the closing of the offering, 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 Tranche A Warrants and Tranche B Warrants were issued on August 7, 2025. 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.

Tranche A Warrants

Each Tranche A Warrant had an exercise price of $12.60 per share, subject to certain adjustments. During the year ended December 31, 2025, Tranche A Warrants were exercised to purchase 1,825,355 shares of the Company's common stock for total proceeds of $23.0 million, $4.1 million of which was received in January 2026. The remaining unexercised 42 warrants were cancelled on December 30, 2025, upon expiration of the Company's call option pursuant to the terms of the Tranche A Warrants, which the Company exercised in December 2025. No Tranche A Warrants were outstanding as of December 31, 2025, or September 30, 2026, and no associated warrant liabilities were recorded as of either date.

The fair value of the Tranche A Warrants was recorded as part of the warrant liabilities on the condensed consolidated balance sheet. The Company remeasured the fair value at the end of each reporting period and again upon exercise, 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

Each Tranche B Warrant has an exercise price of $12.60 per share, subject to certain adjustments. The Tranche B Warrants became exercisable upon receipt of required stockholder approval at the Special Meeting of Stockholders on October 3, 2025. Any unexercised Tranche B Warrants will expire on October 3, 2030, which is the date that is five years from the date that stockholder approval was received.

The fair value of the Tranche B Warrants 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. As of September 30, 2026, Tranche B Warrants to purchase 1,762,250 shares of the Company's common stock remained outstanding.

Tranche B Warrants fair value was determined using the Black-Scholes valuation model with the following key assumptions, which were based on significant inputs that are not observable in the market and represented a Level 3 measurement.

	September 30, 2026
Risk-free interest rate	5.0%
Expected term (in years)	4.0
Expected volatility	101.0%
Expected dividend yield	0%

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

(in thousands)	Fair Value
Balance as of December 31, 2025	$ 35,104
Decrease in fair value	(28,055)
Balance as of September 30, 2026	$ 7,049

7. Commitments and Contingencies

Leases

The following table summarizes the future minimum lease payments for operating and finance leases as of September 30, 2026:

(in thousands)	
2026 (Remaining)	$ 1,515
2027	5,817
2028	5,735
2029	5,907
2030	6,084
Thereafter	22,776
Total future minimum lease payments	$ 47,834

Please see Note 7—"Leases" in the Notes to the consolidated financial statements included in Item 8 of the Company's Annual Report for further discussion of the Company's material lease agreements.

Litigation

On August 21, 2026, a putative securities class action lawsuit captioned Lorne v. Fractyl Health, Inc., et al., Case No. 1:26-cv-07167, was filed in the United States District Court for the Southern District of New York against the Company and certain of its current and former officers. The complaint purports to assert claims on behalf of persons who purchased or otherwise acquired the Company's securities between January 13, 2025 and January 29, 2026, and alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaint generally alleges that the defendants made materially false or misleading statements or omissions concerning the clinical efficacy of the Company's Revita DMR System and the results of its REMAIN-1 clinical study, including alleged operational issues at certain clinical study sites that purportedly affected the reliability of reported efficacy results. The complaint seeks unspecified monetary damages, interest, attorneys' fees and other relief. On October 20, 2026, three movants filed motions seeking appointment as lead plaintiff. On October 23, 2026, one movant filed a notice of withdrawal. On November 3, 2026, another movant filed a notice of non-opposition. Following appointment of lead plaintiff, the court

will issue an order setting a deadline for lead plaintiff to file an amended complaint and for defendants to file a response thereto.

The Company makes provisions for liabilities when it is both probable that a liability has been incurred and the amount can be reasonably estimated. No such liability has been recorded related to this matter. With regard to legal fees, such as attorney fees related to this matter or any other legal matters, the Company recognizes such costs as incurred.

8. Preferred and Common Stock

Preferred Stock

On January 26, 2024, the Company's board of directors 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, 2026.

Common Stock

On January 26, 2024, the Company's board of directors 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.

In November 2025, the Company entered into exchange agreements with certain investors pursuant to which these investors exchanged 404,167 shares of the Company's common stock for an equal number of pre-funded warrants with an exercise price of $0.012 per share. In January 2026, these investors exercised all 404,167 shares of pre-funded warrants, resulting in the issuance by the Company of 403,598 shares of common stock, with the remaining 569 shares withheld to satisfy the aggregate exercise price of the pre-funded warrants.

On October 2, 2026, the Company effected a 1-for-12 reverse stock split of its issued and outstanding common stock. The Reverse Stock Split did not change the par value of the common stock or the number of authorized shares of common stock. All share and per share amounts presented in this Quarterly Report on Form 10-Q have been retroactively adjusted to reflect the Reverse Stock Split. See Note 2—"Summary of Significant Accounting Policies" for additional information.

S-3 Registration Statement

On March 3, 2025, the Company filed a Registration Statement on Form S-3 with the 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

On March 3, 2025, concurrently with the filing of the S-3 Registration Statement, the Company entered into a sales agreement with Jefferies LLC as sales agent (the "Sales Agreement") and filed a prospectus supplement under an at-the-market offering (the "ATM Offering") covering the offering, issuance and sale of up to a maximum aggregate offering price of $100.0 million of the Company's common stock. During the term of the ATM Offering, the Company issued and sold 391,830 shares of its common stock at a weighted average price of $18.36 per share, resulting in net proceeds of approximately $6.8 million, after deducting commissions and offering expenses. On March 23, 2026, the Company notified Jefferies LLC of its intention to terminate the Sales Agreement pursuant to its terms. As a result, the Sales Agreement was terminated effective April 6, 2026 and no further sales have been or will be made thereunder after such date.

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 of directors, or at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting schedules and other restrictions of awards were determined at the discretion of the board of directors or by a committee of the board of directors 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 a stock option could not be greater than ten years. Upon the effective date of the 2024 Incentive Award Plan (the "2024 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 of directors adopted 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 of directors, or at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting schedules and other restrictions on awards are determined at the discretion of the board of directors or by a committee of the board of directors 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 358,235 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 of directors.

There were 383,822 and 252,918 shares available for future grant under the 2024 Plan as of September 30, 2026 and December 31, 2025, respectively.

2024 Employee Stock Purchase Plan

On January 26, 2024, the Company's board of directors 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 40,589 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 of directors.

The 2024 ESPP Plan provides for rolling six-month offering periods. The Company began its first offering period on August 1, 2025, and issued a total of 80,385 shares of common stock during the nine months ended September 30, 2026. There were 128,643 and 81,219 shares available for future grant under the 2024 ESPP Plan as of September 30, 2026 and December 31, 2025, respectively.

Stock-Based Compensation Expense

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

(in thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Research and development	$ 994	$ 855	$ 3,205	$ 2,283
Selling, general and administrative	1,392	783	4,208	2,546
	$ 2,386	$ 1,638	$ 7,413	$ 4,829

During the nine months ended September 30, 2026, the Company granted to its employees stock options to purchase a total of 129,679 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, 2026	Three and Nine Months Ended September 30, 2025
Outstanding stock options	1,581,090	930,877
Common stock under employee stock purchase plan	42,337	—
Common stock warrants	1,775,714	3,664,262
Total	3,399,141	4,595,139

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 issuable upon exercise under these warrants is variable and depends on the exercise price elected by the applicable warrant holders.

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 as significant, while selling, general and administrative expenses are viewed as significant in total, given the direct correlation between operating cash spending and profitability as a pre-commercial company. The following table reconciles reported operating expenses to net loss under the significant expense principle for the three and nine months ended September 30, 2026 and 2025:

(in thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Operating expenses				
Research and development:				
Revita direct program expenses	$ 3,322	$ 7,183	$ 11,964	$ 22,118
Rejuva direct program expenses	1,675	2,315	5,588	10,193
Indirect expenses	2,045	1,826	5,995	5,679
Personnel-related expenses	5,412	6,133	18,317	20,053
Total research and development expenses	12,454	17,457	41,864	58,043
Selling, general and administrative	6,195	5,237	16,701	15,489
Total operating expenses	18,649	22,694	58,565	73,532
Other income (expense), net	4,499	(22,909)	28,095	(23,695)
Segment net loss	$ (14,150)	$ (45,603)	$ (30,470)	$ (97,227)

12. Subsequent Events

Reverse Stock Split

On October 2, 2026, the Company effected a 1-for-12 reverse stock split of its issued and outstanding common stock, pursuant to a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on September 30, 2026. The Reverse Stock Split was approved by the Company's stockholders at a special meeting of stockholders held on September 24, 2026, and the final ratio was approved by the board of directors on September 24, 2026. The Reverse Stock Split took effect at 5:00 p.m. Eastern Time on October 2, 2026 and the Company's common stock began trading on a split-adjusted basis on The Nasdaq Global Market on October 5, 2026.

As a result of the Reverse Stock Split, every 12 shares of the Company's issued and outstanding common stock were automatically combined into one share of common stock. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise have been entitled to a fractional share received a cash payment in lieu thereof. The Reverse Stock Split did not change the par value of the common stock or the number of authorized shares of common stock.

REMAIN-1 Pivotal Cohort Topline Six-Month Results

On October 16, 2026, the Company reported topline six-month results from the REMAIN-1 Pivotal Cohort. See Note 1— "Nature of the Business" for additional information.

Strategic Reprioritization and Workforce Reduction

On October 21, 2026, the Company adopted a plan to sharpen its strategic focus on its Revita program in connection with the Reprioritization. As part of the Reprioritization, the Company will reduce its workforce by approximately 45% of the Company's current headcount. The reduction in force is expected to be completed during the fourth quarter of 2026. The Company estimates that it will incur charges of approximately $2 million for severance and other employee termination-related costs, with the majority of such costs to be incurred in the fourth quarter of 2026. The estimated costs that the Company expects to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ. The Company may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction, including potential impairment charges, if any.

In connection with the Reprioritization, Jay Caplan, the Company's Co-Founder, President and Chief Product Officer, retired from his executive roles with the Company, effective October 30, 2026 (the "Separation Date"). Mr. Caplan is expected to continue to support the Company as a senior advisor to the leadership team and is entitled to severance benefits as set forth in his employment agreement. On October 21, 2026, the board of directors of the Company appointed Harith Rajagopalan, M.D., Ph.D., the Company's Co-Founder, Chief Executive Officer and a member of the board of directors, to serve as President of the Company, effective as of the Separation Date, in addition to his continuing roles as Chief Executive Officer and as a director of the Company. Dr. Rajagopalan will continue to serve as the Company's principal executive officer.

In connection with the Reprioritization, the Company is discontinuing internal development of its Rejuva gene therapy program and is seeking strategic alternatives for the program. There can be no assurance that the Company's review of strategic alternatives for Rejuva will result in any transaction and the Company does not intend to disclose further developments unless and until it determines that disclosure is appropriate or required.

Appointment of Michael Wartell as Independent Director

On November 6, 2026, the Company announced that effective November 2, 2026, the board of directors increased the size of the board of directors from nine to ten and appointed Michael Wartell as a Class III director, with a term expiring at the Company's 2027 annual meeting of stockholders and until his successor is duly elected and qualified or until his earlier resignation or removal. Mr. Wartell is the President of Bluerose Associates LLC and has extensive experience serving as an independent director for both public and private corporations, specializing in guiding companies through complex situations.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with (i) our unaudited condensed consolidated financial statements and related notes, appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) the audited consolidated financial statements and related notes and management's discussion and analysis of financial condition and results of operations for the fiscal year ended December 31, 2025 included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC"), on March 24, 2026 ("Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, contains forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" sections of this Quarterly Report on Form 10-Q and our Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Business Overview

We are a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes ("T2D"). Our lead product candidate, Revita®, is an endoscopic procedural therapy in pivotal development for post-GLP-1 weight maintenance. For a detailed description of our business, product candidates, and development programs, refer to our Annual Report.

Key Developments During and Subsequent to the Three Months Ended September 30, 2026

Revita. REMAIN-1 Midpoint Cohort.

In July 2026, we announced one-year data from the REMAIN-1 Midpoint Cohort. In the full modified intention-to-treat ("mITT") population (N=45), a single Revita procedure reduced weight regain by approximately 40% versus sham at one year (least-squares mean weight regain of 7.8% versus 13.0% of body weight; n=29 versus 16 for Revita versus sham). The REMAIN-1 Midpoint Cohort is not powered for formal statistical significance, and results are descriptive. Participants who received complete duodenal ablation (>14 cm) maintained approximately 81% of GLP-1-induced weight loss at one year, compared with 48% in sham participants (least-squares mean weight regain of 4.8% versus 13.0% of body weight; n=17 versus 16 for Revita versus sham), reflecting a reduction in weight regain of over 60% versus sham, consistent with earlier findings that more complete duodenal ablation drives greater treatment effect. In an optimized population of participants who received complete duodenal ablation (>14 cm) and had higher GLP-1 run-in weight loss (≥17.5%), Revita maintained approximately 84% of GLP-1-induced weight loss at one year versus 46% with sham (least-squares mean weight regain of 4.1% versus 13.5% of body weight; n=10 versus 8 for Revita versus sham). As a reference point for the REMAIN-1 Pivotal Cohort, the proportion of Revita participants maintaining at least 5% total body weight loss relative to their pre-tirzepatide weight at one year was 73% in the REMAIN-1 Midpoint Cohort mITT population, rising to 91% in those with complete duodenal ablation (>14 cm). No device- or procedure-related serious adverse events occurred, and no new device-related treatment-emergent adverse events were observed between six and 12 months. Overall treatment-emergent adverse event rates were comparable between arms through one year (24% Revita versus 25% sham).

Revita. REMAIN-1 Pivotal Cohort.

On October 16, 2026, we reported topline six-month results from our REMAIN-1 Pivotal Cohort, a 308-participant, multicenter, randomized, double-blind, sham-controlled study of Revita for weight maintenance in adults with obesity following discontinuation of GLP-1 therapy. REMAIN-1 met its pre-specified six-month co-primary endpoint of weight loss retention, as patients treated with a single Revita procedure demonstrated a highly statistically significant reduction in weight regain compared to sham (p=0.0023).

Key findings:

- **Six-month co-primary endpoint met:** In the modified intention-to-treat (mITT) population (N=308), Revita participants maintained approximately 80% of their GLP-1-induced weight loss after a single treatment at six months with high statistical significance versus sham (p=0.0023). 32% of Revita participants were either weight stable or had further weight loss at six-months post GLP-1 discontinuation (<2% regain or incremental loss) versus 18% for sham (post hoc; nominal p=0.020).

- **Dose-dependent effect observed:** In a post hoc analysis by ablation length, participants who received 12 to 18 cm of duodenal ablation had 43% less regain than sham (observed mean weight regain of 4.7% versus 8.2%; n=107 versus 74). Participants who received 20 cm or more had 53% less regain than sham (mean regain of 3.8%; n=47). This is consistent with results from the REMAIN-1 Midpoint Cohort that indicated more complete duodenal ablation drove greater treatment effect.
- **Treatment effect grew over time:** The difference in weight regain between Revita and sham widened at each assessment, nearly doubling from Month 3 to Month 6.
- **Favorable interim safety data:** Revita has been well-tolerated in this ongoing study. There have been no device- or procedure-related serious adverse events, no deaths, and no unanticipated adverse device effects observed as of the September 24, 2026, data cut-off date. Related adverse events were predominantly mild and peri-procedural, with 94% occurring within seven days of the procedure and the vast majority within two days. Consistent with upper GI endoscopy, we believe these generally mild peri-procedural adverse events support potentially broad outpatient use for Revita, if approved.

Rejuva.

In April 2026, we received clinical trial application ("CTA") authorization in the Netherlands for RJVA-001, our lead gene therapy candidate, enabling initiation of the anticipated Phase 1/2 first-in-human study evaluating RJVA-001 in adults with inadequately controlled T2D. In July 2026, we received ethics committee approval in Australia. We also advanced RJVA-002, our dual GIP/GLP-1 gene therapy candidate, through preclinical development.

In connection with our strategic reprioritization adopted on October 21, 2026 (the "Reprioritization"), as explained in greater detail in the section below titled "Strategic Reprioritization and Workforce Reduction," we are discontinuing internal development of our Rejuva gene therapy program and are seeking strategic alternatives for the program. There can be no assurance that our review of strategic alternatives for Rejuva will result in any transaction, and we do not intend to disclose further developments unless and until we determine that disclosure is appropriate or required.

Strategic Reprioritization and Workforce Reduction

On October 21, 2026, we adopted a plan to sharpen our strategic focus on our Revita program in connection with the Reprioritization. As part of the Reprioritization, we will reduce our workforce by approximately 45% of our current headcount. The reduction in force is expected to be completed during the fourth quarter of 2026. These actions are intended to create a streamlined, Revita-focused organization, reduce quarterly operating cash spending by approximately 50% by the end of the second quarter of 2027 and concentrate resources on realizing Revita's clinical and commercial potential. We estimate that we will incur charges of approximately $2 million for severance and other employee termination-related costs, with the majority of such costs to be incurred in the fourth quarter of 2026. The estimated costs that we expect to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction, including potential impairment charges, if any. As cost reductions take effect and REMAIN-1 Pivotal Cohort expenditures decline, we expect quarterly operating cash spending to be reduced to approximately $8 million, by the end of the second quarter of 2027.

In conjunction with the Reprioritization, Jay Caplan, our Co-Founder, President and Chief Product Officer, retired from his executive roles with the Company, effective October 30, 2026 (the "Separation Date"). Mr. Caplan is expected to continue to support the Company as a senior advisor to the leadership team and is entitled to severance benefits as set forth in his employment agreement. On October 21, 2026, our board of directors appointed Harith Rajagopalan, M.D., Ph.D., our Co-Founder, Chief Executive Officer and a member of the board of directors, to serve as President of the Company, effective as of the Separation Date, in addition to his continuing roles as Chief Executive Officer and as a director of the Company.

Appointment of Michael Wartell as Independent Director

On November 6, 2026, we announced that effective November 2, 2026, the board of directors increased the size of the board of directors from nine to ten and appointed Michael Wartell as a Class III director, with a term expiring at the Company's 2027 annual meeting of stockholders and until his successor is duly elected and qualified or until his earlier resignation or removal. Mr. Wartell is the President of Bluerose Associates LLC and has extensive experience serving as an independent director for both public and private corporations, specializing in guiding companies through complex situations.

Anticipated Revita Milestones

Following the topline six-month results from the REMAIN-1 Pivotal Cohort, we are advancing toward multiple anticipated clinical and regulatory milestones toward pivotal readout and potential U.S. regulatory submission. In March 2026, in connection with our regulatory strategy, we received pre-submission feedback from the FDA in which it acknowledged that the safety profile of the Revita DMR System, based on clinical data from over 300 procedures, is consistent with a Class II device classification. As in all applications, the FDA indicated that final pathway determinations will be made following review of the complete safety dataset which we intend to include in our planned De Novo marketing application submission.

- Planned FDA De Novo submission for Revita in post-GLP-1 weight maintenance in the late fourth quarter of 2026.
- Category III CPT code 1122T for the Revita procedure takes effect January 1, 2027.
- Topline one-year data from the REMAIN-1 Pivotal Cohort, including the second co-primary endpoint, in the first quarter of 2027.
- Potential FDA marketing authorization in late 2027.
- Potential U.S. commercial launch in early 2028.

We are pursuing opportunities to strengthen our balance sheet and fund our path toward potential commercialization, leveraging the achievement of clinical data milestones.

Based on our current operating plan and anticipated expense reductions, including the expected cash costs associated with the Reprioritization, management believes that our available cash and cash equivalents balance of $31.5 million as of September 30, 2026 will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2027, through our planned De Novo marketing application submission and the anticipated topline one-year data from the REMAIN-1 Pivotal Cohort. For additional information regarding our liquidity, funding requirements and going concern assessment, see “Funding Requirements and Going Concern” below and the section titled “Risk Factors” in our Annual Report.

Reverse Stock Split

On October 2, 2026, we effected a 1-for-12 reverse stock split of our issued and outstanding common stock, pursuant to a Certificate of Amendment to the Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware on September 30, 2026. The Reverse Stock Split was approved by our stockholders at a special meeting of stockholders held on September 24, 2026, and the final ratio was approved by the board of directors on September 24, 2026. The Reverse Stock Split took effect at 5:00 p.m. Eastern Time on October 2, 2026 and our common stock began trading on a split-adjusted basis on The Nasdaq Global Market on October 5, 2026.

As a result of the Reverse Stock Split, every 12 shares of our issued and outstanding common stock were automatically combined into one share of common stock. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise have been entitled to a fractional share received a cash payment in lieu thereof. The Reverse Stock Split did not change the par value of the common stock or the number of authorized shares of common stock.

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, except as stated below.

The following table reflects our research and development expenses, including direct program-specific expenses summarized by program, indirect expenses, and personnel-related expenses recognized during each period presented:

(in thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Direct program-specific expenses:				
Revita	$ 3,322	$ 7,183	$ 11,964	$ 22,118
Rejuva	1,675	2,315	5,588	10,193
Total direct program-specific expenses	4,997	9,498	17,552	32,311
Indirect expenses	2,045	1,826	5,995	5,679
Personnel-related expenses (including stock-based compensation)	5,412	6,133	18,317	20,053
Total research and development expenses	$ 12,454	$ 17,457	$ 41,864	$ 58,043

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 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–"Summary of Significant Accounting Policies" to our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q as well as Note 2–"Significant Accounting Policies" to our audited financial statements as of and for the year ended December 31, 2025 included in our Annual Report.

Results of Operations

Comparison of three months ended September 30, 2026 and 2025

The following table summarizes our condensed consolidated results of operations for the three months ended September 30, 2026 and 2025.

(in thousands)	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Change Amount	Change %
Operating expenses:				
Research and development	$ 12,454	$ 17,457	$ (5,003)	(28.7%)
Selling, general and administrative	6,195	5,237	958	18.3%
Total operating expenses	18,649	22,694	(4,045)	(17.8%)
Loss from operations	(18,649)	(22,694)	4,045	(17.8%)
Other income (expense), net	4,499	(22,909)	27,408	(119.6%)
Net loss and comprehensive loss	$ (14,150)	$ (45,603)	$ 31,453	(69.0%)

Research and Development Expenses

Research and development expenses decreased by $5.0 million, or 28.7%, during the three months ended September 30, 2026, as compared to the three months ended September 30, 2025. The decrease was primarily related to reduced spending on our Revita and Rejuva programs, as well as lower personnel-related expenses.

Personnel-related expenses decreased by $0.7 million primarily due to lower headcount and the transition of certain employees from clinical study support roles to commercial readiness roles beginning in the third quarter of 2026. Revita-related expenses decreased by $3.9 million primarily due to decreased clinical expenses. Rejuva-related expenses decreased by $0.6 million, primarily driven by lower spending on device engineering activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.0 million, or 18.3%, during the three months ended September 30, 2026, as compared to the three months ended September 30, 2025. The increase was primarily driven by higher personnel-related expenses and stock compensation expenses, partially offset by decreased professional service fees.

Personnel-related expenses increased by $0.6 million primarily due to the transition of certain employees from clinical study support roles to commercial readiness roles beginning in the third quarter of 2026. Stock compensation expenses increased by $0.6 million as a result of new options granted. These increases were partially offset by decreased professional service fees. During the three months ended September 30, 2025, we 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 income, net, of $4.5 million during the three months ended September 30, 2026 was primarily attributable to a $4.5 million gain from the change in fair value of our warrant liabilities and $0.3 million of net interest income, partially offset by a $0.3 million loss from the change in fair value of the 2023 Notes. 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 our 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.

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 was 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, 2026 and 2025

The following table summarizes our condensed consolidated results of operations for the nine months ended September 30, 2026 and 2025.

(in thousands)	Nine Months Ended September 30, 2026	2025	Change Amount	%
Operating expenses:				
Research and development	$ 41,864	$ 58,043	$ (16,179)	(27.9%)
Selling, general and administrative	16,701	15,489	1,212	7.8%
Total operating expenses	58,565	73,532	(14,967)	(20.4%)
Loss from operations	(58,565)	(73,532)	14,967	(20.4%)
Other income (expense), net	28,095	(23,695)	51,790	(218.6%)
Net loss and comprehensive loss	$ (30,470)	$ (97,227)	$ 66,757	(68.7%)

Research and Development Expenses

Research and development expenses decreased by $16.2 million, or 27.9%, during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025. The decrease was primarily related to reduced spending on our Revita and Rejuva programs, as well as lower personnel-related expenses, offset by higher stock compensation expenses.

Revita-related expenses decreased by $10.2 million primarily due to decreased clinical expenses. Rejuva-related expenses decreased by $4.6 million, primarily driven by lower spending on device engineering and pre-clinical research activities. Personnel-related expenses decreased by $1.7 million, primarily driven by lower headcount as a result of our strategic reprioritization adopted in the first quarter of 2025. In addition, certain employees transitioned from clinical study support roles to commercial readiness roles beginning in the third quarter of 2026. Stock compensation expenses increased by $0.9 million as a result of new options granted.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.2 million, or 7.8%, during the nine months ended September 30, 2026, as compared to the nine months ended September 30, 2025. The increase was driven by higher personnel-related expenses and stock compensation expenses, partially offset by decreased professional services expenses.

Personnel-related expenses increased by $0.5 million primarily due to the transition of certain employees from clinical study support roles to commercial readiness roles beginning in the third quarter of 2026. Stock compensation expenses increased by $1.7 million as a result of new options granted. These increases were partially offset by decreased professional service fees. During the nine months ended September 30, 2025, we incurred professional service fees of $0.5 million 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. Legal fees also decreased by $0.5 million.

Other Income (Expense), Net

Other income, net, of $28.1 million during the nine months ended September 30, 2026 was primarily attributable to a $29.1 million gain from the change in fair value of our warrant liabilities and $1.3 million of net interest income, partially offset by a $2.3 million loss from the change in fair value of the 2023 Notes. 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 our 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.

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 was primarily driven by a combination of interest on the notes payable and the fluctuation of market interest rates.

Non-GAAP Financial Measures

In addition to our results determined in accordance with U.S. GAAP, we also evaluate our performance using Adjusted EBITDA, a non-GAAP financial measure. We define Adjusted EBITDA as net loss adjusted to exclude (i) interest income, net, (ii) depreciation expense, (iii) stock-based compensation expense, (iv) changes in the fair value of notes payable and (v) changes in the fair value of warrant liabilities.

We present Adjusted EBITDA as supplemental information because management believes it provides additional insight into our operating performance and facilitates comparisons of our results from period to period by excluding items that are non-cash or non-operational in nature and may vary in magnitude. Management uses Adjusted EBITDA in evaluating our operating performance and in planning and forecasting future periods.

Adjusted EBITDA should not be considered in isolation or as a substitute for, or superior to, net loss or any other measure of financial performance prepared in accordance with GAAP. Adjusted EBITDA does not reflect interest income, depreciation, stock-based compensation expense, or changes in the fair value of certain financial instruments, each of which may be significant. In addition, our definition of Adjusted EBITDA may differ from similarly titled measures used by other

companies and therefore may not be comparable.

A reconciliation of net loss, the most directly comparable GAAP financial measure, to Adjusted EBITDA is presented below.

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net loss	$ (14,150)	$ (45,603)	$ (30,470)	$ (97,227)
Interest income, net	(297)	(166)	(1,321)	(895)
Depreciation	276	290	835	850
EBITDA	(14,171)	(45,479)	(30,956)	(97,272)
Stock-based compensation expense	2,386	1,638	7,413	4,829
Change in fair value of notes payable	284	1,868	2,276	3,824
Change in fair value of warrant liabilities	(4,499)	21,201	(29,070)	20,724
Adjusted EBITDA	$ (16,000)	$ (20,772)	$ (50,337)	$ (67,895)

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.

October 2026 Reprioritization

On October 21, 2026, we adopted the Reprioritization. As part of the Reprioritization, we will reduce our workforce by approximately 45% of our current headcount. The reduction in force is expected to be completed during the fourth quarter of 2026. As cost reductions take effect and REMAIN-1 Pivotal Cohort expenditures decline, we expect quarterly operating cash spending to be reduced by approximately 50%, to approximately $8 million, by the end of the second quarter of 2027.

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. Due to a shift in business strategy 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.

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. The Credit Agreement, as amended, 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. As of September 30, 2026, 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 were originally scheduled 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 will be 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, 2026, the balance of the 2023 Notes was carried at its fair value of $29.6 million.

S-3 Registration Statement

On March 3, 2025, we filed a Registration Statement on Form S-3 with the 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.

August 2025 Warrants

In connection with our underwritten public offering that closed on August 7, 2025 (the "August 2025 Offering"), we issued warrants to purchase shares of our common stock, including the Tranche A and Tranche B Warrants (collectively the "August 2025 Warrants"). For additional information regarding the August 2025 Offering and the terms of the August 2025 Warrants, refer to Note 1 to the consolidated financial statements included in our Annual Report.

All Tranche A Warrants were exercised or expired by December 31, 2025. No Tranche B Warrants were exercised during the three and nine months ended September 30, 2026. As of September 30, 2026, Tranche B Warrants to purchase 1,762,250 shares of our common stock remained outstanding, each with an exercise price of $12.60 per share, subject to certain adjustments, and expiring on October 3, 2030.

Funding Requirements and Going Concern

Our future success is dependent on our ability to develop product candidates, generate significant revenue, and 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 $586.7 million as of September 30, 2026. Based on our current operating plan and anticipated expense reductions, including the expected cash costs associated with the Reprioritization described above, we believe that our available cash and cash equivalents of $31.5 million as of September 30, 2026 will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 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. However, we believe our existing cash resources will not be sufficient to fund our current operating plan for at least twelve months from the issuance date of this Quarterly Report on Form 10-Q. As a result, 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.

Without additional financing, we may not be able to maintain the minimum liquidity covenant related to the Credit Agreement, as discussed in the "Loan and Security Agreements" section above, by the end of the first quarter of 2027. Management intends to mitigate the conditions and events that raise substantial doubt about our ability to continue as a going concern entity by (i) negotiating other cash equity, debt or strategic financing, (ii) continuing to pursue the necessary regulatory approvals to launch commercially in the U.S. market, (iii) executing cost-cutting measures to manage operating cash spending, including the workforce reduction described above, and (iv) pursuing strategic alternatives for our Rejuva Program. However, there can be no assurances that the current plans will generate any liquidity to us or be available on terms acceptable to us.

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;
- obligations related to our Credit Agreement, including the financial covenant to maintain minimum liquidity of $10.0 million;
- 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 the section titled “Risk Factors” in our Annual Report.

We will require substantial additional capital beyond the proceeds from our prior financings to fund 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:

	Nine Months Ended September 30,	
(in thousands)	**2026**	**2025**
Net cash used in operating activities	$ (54,086)	$ (68,992)
Net cash used in investing activities	—	(554)
Net cash provided by financing activities	4,061	79,739
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (50,025)	$ 10,193

Operating Activities

Cash used in operating activities of $54.1 million for the nine months ended September 30, 2026 was primarily driven by spending on our ongoing clinical studies, Rejuva-related research and clinical readiness 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 $30.5 million adjusted for net non-cash activities of $20.3 million. These non-cash activities primarily consisted of a $29.1 million non-cash gain from the change in fair value of warrant liabilities, a $0.9 million non-cash gain from the change in fair value of notes payable, $7.4 million in stock-based compensation expense, $1.3 million non-cash operating lease expense, and $0.8 million depreciation expense. Cash used in operating activities was also impacted by changes in working capital and other assets and liabilities of $3.3 million.

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.

Investing Activities

We did not have any investing related cash flow activities for the nine months ended September 30, 2026. Cash used in investing activities for the nine months ended September 30, 2025, was primarily related to the purchase of laboratory and manufacturing equipment.

Financing Activities

Cash provided by financing activities of $4.1 million for the nine months ended September 30, 2026 was related to $4.1 million proceeds received in January 2026 from Tranche A warrants that were exercised in December 2025 and $0.4 million proceeds received from issuance of common stock under employee stock purchase plan, partially offset by $0.4 million principal payments made on finance lease obligations. 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.

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, 2026, 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, 2026, our future contractual commitments for our leases were $47.8 million, of which $47.4 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.

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the 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 a smaller reporting company as defined in Item 10(f)(1) of Regulation S-K. As a result, pursuant to Item 305(e) of Regulation S-K, we are not required to provide the information required by this Item 3.

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, 2026, 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, 2026 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.

On August 21, 2026, a putative securities class action lawsuit captioned Lorne v. Fractyl Health, Inc., et al., Case No. 1:26-cv-07167, was filed in the United States District Court for the Southern District of New York against Fractyl Health, Inc. and certain of its current and former officers. The complaint purports to assert claims on behalf of persons who purchased or otherwise acquired our securities between January 13, 2025 and January 29, 2026, and alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaint generally alleges that the defendants made materially false or misleading statements or omissions concerning the clinical efficacy of our Revita DMR System and the results of its REMAIN-1 clinical study, including alleged operational issues at certain clinical study sites that purportedly affected the reliability of reported efficacy results. The complaint seeks unspecified monetary damages, interest, attorneys' fees and other relief. On October 20, 2026, three movants filed motions seeking appointment as lead plaintiff. On October 23, 2026, one movant filed a notice of withdrawal. Following appointment of lead plaintiff, the court will issue an order setting a deadline for lead plaintiff to file an amended complaint and for defendants to file a response thereto. We intend to vigorously defend against the claims in this action. Any potential loss arising from this lawsuit is not currently probable or estimable.

Item 1A. Risk Factors.

In addition to the information set forth 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, you should carefully consider the risks and uncertainties described in the Annual Report, including the disclosure therein under Part I, Item 1A, "Risk Factors." 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.

There were no material changes during the period covered in this Quarterly Report on Form 10-Q to the Risk Factors previously disclosed in Part I, Item 1A of the Annual Report, other than as set forth below.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock, which could negatively impact the market price and liquidity of our common stock and our ability to access the capital markets.

In order to maintain this listing, we must satisfy the continued listing requirements and standards of Nasdaq, including a minimum closing bid price requirement for our common stock of $1.00 per share. On March 13, 2026, we received a notification letter from Nasdaq notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock had been below the minimum $1.00 per share required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5450(a)(1) ("Rule 5450(a)(1)"). As we did not regain compliance with the minimum bid price requirement within the 180-calendar day compliance period set forth by Nasdaq Listing Rule 5810(c)(3)(A), by September 9, 2026, Nasdaq notified us by letter dated September 10, 2026, that our securities are subject to delisting from Nasdaq unless we timely request a hearing before a Nasdaq Hearings Panel (the "Panel"). We timely requested a hearing before the Panel. The hearing request automatically stayed any suspension or delisting of our securities and, as a result, our common stock has continued to be listed and traded on Nasdaq pending the conclusion of the hearings process. On October 19, 2026, we appeared before the Panel at a hearing regarding our continued listing on Nasdaq. As of the date of this Quarterly Report, we have not received a decision from the Panel.

Pursuant to Listing Rule 5810(c)(3)(H), in order to regain compliance with the minimum bid price requirement, the closing minimum bid price of our common stock must be at least $1.00 per share for at least 10 consecutive business days and up to 20 consecutive business days, at Nasdaq staff's discretion. On October 2, 2026, we effected a 1-for-12 reverse stock split of our common stock in order to regain compliance with the minimum bid price requirement. Following the reverse stock split, the closing bid price of our common stock remained above $1.00 per share for 16 consecutive business days from October 5, 2026 through October 26, 2026. However, we did not receive notice from Nasdaq that we had regained compliance with the minimum bid price requirement, and on October 27, 2026, the closing bid price of our common stock again fell below $1.00 per share and has remained below $1.00 per share through the date of this Quarterly Report. There can be no assurance that we will be successful in maintaining the listing of our common stock on the Nasdaq Global Market, that the Panel will determine to continue our listing or grant us additional time to regain compliance with the minimum bid price requirement, or that we will be able to regain compliance with the minimum bid price requirement or any other applicable continued listing requirement within any compliance period that may be granted by the Panel.

If we are unable to regain compliance within any period permitted by the Panel, or if the Panel denies our request for continued listing, our common stock would be subject to suspension and delisting from Nasdaq. A delisting of our common stock could negatively impact us by, among other things, (i) reducing the liquidity and market price of our common stock; (ii) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (iii) decreasing the amount of news and analyst coverage of us; (iv) limiting our ability to issue additional securities or obtain additional financing in the future; (v) limiting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing us from accessing the public capital markets; and (vi) impairing our ability to provide equity incentives to our employees. In addition, delisting from Nasdaq may negatively impact our reputation and, consequently, our business.

We are subject to securities litigation, which is expensive and could divert management attention and adversely impact our business.

The market price of our common stock has been and may continue to be volatile. Companies that have experienced volatility in the market price of their common stock are often subject to securities class action litigation. For example, in August 2026, a securities class action complaint was filed in the U.S. District Court for the Southern District of New York against us and certain of our current and former executive officers. The case is still in the early stages. However, regardless of outcome, this or any future securities litigation could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. In addition, litigation, including securities class action litigation, has often followed certain significant business transactions, such as announcement of a strategic transaction, and may also result in investigations by the SEC. We may be exposed to such litigation even if no wrongdoing occurred. Any adverse determination in litigation could also subject us to significant liabilities. See Part II, Item 1, "Legal Proceedings," for additional information regarding this matter.

Our strategic reprioritization and workforce reduction may not achieve the intended benefits and could disrupt our business.

On October 21, 2026, we adopted a plan to sharpen our strategic focus on our Revita program in connection with a strategic reprioritization (the "Reprioritization"), including a reduction in our workforce by approximately 45% of our current headcount and the discontinuation of internal development of our Rejuva gene therapy program. These actions are intended to create a streamlined, Revita-focused organization, reduce quarterly operating cash spending and concentrate resources on realizing Revita's clinical and commercial potential. The estimated costs that we expect to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction, including potential impairment charges, if any.

In light of this Reprioritization and 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.

There can be no assurance that our review of strategic alternatives for Rejuva will result in any transaction, and we do not intend to disclose further developments unless and until we determine that disclosure is appropriate or required.

The regulatory review processes 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 clearance, approval or certification for any of our product candidates, and any such clearance, 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 are subject to extensive regulation by the FDA and other regulatory authorities in and outside the U.S. We are currently in clinical-stage development of Revita, which is an investigational medical device.

In the U.S., 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"), clearance of a De novo application, or approval of a PMA application from the FDA. In the process of obtaining clearance or 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. We plan to seek De novo clearance from the FDA for Revita for weight maintenance. If at the time of filing the FDA disagrees and requires us to instead submit a PMA, we may be materially delayed in our efforts to market Revita.

The FDA clearance process can be expensive, lengthy and uncertain. 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.

Our product candidates could fail to receive regulatory clearance 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 or effective;
- 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 nonclinical or clinical studies;
- the insufficiency of data collected from clinical studies of our product candidates to support the submission 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 nonclinical 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 clearance 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 nonclinical or clinical data to support clearance, approval or certification, which may delay or prevent our commercialization plans, or we may decide to abandon the development program. If we were to obtain clearance 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 authorize 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 clearance or certification.

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 pathway for our product candidates may be uncertain, complex, expensive and lengthy, and marketing authorization may not ultimately be obtained. In addition, the FDA and comparable foreign regulatory authorities may change their approval policies and new regulations may be enacted, delaying or preventing our commercial plans.

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 to continue to incur significant expenses in connection with our ongoing activities, particularly as we conduct clinical studies of, and seek marketing authorization 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 authorization 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, 2026, we had approximately $31.5 million in cash and cash equivalents which we believe will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 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 the first quarter of 2027.

Given the inherent risk and uncertainty of future cash flow estimates as well as the minimum liquidity covenant requirement, our management has concluded that substantial doubt exists about our ability to continue as a going concern for at least one year after the date that these condensed consolidated 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.

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. Without additional financing, we may not be able to maintain the minimum liquidity covenant related to the Credit Agreement by the end of the first quarter of 2027. 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. 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.

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 of directors.

None.

(c) Insider Trading Arrangements and Policies.

During the three months ended September 30, 2026, 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	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Fractyl Health, Inc.	8-K	001-41942	3.1	10/1/2026	
3.3	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	
10.1†	Independent Director Letter Agreement dated November 2, 2026, by and between Fractyl Health, Inc. and Michael Wartell	8-K	001-41942	10.1	11/6/2026	
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)					*

† Indicates a management contract or compensatory plan or arrangement.

* 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, 2026

By: /s/ Harith Rajagopalan

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

Date: November 12, 2026

By: /s/ Lara Smith Weber

Lara Smith Weber
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, 2026

By: /s/ Harith Rajagopalan

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

Exhibit 31.2

CERTIFICATIONS

I, Lara Smith Weber, 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, 2026

By: /s/ Lara Smith Weber

Lara Smith Weber
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, 2026, 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, 2026

By: /s/ Harith Rajagopalan

Harith Rajagopalan, M.D., Ph.D.
Co-Founder, President, 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), Lara Smith Weber, Chief Financial Officer and Treasurer 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, 2026, 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, 2026

By: /s/ Lara Smith Weber

Lara Smith Weber
Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)