

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

Form 10-Q

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

For the quarterly period ended December 31, 2025

OR

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

For the transition period from _____ to _____

Commission File Number 001-35996

VivoSim Labs, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

**11555 Sorrento Valley Rd, Suite 100,
San Diego, CA 92121**
(Address of principal executive offices and zip code)

27-1488943
(I.R.S. Employer
Identification No.)

(858) 224-1000
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol	Name of Each Exchange on which registered
Common Stock, \$0.001 par value	VIVS	The Nasdaq Stock Market LLC

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 February 1, 2026, a total of 2,607,962 shares of the registrant's Common Stock, \$0.001 par value, were outstanding.

VIVOSIM LABS, INC.

INDEX

PART I. FINANCIAL INFORMATION

Item 1.	<u>Financial Statements</u>	3
	<u>Condensed Consolidated Balance Sheets as of December 31, 2025 (Unaudited) and March 31, 2025</u>	3
	<u>Unaudited Condensed Consolidated Statements of Operations and Other Comprehensive Loss for the Three and Nine Months Ended December 31, 2025 and 2024</u>	4
	<u>Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Three and Nine Months Ended December 31, 2025 and 2024</u>	5
	<u>Unaudited Condensed Consolidated Statements of Cash Flows for the Nine Months Ended December 31, 2025 and 2024</u>	6
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	7
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	27
Item 4.	<u>Controls and Procedures</u>	27

PART II. OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	28
Item 1A.	<u>Risk Factors</u>	28
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	50
Item 3.	<u>Defaults Upon Senior Securities</u>	50
Item 4.	<u>Mine Safety Disclosure</u>	50
Item 5.	<u>Other Information</u>	50
Item 6.	<u>Exhibits</u>	51

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

VIVOSIM LABS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands except for share and per share data)

	<u>December 31, 2025</u>	<u>March 31, 2025</u>
	(Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	\$ 4,288	\$ 11,312
Accounts receivable	33	30
Escrow receivable	1,011	—
Prepaid expenses and other current assets	709	789
Total current assets	<u>6,041</u>	<u>12,131</u>
Fixed assets, net	248	419
Restricted cash	143	143
Operating lease right-of-use assets	525	867
Escrow receivable	—	1,000
Prepaid expenses and other assets, net	3	90
Total assets	<u>\$ 6,960</u>	<u>\$ 14,650</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 671	\$ 1,644
Accrued expenses	818	1,226
Insurance premium financing liability	235	128
Liability to be settled in equity	218	218
Operating lease liability, current portion	533	521
Total current liabilities	<u>2,475</u>	<u>3,737</u>
Operating lease liability, net of current portion	44	421
Total liabilities	<u>2,519</u>	<u>4,158</u>
Commitments and Contingencies (Note 6)		
Stockholders' Equity		
Common stock, \$0.001 par value; 200,000,000 shares authorized, 2,607,962 and 1,898,068 shares issued and outstanding at December 31, 2025 and March 31, 2025, respectively	3	2
Additional paid-in capital	354,674	352,648
Accumulated deficit	(350,236)	(342,157)
Treasury stock, 3 shares at cost at December 31, 2025 and March 31, 2025	—	(1)
Total stockholders' equity	<u>4,441</u>	<u>10,492</u>
Total Liabilities and Stockholders' Equity	<u>\$ 6,960</u>	<u>\$ 14,650</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VIVOSIM LABS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS
(in thousands except share and per share data)

	Three Months Ended December 31, 2025	Three Months Ended December 31, 2024	Nine Months Ended December 31, 2025	Nine Months Ended December 31, 2024
Revenues				
Royalty revenue	\$ 26	\$ 15	\$ 91	\$ 68
Product revenue	—	9	—	25
Total Revenues	<u>26</u>	<u>24</u>	<u>91</u>	<u>93</u>
Cost of revenues	—	2	—	5
Research and development expenses	1,140	1,780	3,064	4,166
Selling, general and administrative expenses	1,636	1,710	5,327	5,384
Total costs and expenses	<u>2,776</u>	<u>3,492</u>	<u>8,391</u>	<u>9,555</u>
Loss from Operations	<u>(2,750)</u>	<u>(3,468)</u>	<u>(8,300)</u>	<u>(9,462)</u>
Other Income (Expense)				
Interest income	63	26	231	129
Interest expense	(4)	(5)	(8)	(5)
Total Other Income	<u>59</u>	<u>21</u>	<u>223</u>	<u>124</u>
Income Tax Expense	<u>—</u>	<u>—</u>	<u>(2)</u>	<u>(2)</u>
Net Loss	<u>\$ (2,691)</u>	<u>\$ (3,447)</u>	<u>\$ (8,079)</u>	<u>\$ (9,340)</u>
Other Comprehensive loss:				
Unrealized loss on available-for-sale debt securities	\$ —	\$ (1)	\$ —	\$ —
Comprehensive Loss	<u>\$ (2,691)</u>	<u>\$ (3,448)</u>	<u>\$ (8,079)</u>	<u>\$ (9,340)</u>
Net loss per common share—basic and diluted	\$ (1.03)	\$ (2.28)	\$ (3.14)	\$ (6.60)
Weighted average shares used in computing net loss per common share—basic and diluted	2,607,962	1,504,713	2,572,331	1,409,423

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VIVOSIM LABS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Three and Nine Months Ended December 31, 2025							
	Common Stock			Treasury Stock			Accumulated Other Comprehensive Income	Total
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulated Deficit		
Balance at March 31, 2025	1,898	\$ 2	\$ 352,648	—	\$ (1)	\$ (342,157)	\$ —	\$ 10,492
Retirement of treasury stock	—	—	(1)	—	1	—	—	—
Issuance of common stock from public offering, net	702	1	1,810	—	—	—	—	1,811
Stock-based compensation expense	—	—	78	—	—	—	—	78
Net loss	—	—	—	—	—	(2,843)	—	(2,843)
Balance at June 30, 2025 (Unaudited)	2,600	\$ 3	\$ 354,535	—	\$ —	\$ (345,000)	\$ —	\$ 9,538
Issuance of common stock under employee and director stock option, RSU, and purchase plans	8	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	72	—	—	—	—	72
Net loss	—	—	—	—	—	(2,545)	—	(2,545)
Balance at September 30, 2025 (Unaudited)	2,608	\$ 3	\$ 354,607	—	\$ —	\$ (347,545)	\$ —	\$ 7,065
Stock-based compensation expense	—	—	67	—	—	—	—	67
Net loss	—	—	—	—	—	(2,691)	—	(2,691)
Balance at December 31, 2025 (Unaudited)	2,608	\$ 3	\$ 354,674	—	\$ —	\$ (350,236)	\$ —	\$ 4,441

	Three and Nine Months Ended December 31, 2024							
	Common Stock			Treasury Stock			Accumulated Other Comprehensive Income	Total
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulated Deficit		
Balance at March 31, 2024	840	\$ 1	\$ 343,270	—	\$ (1)	\$ (339,669)	\$ —	\$ 3,601
Issuance of common stock from exercise of pre-funded warrants	115	—	1	—	—	—	—	1
Issuance of common stock from public offering, net	243	—	6,248	—	—	—	—	6,248
Stock-based compensation expense	—	—	156	—	—	—	—	156
Net loss	—	—	—	—	—	(3,344)	—	(3,344)
Balance at June 30, 2024 (Unaudited)	1,198	\$ 1	\$ 349,675	—	\$ (1)	\$ (343,013)	\$ —	\$ 6,662
Issuance of common stock from exercise of pre-funded warrants	83	—	1	—	—	—	—	1
Stock-based compensation expense	—	—	155	—	—	—	—	155
Financing Fees	—	—	(590)	—	—	—	—	(590)
Net loss	—	—	—	—	—	(2,549)	—	(2,549)
Unrealized gain on available-for-sale debt securities	—	—	—	—	—	—	1	1
Balance at September 30, 2024 (Unaudited)	1,281	\$ 1	\$ 349,241	—	\$ (1)	\$ (345,562)	\$ 1	\$ 3,680
Issuance of common stock under employee and director stock option, RSU, and purchase plans	10	—	—	—	—	—	—	—
Issuance of common stock under pre-funded warrants exercise	133	—	2	—	—	—	—	2
Issuance of common stock from public offering, net	4	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	130	—	—	—	—	130
Net loss	—	—	—	—	—	(3,447)	—	(3,447)
Unrealized gain on available-for-sale debt securities	—	—	—	—	—	—	(1)	(1)
Balance at December 31, 2024 (Unaudited)	1,428	\$ 1	\$ 349,373	—	\$ (1)	\$ (349,009)	\$ 1	\$ 364

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VIVOSIM LABS, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Nine Months Ended December 31, 2025	Nine Months Ended December 31, 2024
Cash Flows From Operating Activities		
Net loss	\$ (8,079)	\$ (9,340)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest accretion on escrow receivable	(11)	—
Accretion on investments	—	(37)
Write-downs of inventory	—	798
Depreciation and amortization	172	205
Stock-based compensation	217	441
Non-cash lease expense	342	321
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(3)	7
Inventory	—	(501)
Prepaid expenses and other assets	519	205
Accounts payable	(973)	303
Accrued expenses	(408)	506
Operating lease liability	(365)	(334)
Net cash used in operating activities	(8,589)	(7,426)
Cash Flows From Investing Activities		
Purchases of fixed assets	—	(13)
Purchases of investments	—	(2,463)
Maturities of investments	—	2,500
Net cash provided by investing activities	—	24
Cash Flows From Financing Activities		
Proceeds from issuance of common stock, net	1,811	5,662
Repayment of insurance premium financing liability	(246)	—
Net cash provided by financing activities	1,565	5,662
Net decrease in cash, cash equivalents, and restricted cash	(7,024)	(1,740)
Cash, cash equivalents, and restricted cash at beginning of period	11,455	3,044
Cash, cash equivalents, and restricted cash at end of period	\$ 4,431	\$ 1,304
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	\$ 4,288	\$ 1,161
Restricted cash	143	143
Total cash, cash equivalents, and restricted cash	\$ 4,431	\$ 1,304
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	\$ 2	\$ 2
Financed insurance premium exchanged for prepaid insurance	\$ 352	\$ 385
Liability to be settled in equity	\$ —	\$ 218
Interest paid	\$ 8	\$ 5

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

VivoSim Labs, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. Description of Business

Nature of Operations

VivoSim Labs, Inc., formerly known as Organovo Holdings, Inc. ("VivoSim" and the "Company"), is a pharmaceutical and biotechnology services company that is focused on providing testing of drugs and drug candidates in three-dimensional ("3D") human tissue models of liver and intestine. The Company offers partners liver and intestinal toxicology insights using its new approach methodologies ("NAM") models. The Company anticipates accelerated adoption of human tissue models following the U.S. Food and Drug Administration ("FDA") announcement on April 10, 2025 to refine animal testing requirements in favor of these non-animal NAM methods. The Company will also offer bespoke services in the areas of investigational toxicology, mechanism of drug action elucidation, and other applications of these complex human tissue models.

The Company also advances product candidates to treat inflammatory bowel disease ("IBD") discovered and developed using its complex human tissue intestinal models. Prior to March 2025, the Company was a clinical stage biotechnology company that was focused on developing FXR314 in IBD, including ulcerative colitis ("UC"), based on demonstration of clinical promise in 3D human tissues as well as strong preclinical data. The Company's clinical focus was in advancing FXR314 in IBD, including UC and Crohn's disease ("CD"). The Company planned to start a Phase 2a clinical trial in UC in the calendar year 2025 and was also exploring the potential for combination therapies using FXR314 and approved mechanisms in preclinical animal studies and the Company's IBD disease models. The Company also has advanced a second program since 2023, a novel drug that will be a new chemical entity ("NCE") to an undisclosed target discovered in its intestinal models to have activity for UC and CD. This drug program (the "Preclinical IBD Program") has now left the in-silico phase in recent quarters, and has moved to medicinal chemistry stage, the real-world synthesis of novel candidate compounds.

In March 2025, the Company sold its FXR program for \$10.0 million, with \$9.0 million paid at closing and \$1.0 million held in escrow for a period of 15 months, with future milestones of up to \$50.0 million in the aggregate to be paid if the asset, FXR314, hits key development, regulatory and commercial milestones.

Effective April 24, 2025, the Company changed its corporate name to VivoSim Labs, Inc. by filing a Certificate of Amendment to its Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. The Company changed its name to reflect its new business model, which includes the use of other longstanding assets of the Company, intestinal and liver tox models and expertise, and its IP portfolio for 3D bioprinting.

The Company continues to advance its Preclinical IBD Program, with the goal of having a product candidate ready for an Investigational New Drug ("IND Application") with the FDA by December 2026.

The Company is now offering liver toxicology predictive screening and research services as well as working on predicting and studying the intestinal side effect profiles of drugs that are therapeutic candidates of pharmaceutical and biotech companies at all stages of drug development. The Company plans to not only market this directly to pharmaceutical and biotech companies, but also partner with specific contract research organizations to complement its offering and to quickly grow its portfolio of clients. The Company's services offer the potential benefit of reducing the significant risk and cost of bringing therapeutics to market through the regulatory process. It is estimated that less than 10% of drug candidates entering clinical trials are approved, with a portion of the failures due to unexpected liver toxicity or intestinal intolerance. In addition, even approved drugs are occasionally withdrawn after liver toxicity is determined to be caused by the drug in a phenomenon called drug induced liver injury. The Company presented findings at the May 2025 Digestive Disease Week scientific conference showing that the liver toxicology platform had a best-in-class predictive power. VivoSim's liver predictive power was shown to be 87.5% for a set of challenging liver toxicity cases – inclusive of classic cases of "liver tox misses" drugs with unforeseen liver toxicity found in clinical trials or drugs that were withdrawn from the market after liver toxicity issues emerged later. The platform identified correctly that 87.5% of the known liver-toxic drugs could be seen as liver toxic using NAMkind™ liver. This is known as the sensitivity of the platform, which at 87.5% is the world's best. Importantly, the specificity was 100%, meaning that none of the compounds tested that are not liver toxic were incorrectly identified as having liver toxicity issues by the platform.

The Company uses its proprietary technologies to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function, and disease. The Company believes these attributes can enable critical complex, multicellular disease models that can be used to study and develop clinically effective drugs across multiple therapeutic areas.

The Company has also used these human disease models to identify new molecular targets responsible for driving IBD and to explore the mechanism of action of known drugs including JAK inhibitors and related molecules. A portion of its internal research continues to focus on early stage internal drug discovery programs, validating targets, and testing potentially licensable or transactable external drug compounds to identify drug candidates for partnering and/or internal clinical development. This includes the Preclinical IND Program, which has reached a more mature stage than other efforts in this area.

Except where specifically noted or the context otherwise requires, references to “VivoSim” and “the Company” in these notes to the unaudited condensed consolidated financial statements refers to VivoSim Labs, Inc. and its wholly owned subsidiaries, Organovo, Inc., and VivoSim, Inc.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not necessarily include all information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at March 31, 2025 is derived from the Company’s audited consolidated balance sheet as filed with the Securities and Exchange Commission (“SEC”) on June 5, 2025.

The unaudited condensed consolidated financial statements include the accounts of VivoSim and its wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of the Company’s financial position, results of operations, stockholders’ equity and cash flows. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes included in the Company’s Annual Report on Form 10-K for the year ended March 31, 2025, as filed with the SEC. Operating results for any interim period are not necessarily indicative of the operating results for any other interim period or the Company’s full fiscal year ending March 31, 2026 (see “Note 1. Description of Business”).

Liquidity and Going Concern

The accompanying condensed consolidated financial statements have been prepared on the basis that the Company is a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. As of December 31, 2025, the Company had cash and cash equivalents of approximately \$4.3 million, restricted cash of approximately \$0.1 million and an accumulated deficit of approximately \$350.2 million. The restricted cash was pledged as collateral for a letter of credit that the Company is required to maintain as a security deposit under the terms of the lease agreements for its facilities. The Company also had negative cash flows from operations of approximately \$8.6 million during the nine months ended December 31, 2025. As of December 31, 2025, the Company had total current assets of approximately \$6.0 million and current liabilities of approximately \$2.5 million, resulting in working capital of \$3.5 million.

Through December 31, 2025, the Company has financed its operations primarily through the sale of common stock through public and at-the-market (“ATM”) offerings, the private placement of equity securities, from revenue derived from the licensing of intellectual property, products and research-based services, grants, and collaborative research agreements, and from the sale of convertible notes. During the nine months ended December 31, 2025, the Company issued 701,729 shares of its common stock through its ATM facility, for net proceeds of approximately \$1.8 million.

On March 25, 2025, the Company sold its FXR program for \$10.0 million, with \$9.0 million paid at closing and \$1.0 million held in escrow for a period of 15 months, with future milestones of up to \$50.0 million to be paid if the lead asset, FXR314, hits key regulatory and commercial milestones. As of December 31, 2025, the \$1.0 million held in escrow receivable was considered a current asset on the condensed consolidated balance sheet.

Based on the Company’s current operating plan and available cash resources, the Company will need substantial additional funding to support future operating activities. The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by the Company raise substantial doubt about its ability to continue as a going concern for at least one year following the date these condensed consolidated financial statements are issued. The accompanying condensed consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern. As the Company continues its operations and is focusing its efforts on services, research, and development, the Company will need to raise additional capital to implement this business plan. The Company cannot predict with certainty the exact amount or timing for any future capital raises. The Company will seek to raise additional capital through debt or equity financings, or through some other financing

arrangement. However, the Company cannot be sure that additional financing will be available if and when needed, or that, if available, it can obtain financing on terms favorable to its stockholders. Any failure to obtain financing when required will have a material adverse effect on the Company's business, operating results, and financial condition.

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates. On an ongoing basis, management reviews these estimates and assumptions.

Fair value measurement

Financial assets and liabilities are measured at fair value, which is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The following is a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Insurance Premium Financing Liability

In September 2025, the Company entered into an insurance premium financing agreement for \$0.4 million, with a term of nine months and an annual interest rate of 7.82%. The Company made a down payment of 10% and is required to make monthly principal and interest payments of \$40,468 over the term of the agreement, which will mature in June 2026. The insurance premium financing liability was approximately \$0.2 million and \$0.1 million as of December 31, 2025 and March 31, 2025, respectively. Related prepaid insurance at December 31, 2025 and March 31, 2025 of \$0.3 million and \$0.2 million, respectively, is included in prepaid expenses and other current assets on the accompanying condensed consolidated balance sheets.

Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share includes the assumed exercise of any outstanding pre-funded warrants, and excludes any assumed exercise of stock options, shares reserved for purchase under the Company's 2023 Employee Stock Purchase Plan ("ESPP"), the assumed vesting of restricted stock units ("RSUs"), the exercise of common warrants, and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the nine months ended December 31, 2025 and 2024 as the Company reported a net loss for each respective period and the effect would have been anti-dilutive.

Common stock equivalents excluded from computing diluted net loss per share due to their anti-dilutive effect were approximately 0.8 million shares and 0.8 million shares at December 31, 2025 and 2024, respectively. The common stock equivalents excluded include unexercised stock options and common warrants.

Revenue recognition

Royalty revenue

The Company has entered into an intellectual property license agreement with another company that includes royalties based on specified percentages of net product sales, if any. At the initiation of the agreement, the Company analyzed whether it results in a contract with a customer under Accounting Standards Codification ("ASC") Topic 606.

The Company considered a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the Company is a principal vs. agent, whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company evaluates each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, sales-based royalty

payments have been identified as variable consideration which must be evaluated to determine if it has been constrained and, therefore, excluded from the transaction price. Please refer to “Note 5. Collaborative Research, Development, and License Agreements” for further information.

Product revenue, net

The Company’s former product-based division, Mosaic, produced high-quality cell-based products for use in VivoSim’s R&D and for use by life science customers. The Company recognized product revenue when the performance obligation was satisfied, which is at the point in time the customer obtained control of the Company’s product, typically upon delivery. Product revenues were recorded at the transaction price under Topic 606. The Company provided no right of return to its customers except in cases where a customer obtained authorization from the Company for the return. To date, there have been no product returns. Mosaic's commercial operations ended during the third quarter of fiscal 2025.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies. Unless otherwise stated, the Company believes that the impact of the recently issued accounting pronouncements that are not yet effective will not have a material impact on its consolidated financial position or results of operations upon adoption.

In December 2023, the FASB issued Accounting Standards Update (“ASU”) 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The update requires a public business entity to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. Adoption of the ASU allows for either the prospective or retrospective application of the amendment and is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The new disclosure requirements will be included in the Company's Form 10-K for the fiscal year ending March 31, 2026 and will be applied retrospectively.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which is intended to improve the disclosures of expenses by providing more detailed information about the types of expenses in commonly presented expense captions. The standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The standard can be applied either prospectively or retrospectively. The Company has not yet completed its assessment of the impact of ASU 2024-03 on the Company’s Consolidated Financial Statements.

Note 3. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2025	March 31, 2025
Accrued payroll and other employee benefits	\$ 232	\$ 652
Accrued legal and professional fees	570	515
Other accrued expenses	16	59
	<u>\$ 818</u>	<u>\$ 1,226</u>

Please refer to “Note 6. Commitments and Contingencies” for further information regarding the accrued loss contingencies presented in the table above.

Note 4. Stockholders’ Equity

Preferred Stock

The Company is authorized to issue 25,000,000 shares of preferred stock. There are no shares of preferred stock currently outstanding, and the Company has no current plans to issue shares of preferred stock.

Common Stock

In March 2021, the Company's Board of Directors ("Board") approved the 2021 Inducement Equity Incentive Plan ("Inducement Plan"). The Inducement Plan authorized the issuance of up to 62,500 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, RSUs, performance units, performance shares, and other stock or cash awards. In February 2022, 4,166 incentive stock options were issued under the Inducement Plan.

On October 12, 2022, the Company's stockholders and the Board approved the 2022 Equity Incentive Plan ("2022 Plan"), and it became effective on that date. The 2022 Plan replaced the Amended and Restated 2012 Equity Incentive Plan ("2012 Plan") on the effective date. Upon the effective date, the Company ceased granting awards under the 2012 Plan and any shares remaining available for future issuance under the 2012 Plan were cancelled and are no longer available for future issuance. The 2012 Plan continues to govern awards previously granted under it. At the time the Board approved the 2022 Plan, an aggregate of 113,583 shares of the Company's common stock was initially reserved for issuance under the 2022 Plan. The Company committed to reducing the new 2022 Plan share reserve by the number of shares that were granted under the 2012 Plan and the Inducement Plan between July 25, 2022 and October 12, 2022. From July 25, 2022 to October 12, 2022, the Company issued 10,521 shares of its common stock under the 2012 Plan. As a result, the number of shares reserved for future issuance under the 2022 Plan was 103,062 shares of common stock. The Company also committed to reducing the aggregate number of shares of its common stock issuable pursuant to the Inducement Plan from 62,500 shares to 4,250 shares (which includes 4,166 shares of its common stock issuable pursuant to an outstanding option to purchase common stock with an exercise price of \$33 per share, leaving only 83 shares available for future issuance under the Inducement Plan) and the share reserve was reduced effective October 12, 2022. On November 20, 2024, the Company's stockholders approved the amendment and restatement of the 2022 Plan (the "A&R 2022 Plan") to increase the number of shares reserved for issuance thereunder by 147,916 shares.

On January 26, 2024, the Company filed a shelf registration statement on Form S-3 (File No. 333-276722) to register \$150.0 million of the Company's common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the "2024 Shelf"). The 2024 Shelf was declared effective by the SEC on February 8, 2024.

On March 16, 2018, the Company entered into a Sales Agreement with Jones Trading Institutional Services LLC (the "Agent").

On January 26, 2024, the Company filed a prospectus with the 2024 Shelf (the "2024 ATM Prospectus"), pursuant to which the Company may offer and sell, from time to time through the Agent, shares of its common stock in ATM sales transactions having an aggregate offering price of up to \$2,605,728. The Company filed amendments to the 2024 ATM Prospectus on February 26, 2025 and again on April 11, 2025, providing that the Company may offer and sell, from time to time through the Agent, shares of its common stock in ATM sales transactions having an additional aggregate offering price of up to \$5,311,508 and \$4,766,105, respectively. Any shares offered and sold in these ATM transactions will be issued pursuant to the 2024 Shelf.

During the three months and nine months ended December 31, 2025, the Company issued zero and 701,729 shares of common stock in ATM offerings, respectively, for net proceeds of approximately \$1.8 million, pursuant to the 2024 Shelf. As of December 31, 2025, the Company has sold an aggregate of 1,198,134 shares of common stock in ATM offerings under the 2024 ATM Prospectus, with gross proceeds of approximately \$6.9 million. As of December 31, 2025, there was approximately \$140.1 million unallocated and available for future offerings under the 2024 Shelf, and approximately \$3.1 million available for future offerings through the Company's ATM program under the 2024 ATM Prospectus.

May 2024 Best Efforts Public Offering

On May 8, 2024, the Company priced a best efforts public offering (the "Offering") of: (i) 130,202 shares of its common stock and accompanying common warrants ("Common Warrants") to purchase up to 130,202 shares of common stock at a combined public offering price of \$9.60 per share and accompanying Common Warrant to purchase one share of common stock and (ii) pre-funded warrants ("Pre-Funded Warrants") to purchase 416,666 shares of common stock and accompanying Common Warrants to purchase up to 416,666 shares of common stock at a combined public offering price of \$9.588 per Pre-Funded Warrant and accompanying Common Warrant to purchase one share of common stock. In connection with the Offering, the Company entered into Securities Purchase Agreements with the purchasers of the securities in the Offering on May 8, 2024.

The per share exercise price for the Pre-Funded Warrants was \$0.001, subject to adjustment as provided therein. The Pre-Funded Warrants were immediately exercisable, subject to certain beneficial ownership limitations, and were to expire when exercised in full. The holders could exercise the Pre-Funded Warrants by means of a "cashless exercise." During the year ended March 31, 2025, all 416,666 Pre-Funded Warrants were exercised.

The per share exercise price for the Common Warrants is \$9.60, subject to adjustment as provided therein. The Common Warrants were immediately exercisable, subject to certain beneficial ownership limitations, and will expire on the date that is five years following the original issuance date. If a registration statement covering the issuance of the shares of common stock issuable upon exercise of the Common Warrants is not available for the issuance, then the holders may exercise the Common Warrants by means of a “cashless exercise.”

In connection with the Offering, the Company paid JonesTrading Institutional Services LLC, which acted as the placement agent in connection with the Offering, a cash fee of 5.0% of the aggregate gross proceeds raised in the Offering.

The closing of the Offering occurred on May 13, 2024. The Company received net proceeds of approximately \$4.5 million from the Offering, after deducting the offering expenses payable by the Company, including the Placement Agent fees.

The Company sold (i) 130,202 shares of its common stock and Common Warrants to purchase up to 130,202 shares of common stock and (ii) Pre-Funded Warrants to purchase 416,666 shares of common stock and accompanying Common Warrants to purchase up to 416,666 shares of common stock.

Restricted Stock Units

The following table summarizes the Company’s RSUs activity for the nine months ended December 31, 2025:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2025	8,165	\$ 6.57
Granted	—	\$ —
Vested	(8,165)	\$ 6.57
Cancelled / forfeited	—	\$ —
Unvested at December 31, 2025	—	\$ —

Stock Options

During the three and nine months ended December 31, 2025, under the A&R 2022 Plan, 53,500 and 101,474 stock options were granted at various exercise prices, respectively.

On August 5, 2024, the Company granted 83,841 stock options to its Executive Chairman under the A&R 2022 Plan. Of the stock options granted, 47,910 will vest evenly on an annual basis over three years. 11,977 of the options granted have unique vesting criteria based on market conditions, more specifically the Company’s stock price. As the market condition based stock options require significant estimates and assumptions to calculate their fair value, the Company engaged with valuation specialists to calculate the fair value and requisite service periods using Monte Carlo simulations. The grant date fair value of the market-based awards was approximately \$62,000. The market-based awards will be expensed over their determined requisite service periods. The remaining 23,954 options granted have unique vesting criteria based on specific Company performance conditions. The vesting criteria for 11,977 of these options includes the Company achieving cumulative revenue of \$1.5 million. The vesting criteria for the remaining 11,977 options includes the Company entering into a definitive agreement that constitutes a major strategic partnership, at the discretion of the Board. As of December 31, 2025, no performance conditions have been met. The grant date fair value of the performance based awards is \$118,000 in the aggregate, which will be recognized when the performance condition is probable of being satisfied.

The following table summarizes the Company’s stock option activity from March 31, 2025 to December 31, 2025:

	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2025	141,397	\$ 22.66	\$ —
Options granted	101,474	\$ 2.01	\$ —
Options cancelled / forfeited	(2,552)	\$ 14.51	\$ —
Options expired	(5,713)	\$ 33.63	\$ —
Outstanding at December 31, 2025	234,606	\$ 13.55	\$ 1,200
Vested and Exercisable at December 31, 2025	57,964	\$ 41.27	\$ —

The weighted average remaining contractual term of stock options exercisable and outstanding at December 31, 2025 was approximately 8.63 years.

Warrants

In connection with the Offering described above, the Company issued Common Warrants to purchase up to 130,202 shares of common stock at a combined public offering price of \$9.60 per share and accompanying Common Warrant to purchase one share of common stock and (ii) Pre-Funded Warrants to purchase 416,666 shares of common stock and accompanying Common Warrants to purchase up to 416,666 shares of common stock at a combined public offering price of \$9.588 per Pre-Funded Warrant and accompanying Common Warrant to purchase one share of common stock. The Company has determined that these warrants should be classified as equity instruments since they do not require the Company to repurchase the underlying common stock and do not require the Company to issue a variable amount of common stock. In addition, these warrants are indexed to common stock and do not have any antidilution rights.

The following table summarizes the Company's Common Warrant activity from March 31, 2025 to December 31, 2025:

	Number of Warrants	Exercise Price
Outstanding at March 31, 2025	539,060	\$ 9.60
Issued	—	—
Exercised	—	—
Outstanding at December 31, 2025	<u>539,060</u>	<u>\$ 9.60</u>

Employee Stock Purchase Plan

In July 2023, the Board adopted, and subsequently on October 31, 2023, the Company's stockholders approved, the ESPP. The ESPP became effective on October 31, 2023. The Company reserved 3,750 shares of common stock for issuance thereunder. The ESPP permits employees to purchase common stock through payroll deductions, limited to 15 percent of each employee's compensation up to \$25,000 per employee per year or 42 shares per employee per six-month purchase period. Shares under the ESPP are purchased at 85 percent of the fair market value at the lower of (i) the closing price on the first trading day of the six-month purchase period or (ii) the closing price on the last trading day of the six-month purchase period. The initial offering under the ESPP commenced on March 1, 2024. During the nine months ended December 31, 2025 there were no shares issued under the ESPP. At December 31, 2025, there were 3,708 shares remaining available for purchase under the ESPP.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following at December 31, 2025:

Common stock issuable pursuant to options outstanding and reserved under the 2012 Plan	27,565
Common stock reserved under the 2012 Plan	—
Common stock issuable pursuant to options outstanding and reserved under the A&R 2022 Plan	202,875
Common stock reserved under the A&R 2022 Plan	113,730
Common stock reserved under the ESPP	3,708
Common stock reserved under the 2021 Inducement Equity Plan	83
Common stock issuable pursuant to restricted stock units outstanding under the 2012 Plan	—
Common stock issuable pursuant to restricted stock units outstanding under the A&R 2022 Plan	—
Common stock issuable pursuant to options outstanding and reserved under the Inducement Plan	4,166
Common stock issuable pursuant to outstanding pre-funded warrants	—
Common stock issuable pursuant to outstanding common warrants	<u>539,060</u>
Total at December 31, 2025	<u>891,187</u>

Stock-based Compensation Expense and Valuation Information

Stock-based awards include stock options and RSUs under the Company's A&R 2022 Plan, 2012 Plan, Inducement Plan, and rights to purchase stock under the ESPP.

Stock-based compensation expense for all stock-based awards consists of the following (in thousands):

	Three Months Ended December 31, 2025	Three Months Ended December 31, 2024	Nine Months Ended December 31, 2025	Nine Months Ended December 31, 2024
Research and development	\$ 14	\$ 19	\$ 40	\$ 70
General and administrative	53	111	177	371
Total	\$ 67	\$ 130	\$ 217	\$ 441

The total unrecognized compensation cost related to unvested stock option grants as of December 31, 2025 was approximately \$0.5 million and the weighted average period over which these grants are expected to vest is 2.66 years.

The Company uses either the Black-Scholes or Monte Carlo option-pricing models to calculate the fair value of stock options, depending on the complexity of the equity grants. Stock-based compensation expense is recognized over the vesting period using the straight-line method. The assumed dividend yield is based on the Company's expectation of not paying dividends in the foreseeable future. The Company uses the Company-specific historical volatility rate as the indicator of expected volatility. The risk-free interest rate assumption is based on U.S. Treasury rates. The weighted average expected life of options was estimated using the simplified method, which is the average of the contractual term and the weighted average vesting term of the options. The measurement and classification of share-based payments to non-employees is consistent with the measurement and classification of share-based payments to employees. The fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	Three Months Ended December 31, 2025	Three Months Ended December 31, 2024	Nine Months Ended December 31, 2025	Nine Months Ended December 31, 2024
Dividend yield	—	—	—	—
Volatility	113.12%	100.83%	112.72%	99.38%
Risk-free interest rate	3.55%	4.32%	3.70%	3.75%
Expected life of options	6 years	6 years	6 years	6 years
Weighted average grant date fair value	\$ 1.86	\$ 3.84	\$ 1.71	\$ 5.64

The fair value of each RSU is recognized as stock-based compensation expense over the vesting term of the award. The fair value is based on the closing stock price on the date of the grant.

The Company uses the Black-Scholes valuation model to calculate the fair value of shares issued pursuant to the ESPP. Stock-based compensation expense is recognized over the purchase period using the straight-line method. The fair value of ESPP shares was estimated at the purchase period commencement date using the following assumptions:

	Three Months Ended December 31, 2025*	Three Months Ended December 31, 2024*	Nine Months Ended December 31, 2025*	Nine Months Ended December 31, 2024
Dividend yield	—	—	—	—
Volatility	0.00%	0.00%	0.00%	95.20%
Risk-free interest rate	0.00%	0.00%	0.00%	5.27%
Expected term	—	—	—	6 months
Grant date fair value	\$ —	\$ —	\$ —	\$ 4.68

*There were no participants in the ESPP for the purchase periods that commenced on September 1, 2024, September 1, 2025, or March 1, 2025.

The assumed dividend yield is based on the Company's expectation of not paying dividends in the foreseeable future. The Company uses the Company-specific historical volatility rate as the indicator of expected volatility. The risk-free interest rate assumption is based on U.S. Treasury rates. The expected life is the 6-month purchase period.

Note 5. Collaborative Research, Development, and License Agreements

License Agreements

BICO Group AB

In February 2022, the Company entered into a license agreement with Cellink AB and its subsidiaries (collectively, "BICO Group AB"), where the Company agreed to grant a non-exclusive license to BICO Group AB to use the Company's aforementioned patents for its business operations of manufacturing and selling bioprinters as well as bioinks. As part of the license agreement, BICO Group AB agreed to pay the Company a one time, nonrefundable upfront fee of \$1,500,000, as well as ongoing sales-based royalties (based on percentages of BICO Group AB's net sales) for the use of the granted license, which is recorded as revenue. The sales-based royalties became effective beginning on February 22, 2022, the effective date of the license agreement, and continues until the expiration of the last surviving licensed patent. As the sales-based royalties are required to be paid 45 days after the end of every quarter, there is variable consideration that must be estimated to determine royalty revenue within a given reporting period. Once actual revenue earned is determined in the following fiscal quarter, an adjustment is made from the previously estimated amount. For the three and nine months ended December 31, 2025, the Company recorded \$26,000 and \$91,000 of royalty revenue, respectively, based on sales-based royalties from the license Agreement. Royalty revenue presented on the statements of operations and other comprehensive loss was \$15,000 and \$68,000 for the three and nine months ended December 31, 2024, respectively.

Also as part of the license agreement, certain patents involved in the agreement are sublicensed by the Company from the University of Missouri. See below for further information.

University of Missouri

In March 2009, the Company entered into a license agreement with the Curators of the University of Missouri ("University of Missouri") to in-license certain technology and intellectual property relating to self-assembling cell aggregates and intermediate cellular units. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company was required to pay the University of Missouri royalties ranging from 1% to 3% of net sales of covered tissue products, and of the fair market value of covered tissues transferred internally for use in the Company's commercial service business, depending on the level of net sales achieved by the Company each year.

On December 5, 2022, the Company amended the license agreement with the University of Missouri, whereby the Company agreed to pay a single, up-front payment of \$50,000 to the University of Missouri in exchange for the aforementioned licensed intellectual property to be fully paid up by the Company. As a result, the Company will continue to have rights to the licensed intellectual property until its expiration, but will no longer owe minimum annual royalty payments, royalty payments based on net sales, or any other payments (other than patent annuities and any prosecution costs) in the future.

Note 6. Commitments and Contingencies

Legal Matters

In addition to commitments and obligations in the ordinary course of business, the Company may be subject, from time to time, to various claims and pending and potential legal actions arising out of the normal conduct of its business.

On August 27, 2024, H.C. Wainwright & Co., LLC ("H.C. Wainwright") filed a complaint against the Company in the State of New York alleging that the Company breached a tail financing provision included in an engagement agreement the Company entered into with H.C. Wainwright in May 2023. In its complaint, H.C. Wainwright is seeking compensatory and consequential damages and attorneys' fees. On October 18, 2024, the Company filed an answer to the complaint and on September 2, 2025, the Company filed an amended answer and counterclaimed for rescission, fraudulent inducement, and breach of contract, alleging that the Court should rescind the engagement agreement and award the Company damages, interest, costs, and attorneys' fees because H.C. Wainwright misrepresented the services it would provide and breached its duties to the Company under the engagement agreement. The parties have briefed H.C. Wainwright's motion to dismiss the Company's counterclaims. The Company is defending against H.C. Wainwright's claims and pursuing its counterclaims vigorously, but there is no guarantee that the Company will be successful in these efforts.

The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its financial statements. Because litigation is inherently unpredictable and unfavorable resolutions could occur, assessing litigation contingencies is subjective and requires judgments about future events. When evaluating contingencies, the Company may be unable to provide a meaningful estimate due to a number of factors, including the procedural status of the matter in question, the presence of complex or novel legal theories, and/or the ongoing discovery and development of information important to the matters. In addition, damage amounts claimed in litigation against it may be unsupported, exaggerated or unrelated to possible outcomes, and as such are not meaningful indicators of its potential liability.

The Company regularly reviews contingencies to determine the adequacy of its accruals and related disclosures and monitors each related legal issue and adjusts accruals as might be warranted based on new information and further developments. During the three months ended September 30, 2024, the Company recognized an accrual of \$0.6 million (which was considered a financing fee related to the Offering discussed in Note 4. Stockholders' Equity) for the loss contingencies associated with the above described H.C. Wainwright complaint. As of December 31, 2025, the accrual has not changed. Of the \$0.6 million loss contingency accrual, \$0.4

million is included in accrued expenses on the accompanying condensed consolidated balance sheets. The remaining \$0.2 million of the loss contingency accrual is classified as a liability to be settled in equity on the accompanying condensed consolidated balance sheets. The liability to be settled in equity relates to a fixed number of warrants that were included in the complaint as part of the sought compensatory damages. The Company recorded the loss contingency accrual as it determined that an unfavorable outcome is probable or reasonably possible and believed that the amount or range of any possible loss was reasonably estimable. However, amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments, and the outcome of legal proceedings and claims brought against the Company is subject to significant uncertainty. If one or more legal matters were resolved against the Company in a reporting period, the Company's consolidated financial statements for that reporting period could be materially adversely affected.

Note 7. Leases

After the initial adoption of ASC Topic 842 ("ASC 842"), on an on-going basis, the Company evaluates all contracts upon inception and determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use of the identified asset in exchange for consideration over a period of time. If a lease is identified, the Company will apply the guidance from ASC 842 to properly account for the lease.

Operating Leases

On November 23, 2020, the Company entered into a lease agreement, pursuant to which the Company permanently leased approximately 8,051 square feet of lab and office space (the "Permanent Lease") in San Diego once certain tenant improvements were completed by the landlord and the premises were ready for occupancy. Additionally, on November 17, 2021, the Permanent Lease was amended to add an additional 2,892 square feet of office space in the same building. The Permanent Lease commenced on December 17, 2021 and is intended to serve as the Company's permanent premises for approximately sixty-two months. Monthly rental payments will be approximately \$40,800 with 3% annual escalators.

The Company determined that the Permanent Lease is considered an operating lease under ASC 842, and therefore upon the lease commencement date of December 17, 2021, recognized lease liabilities and corresponding right-of-use assets of \$2.3 million. The Company records operating lease expense on a straight-line basis over the life of the lease (referred to as "operating lease expense"). Variable lease expenses associated with the Company's leases, such as payments for additional monthly fees to cover the Company's share of certain facility expenses (common area maintenance) are expensed as incurred.

The table below summarizes the Company's lease liabilities and corresponding right-of-use assets as of December 31, 2025 (in thousands except the year and percentage):

	December 31, 2025
ASSETS	
Operating lease right-of-use assets	\$ 525
Total lease right-of-use assets	<u>\$ 525</u>
LIABILITIES	
Current	
Operating lease liability	\$ 533
Noncurrent	
Operating lease liability, net of current portion	\$ 44
Total lease liabilities	<u>\$ 577</u>
Weighted average remaining lease term:	1.08
Weighted average discount rate:	6%

Variable lease expense was approximately \$40,000 and \$113,000 for the three and nine months ended December 31, 2025, respectively, and approximately \$34,000 and \$56,000 for the three and nine months ended December 31, 2024, respectively. Operating lease expense was approximately \$126,000 and \$378,000 for the three and nine months ended December 31, 2025, respectively, and approximately \$126,000 and \$378,000 for the three and nine months ended December 31, 2024, respectively.

Cash outflows associated with the Company's operating lease for the three and nine months ended December 31, 2025, were approximately \$135,000 and \$402,000, respectively, and approximately \$129,000 and \$389,000 for the three and nine months ended December 31, 2024, respectively.

Future lease payments relating to the Company's operating lease liabilities as of December 31, 2025 are as follows (in thousands):

Fiscal year ending March 31, 2026	138
Fiscal year ending March 31, 2027	459
Total future lease payments	597
Less: Imputed interest	(20)
Total lease obligations	577
Less: Current obligations	(533)
Noncurrent lease obligations	<u>\$ 44</u>

Note 8. Concentrations

Credit risk and significant customers

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents and short-term investments. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any material losses in such accounts and believes it is not exposed to significant risk. The Company has invested its excess cash primarily in money market funds and U.S. Treasury securities. Additionally, the Company adheres to established guidelines regarding approved investments and maturities of investments, which are designed to preserve their principal value and maintain liquidity.

The Company is also potentially subject to concentrations of credit risk in its revenues and receivable accounts. The Company's receivables to date related to royalty revenue have been derived from one customer. The Company makes judgment as to its ability to collect outstanding receivables and provides reserves against receivables for estimated losses that may result from a customer or third party's ability to pay. Specific amounts determined to be uncollectible are charged against the reserve. The Company has not historically experienced any receivable write-downs and management does not believe significant credit risk exists as of December 31, 2025.

Note 9. Related Parties

From time to time, the Company will enter into an agreement with a related party in the ordinary course of its business. These agreements are ratified by the Board or a committee thereof pursuant to its related party transaction policy.

Viscient Biosciences

Viscient Biosciences (“Viscient”) is an entity for which Keith Murphy, the Company’s Executive Chairman, serves as the Chief Executive Officer and President. Certain board members of the company are investors of Viscient through convertible promissory notes, but do not serve as employees, officers or directors of Viscient.

On December 28, 2020, the Company entered into an intercompany agreement (the “Intercompany Agreement”) with Viscient and Organovo, Inc., the Company’s wholly-owned subsidiary, which included an asset purchase agreement for certain lab equipment. Pursuant to the Intercompany Agreement, the Company agreed to provide Viscient certain services related to 3D bioprinting technology, which includes, but is not limited to, histology services, cell isolation, and proliferation of cells and Viscient agreed to provide the Company certain services related to 3D bioprinting technology, including bioprinter training, bioprinting services, and qPCR assays, in each case on payment terms specified in the Intercompany Agreement and as may be further determined by the parties. In addition, the Company and Viscient each agreed to share certain facilities and equipment and, subject to further agreement, to each make certain employees available for specified projects for the other party at prices to be determined in good faith by the parties. During the second quarter of fiscal 2025, first quarter of fiscal 2026, second quarter of fiscal 2026, and third quarter of fiscal 2026, the companies added Statements of Work to the Intercompany Agreement, where Viscient agreed to provide the Company with certain testing services related to the Company’s ongoing R&D. The Company evaluated the accounting for the Intercompany Agreement and concluded that any services provided by Viscient to the Company will be expensed as incurred, and any compensation for services provided by the Company to Viscient will be considered a reduction of personnel related expenses. Any services provided to Viscient do not fall under Topic 606 as the Intercompany Agreement is not a contract with a customer. For the three and nine months ended December 31, 2025, the Company incurred \$213,000 and \$428,000 in R&D consulting expenses from Viscient, respectively. As of December 31, 2025 and March 31, 2025, the accounts payable balance to Viscient was approximately \$137,000 and zero, respectively. For the three and nine months ended December 31, 2024, the Company incurred \$48,000 and \$118,000 in R&D consulting expenses from Viscient, respectively. Additionally, for the three and nine months ended December 31, 2025 and 2024, the Company provided approximately \$5,000 and \$4,000 of histology services to Viscient, respectively.

Aegis

On July 25, 2025, the Company entered into a letter agreement with SternAegis Ventures through Aegis Capital Corp. (“Aegis”), pursuant to which the Company retained Aegis to act as the Company’s non-exclusive financial advisor for a period of 12 months, unless earlier terminated pursuant to the terms of agreement. Pursuant to the agreement, the Company agreed to pay Aegis certain fees if the Company consummates, during the term of the agreement and in certain circumstances for a period of time thereafter (i) a placement of the Company’s securities, (ii) an acquisition, sale or purchase of all of the Company’s assets, business combination, merger or related change of control transaction, (iii) an acquisition of a third party, or (iv) a merger, business combination or other change of control transaction with a third party. The Company also agreed to reimburse Aegis for all actual, documented and reasonable out of pocket expenses, up to an agreed-upon cap.

Adam Stern, a member of the Company’s board of directors, is the Head of Private Equity Banking at Aegis and is the CEO of SternAegis Ventures.

Note 10. Business Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the Chief Operating Decision Maker (“CODM”) in deciding how to allocate resources to an individual segment and in assessing performance. The Company identified one operating segment in fiscal 2026, named the R&D segment, which did not impact prior periods. During fiscal 2026, the Company’s operating segment was as follows:

Research & Development

The R&D segment focuses on providing testing of drugs and drug candidates in 3D human tissue models of liver and intestine, offering partners liver and intestinal toxicology insights using its NAM models. The Company plans to work with pharmaceutical and biotech companies at all stages of drug development to reduce the significant risk and cost of bringing therapeutics to market through the regulatory process and offer bespoke services in the areas of investigational toxicology, mechanism of drug action elucidation, and other applications of these complex human tissue models.

For purposes of evaluating performance and allocating resources, the Company's CODM, its Executive Chairman, regularly reviews Consolidated Net Loss as reported in the Company's Condensed Consolidated Statements of Operations and Comprehensive Loss as compared to budget. The measure of segment assets is reported in the Condensed Consolidated Balance Sheets as Total Consolidated Assets.

In addition to the significant expense categories included within Consolidated Net Loss presented in the Company's Condensed Consolidated Statements of Operations and Other Comprehensive Loss, see below for disaggregated expense amounts for the three and nine months ended December 31, 2025 and 2024 (in thousands):

	Three Months Ended December 31, 2025	Three Months Ended December 31, 2024	Nine Months Ended December 31, 2025	Nine Months Ended December 31, 2024
Revenue				
Royalty revenue	\$ 26	\$ 15	\$ 91	\$ 68
Product revenue	—	9	—	25
Total revenue	26	24	91	93
Operating expenses				
Cost of revenues	—	2	—	5
Research and development expenses (a)(b)	1,077	1,705	2,864	3,926
Selling, general, and administrative expenses (a)(b)	1,580	1,588	5,138	4,978
Non-cash stock-based compensation (see Note 4)	67	130	217	441
Depreciation and amortization	52	67	172	205
Total operating expense	\$ 2,776	\$ 3,492	\$ 8,391	\$ 9,555
Consolidated operating loss	\$ (2,750)	\$ (3,468)	\$ (8,300)	\$ (9,462)

(a) Stock-based compensation expense of \$14,000 and \$40,000 related to research and development and \$53,000 and \$177,000, related to selling, general, and administration have been excluded for the three and nine months ended December 31, 2025, respectively. Stock-based compensation expense of \$19,000 and \$70,000 related to research and development and \$111,000 and \$371,000, related to selling, general, and administration have been excluded for the three and nine months ended December 31, 2024, respectively.

(b) Depreciation and amortization expense of \$49,000 and \$160,000 related to research and development as well as \$3,000 and \$12,000 related to selling, general, and administration have been excluded for the three and nine months ended December 31, 2025, respectively. Depreciation and amortization expense of \$56,000 and \$170,000 related to research and development as well as \$11,000 and \$35,000 related to selling, general, and administration have been excluded for the three and nine months ended December 31, 2024, respectively.

Note 11. Subsequent Events

Statements of Work to Intercompany Agreement with Viscient

Effective as of January 6, 2026, the Company added a Statement of Work to the Intercompany Agreement, where Viscient agreed to provide the Company with certain services related to the Company's ongoing R&D until the earlier of six months from the effective date or the date that such services are completed.

Effective as of February 3, 2026, the Company added a Statement of Work to the Intercompany Agreement, where Viscient agreed to provide the Company with certain services related to the Company's ongoing R&D until the earlier of six months from the effective date or the date that such services are completed.

Aegis

As of January 17, 2026, the letter agreement with Aegis was terminated.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis of financial condition and results of operations should be read in conjunction with our historical consolidated financial statements and the related notes thereto included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2025. This management's discussion and analysis contains forward-looking statements, such as statements related to our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions such as "will," "may," "could," "should," or similar expressions, identify certain of these forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties, including those described in this Quarterly Report on Form 10-Q, as well as the risk factors disclosed in our Annual Report on the Form 10-K for the fiscal year ended March 31, 2025, filed with the Securities and Exchange Commission on June 5, 2025, and discussed in the section titled "Risk Factors" under Part II, Item 1A in this Quarterly Report on Form 10-Q, that could cause our actual results or events to differ materially from those expressed or implied by such forward-looking statements. Unless the context otherwise requires, the terms "VivoSim", the "Company", "we", "us" and "our" in this Quarterly Report on Form 10-Q refer to VivoSim Labs, Inc. and its wholly owned subsidiaries, Organovo, Inc. and VivoSim Inc.

Except to the limited extent required by applicable law, we do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Quarterly Report on Form 10-Q.

Basis of Presentation

The unaudited condensed consolidated financial statements included in this Form 10-Q have been prepared in accordance with the Securities and Exchange Commission (the "SEC") instructions to Quarterly Reports on Form 10-Q. Accordingly, the unaudited condensed consolidated financial statements presented elsewhere in this Form 10-Q and discussed below are unaudited and do not contain all the information required by U.S. generally accepted accounting principles ("GAAP") to be included in a full set of financial statements. The audited financial statements for the year ended March 31, 2025, filed with the SEC on Form 10-K on June 5, 2025, include a summary of our significant accounting policies and should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

Overview

We are a pharmaceutical and biotechnology services company that is focused on providing testing of drugs and drug candidates in three-dimensional ("3D") human tissue models of liver and intestine. We offer partners liver and intestinal toxicology insights using our new approach methodologies ("NAM") models. We anticipate accelerated adoption of human tissue models following the U.S. Food and Drug Administration ("FDA") announcement on April 10, 2025 to refine animal testing requirements in favor of these non-animal NAM methods. We will also offer bespoke services in the areas of investigational toxicology, mechanism of drug action elucidation, and other applications of these complex human tissue models.

We also advance product candidates to treat inflammatory bowel disease ("IBD") discovered and developed using our complex human tissue intestinal models. Prior to March 2025, we were a clinical stage biotechnology company that was focused on developing FXR314 in IBD, including ulcerative colitis ("UC"), based on demonstration of clinical promise in 3D human tissues as well as strong preclinical data. Our clinical focus was in advancing FXR314 in IBD, including UC and Crohn's disease ("CD"). We planned to start a Phase 2a clinical trial in UC in the calendar year 2025 and were also exploring the potential for combination therapies using FXR314 and approved mechanisms in preclinical animal studies and our IBD disease models. We have also advanced a second program since 2023, a novel drug that will be a new chemical entity ("NCE") to an undisclosed target discovered in our intestinal models to have activity for UC and CD. This drug program (the "Preclinical IBD Program") has now left the in-silico phase in recent quarters, and has moved to medicinal chemistry stage, the real-world synthesis of novel candidate compounds.

In March 2025, we sold our FXR program for \$10.0 million, with \$9.0 million paid at closing and \$1.0 million held in escrow for a period of 15 months, with future milestones of up to \$50.0 million in the aggregate to be paid if the lead asset, FXR314, hits key development, regulatory and commercial milestones.

Effective April 24, 2025, we changed our corporate name to VivoSim Labs, Inc. by filing a Certificate of Amendment to our Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. We changed our name to reflect our new business model, which includes the use of other longstanding assets of the Company, intestinal and liver tox models and expertise, and our IP portfolio for 3D bioprinting.

We continue to advance our Preclinical IBD Program, with the goal of having a product candidate ready for an Investigational New Drug (“IND Application”) with the FDA by December 2026.

We are now offering liver toxicology predictive screening and research services as well as working on predicting and studying the intestinal side effect profiles of drugs that are therapeutic candidates of pharmaceutical and biotech companies at all stages of drug development. We plan to not only market this directly to pharmaceutical and biotech companies, but also partner with specific contract research organizations to complement our offering and to quickly grow our portfolio of clients. Our services offer the potential benefit of reducing the significant risk and cost of bringing therapeutics to market through the regulatory process. It is estimated that less than 10% of drug candidates entering clinical trials are approved, with a portion of the failures due to unexpected liver toxicity or intestinal intolerability. In addition, even approved drugs are occasionally withdrawn after liver toxicity is determined to be caused by the drug in a phenomenon called drug induced liver injury. We presented findings at the May 2025 Digestive Disease Week scientific conference showing that our liver toxicology platform had a best-in-class predictive power. Our liver predictive power was shown to be 87.5% for a set of challenging liver toxicity cases – inclusive of classic cases of “liver tox misses” drugs with unforeseen liver toxicity found in clinical trials or drugs that were withdrawn from the market after liver toxicity issues emerged later. The platform identified correctly that 87.5% of the known liver-toxic drugs could be seen as liver toxic using NAMkind™ liver. This is known as the sensitivity of the platform, which at 87.5% is a world’s best. Importantly, the specificity was 100%, meaning that none of the compounds tested that are not liver toxic were incorrectly identified as having liver toxicity issues by the platform.

We use our proprietary technologies to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function, and disease. We believe these attributes can enable critical complex, multicellular disease models that can be used to study and develop clinically effective drugs across multiple therapeutic areas.

We have also used these human disease models to identify new molecular targets responsible for driving IBD and to explore the mechanism of action of known drugs including JAK inhibitors and related molecules. A portion of our internal research continues to focus on early stage internal drug discovery programs, validating targets, and testing potentially licensable or transactable external drug compounds to identify drug candidates for partnering and/or internal clinical development. This includes the Preclinical IND Program, which has reached a more mature stage than other efforts in this area.

Critical Accounting Policies, Estimates, and Judgments

Our financial statements are prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments used in preparing our financial statements and related disclosures, none of which are considered critical. All estimates affect reported amounts of assets, liabilities, revenues and expenses, as well as disclosures of contingent assets and liabilities. These estimates and judgments are also based on historical experience and other factors that are believed to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

There have been no significant changes to our critical accounting policies since March 31, 2025. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our condensed consolidated financial statements, refer to Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Note 1. Description of Business and Summary of Significant Accounting Policies” in the Notes to Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended March 31, 2025, filed with the SEC on June 5, 2025.

Results of Operations

Comparison of the three months ended December 31, 2025 and 2024:

The following table summarizes our results of operations for the three months ended December 31, 2025 and 2024 (in thousands, except %):

	Three Months Ended December 31,				Increase (decrease)		
	2025		2024		\$	%	
Royalty revenue	\$	26	\$	15	\$	11	73%
Product revenue	\$	—	\$	9	\$	(9)	(100%)
Cost of revenues	\$	—	\$	2	\$	(2)	(100%)
Research and development	\$	1,140	\$	1,780	\$	(640)	(36%)
Selling, general and administrative	\$	1,636	\$	1,710	\$	(74)	(4%)
Other income	\$	59	\$	21	\$	38	181%

Revenues

For the three months ended December 31, 2025 and 2024, total revenue was less than \$0.1 million. Royalty revenue is related to sales-based royalties from licensing intellectual property. We expect royalty revenue to remain consistent going forward. Product revenue was zero and less than \$0.1 million for the three months ended December 31, 2025 and 2024, respectively. Product revenue is related to the Company's former Mosaic division which ended operations during the third quarter of fiscal 2025. Going forward, we expect to generate service revenues related to our service model.

Cost of Revenues

For the three months ended December 31, 2025 and 2024, cost of revenues was zero and less than \$0.1 million, respectively. Cost of revenue is related to the Company's former Mosaic division which ended operations during the third quarter of fiscal 2025. Going forward, we expect cost of revenues to increase as we execute our service model.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended December 31, 2025 and 2024 (in thousands, except %):

	Three Months Ended December 31, 2025		Three Months Ended December 31, 2024		Increase (decrease)				
	\$	% of total	\$	% of total	\$	%			
Research and development	\$	1,077	95%	\$	1,705	96%	\$	(628)	(37%)
Non-cash stock-based compensation		14	1%		19	1%		(5)	(26%)
Depreciation and amortization		49	4%		56	3%		(7)	(13%)
Total research and development expenses	\$	1,140	100%	\$	1,780	100%	\$	(640)	(36%)

For the three months ended December 31, 2025, total research and development expenses were \$1.1 million, a decrease of approximately \$0.6 million, or 36%, from the prior year period. Our average full-time research and development staff decreased from an average of thirteen full-time employees for the three months ended December 31, 2024, to an average of ten full-time employees for the three months ended December 31, 2025. Our operations for the three months ended December 31, 2025 as compared to the three months ended December 31, 2024 resulted in a \$0.1 million decrease in personnel related expenses, which included salary and share-based compensation expense, due to the decrease in headcount. There was also a \$0.5 million decrease in material related expenses mainly due to the write-down of inventory in the prior fiscal year. Going forward, we expect research and development expenses to increase as we execute our service model.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended December 31, 2025 and 2024 (in thousands, except %):

	Three Months Ended December 31, 2025		Three Months Ended December 31, 2024		Increase (decrease)				
	\$	% of total	\$	% of total	\$	%			
Selling, general and administrative	\$	1,580	97%	\$	1,588	93%	\$	(8)	(1%)
Non-cash stock-based compensation		53	3%		111	6%		(58)	(52%)
Depreciation and amortization		3	0%		11	1%		(8)	(73%)
Total selling, general and administrative expenses	\$	1,636	100%	\$	1,710	100%	\$	(74)	(4%)

For the three months ended December 31, 2025, total selling, general and administrative expenses were approximately \$1.6 million, a decrease of approximately \$0.1 million, or 4%, from the prior year period. Our average full-time selling, general and administrative staff remained at an average of four full-time employees for each of the three months ended December 31, 2025 and 2024. Our operations for the three months ended December 31, 2025 as compared to the three months ended December 31, 2024 resulted in a \$0.2 million decrease in corporate related expenses, mostly due to decreases in legal costs and investor relations costs, which was offset by \$0.1 increase in consulting expenses.

Other Income

Other income was approximately \$0.1 million and less than \$0.1 million for the three months ended December 31, 2025 and 2024, respectively, which was related to interest income.

Comparison of the nine months ended December 31, 2025 and 2024:

The following table summarizes our results of operations for the nine months ended December 31, 2025 and 2024 (in thousands, except %):

	Nine Months Ended December 31,		Increase (decrease)	
	2025	2024	\$	%
Royalty revenue	\$ 91	\$ 68	\$ 23	34%
Product revenue	\$ —	\$ 25	\$ (25)	(100%)
Cost of revenues	\$ —	\$ 5	\$ (5)	(100%)
Research and development	\$ 3,064	\$ 4,166	\$ (1,102)	(26%)
Selling, general and administrative	\$ 5,327	\$ 5,384	\$ (57)	(1%)
Other income	\$ 223	\$ 124	\$ 99	80%

Revenues

For each of the nine months ended December 31, 2025 and 2024, total revenue was \$0.1 million. Royalty revenue is related to sales-based royalties from licensing intellectual property. We expect royalty revenue to remain consistent going forward. Product revenue was zero and less than \$0.1 million for the nine months ended December 31, 2025 and 2024, respectively. Product revenue is related to the Company's former Mosaic division which ended operations during the third quarter of fiscal 2025. Going forward, we expect to generate service revenues related to our service model.

Cost of Revenues

For the nine months ended December 31, 2025 and 2024, total cost of revenues was zero and less than \$0.1 million, respectively, and related to the Company's former Mosaic division which ended operations during the third quarter of fiscal 2025. Going forward, we expect cost of revenues to increase as we execute our service model.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended December 31, 2025 and 2024 (in thousands, except %):

	Nine Months Ended December 31, 2025		Nine Months Ended December 31, 2024		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Research and development	\$ 2,864	94%	\$ 3,926	94%	\$ (1,062)	(27%)
Non-cash stock-based compensation	40	1%	70	2%	(30)	(43%)
Depreciation and amortization	160	5%	170	4%	(10)	(6%)
Total research and development expenses	\$ 3,064	100%	\$ 4,166	100%	\$ (1,102)	(26%)

For the nine months ended December 31, 2025, total research and development expenses were \$3.1 million, a decrease of \$1.1 million, or approximately 26%, from the prior year period. Our average full-time research and development staff decreased from an average of fourteen full-time employees for the nine months ended December 31, 2024 to an average of ten full-time employees for the nine months ended December 31, 2025. Our operations for the nine months ended December 31, 2025 as compared to the nine

months ended December 31, 2024 resulted in a \$0.6 million net decrease in personnel related costs, which includes stock-based compensation, due to the decrease in headcount. The net decrease included a \$0.2 million increase in recruiting expenses related to the hiring of the Chief Scientific Officer. There was also a \$0.6 million decrease in material related costs mainly due to the write-down of inventory in the prior fiscal year. The decreases were offset by a \$0.1 million increase in consulting related costs. Going forward, we expect research and development expenses to increase as we execute our service model.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the nine months ended December 31, 2025 and 2024 (in thousands, except %):

	Nine Months Ended December 31, 2025		Nine Months Ended December 31, 2024		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Selling, general and administrative	\$ 5,138	97%	\$ 4,978	92%	\$ 160	3%
Non-cash stock-based compensation	177	3%	371	7%	(194)	(52%)
Depreciation and amortization	12	0%	35	1%	(23)	(66%)
Total selling, general and administrative expenses	\$ 5,327	100%	\$ 5,384	100%	\$ (57)	(1%)

For the nine months ended December 31, 2025 and 2024, total selling, general and administrative expenses were approximately \$5.3 million, a decrease of \$0.1 million, or approximately 1%, compared to nine months ended December 31, 2024. Our average full-time selling, general and administrative staff decreased from an average of five full-time employees for the nine months ended December 31, 2024 to an average of four full-time employees for the nine months ended December 31, 2025. Our operations for the nine months ended December 31, 2025 as compared to the nine months ended December 31, 2024 resulted in a \$0.1 million net decrease in personnel related expenses, which includes stock-based compensation, due to the decrease in headcount. Of the \$0.1 million net decrease, there was a \$0.2 million decrease in stock-based compensation due to certain equity awards fully vesting in prior year. Additionally, there was a \$0.2 million increase in recruiting expenses related to hiring the new Chief Commercial Officer. The remaining \$0.1 million decrease in personnel related expenses was related to the decrease in salary due to lower headcount. There was also a \$0.3 million decrease in general corporate costs, which includes legal and investor relations expenses. Legal and investor relations expenses decreased due to allocating more budget in fiscal 2026 to the execution of the new service model strategy. The decrease in general corporate costs was offset by a \$0.3 million increase in consulting costs, which was due to consulting costs incurred to execute the new service model strategy.

Other Income

Other income was approximately \$0.2 million and \$0.1 million for the nine months ended December 31, 2025 and 2024, respectively, which was related to interest income.

Financial Condition, Liquidity and Capital Resources

Going forward, we intend to offer partners liver and intestinal toxicology insights using NAM models. We plan to work with pharmaceutical and biotech companies at all stages of drug development to reduce the significant risk and cost of bringing therapeutics to market through the regulatory process. We will also offer bespoke services in the areas of investigational toxicology, mechanism of drug action elucidation, and other applications of these complex human tissue models.

The accompanying Condensed Consolidated Financial Statements have been prepared on the basis that we are a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. As of December 31, 2025, we had cash and cash equivalents of approximately \$4.3 million, restricted cash of approximately \$0.1 million and an accumulated deficit of \$350.2 million. The restricted cash was pledged as collateral for a letter of credit that the Company is required to maintain as a security deposit under the terms of the lease agreement for its facilities. We had negative cash flow from operations of approximately \$8.6 million during the nine months ended December 31, 2025. At March 31, 2025, we had cash and cash equivalents of approximately \$11.3 million, restricted cash of approximately \$0.1 million and an accumulated deficit of approximately \$342.2 million.

At December 31, 2025, we had total current assets of approximately \$6.0 million and current liabilities of approximately \$2.5 million, resulting in working capital of \$3.5 million. At March 31, 2025, we had total current assets of approximately \$12.1 million and current liabilities of approximately \$3.7 million, resulting in working capital of \$8.4 million.

The following table summarizes the primary sources and uses of cash for the nine months ended December 31, 2025 and 2024 (in thousands):

	Nine Months Ended December 31,	
	2025	2024
Net cash (used in) provided by:		
Operating activities	\$ (8,589)	\$ (7,426)
Investing activities	—	24
Financing activities	1,565	5,662
Net decrease in cash, cash equivalents, and restricted cash	\$ (7,024)	\$ (1,740)

Operating activities

Net cash used in operating activities for the nine months ended December 31, 2025, was approximately \$8.6 million as compared to \$7.4 million used in operating activities for the nine months ended December 31, 2024. This \$1.2 million increase in operating cash usage can be attributed primarily to the timing of payables and R&D projects.

Investing activities

There were no investing activities for the nine months ended December 31, 2025. Net cash provided by investing activities was less than \$0.1 million for the nine months ended December 31, 2024, which consisted of interest income.

Financing activities

Net cash provided by financing activities was \$1.6 million and \$5.7 million for the nine months ended December 31, 2025 and 2024, respectively. Financing activities consisted of the sale of common stock through at-the-market ("ATM") share offerings for proceeds of approximately \$1.8 million as well as the repayment of the insurance premium financing liability of \$0.2 million for the nine months ended December 31, 2025. Financing activities consisted of the sale of common stock through at-the-market ("ATM") share offerings and a public offering of common stock and accompanying common warrants and pre-funded warrants for the nine months ended December 31, 2024.

Operations funding requirements

Through December 31, 2025, we have financed our operations primarily through the sale of common stock through public offerings, including our ATM program, from revenue derived from the licensing of intellectual property, products and research-based services, grants, and collaborative research agreements, the sale of our FXR program, and from the sale of convertible notes.

Our ongoing cash requirements include research and development expenses, compensation for personnel, consulting fees, legal and accounting support, insurance premiums, facilities, maintenance of our intellectual property portfolio, license and collaboration agreements, listing on the Nasdaq Capital Market, and other miscellaneous fees to support our operations. We expect our total operating expense for the fiscal year ending March 31, 2026 to be between \$10 million and \$12 million. Based on our current operating plan and available cash resources, we will need substantial additional funding to support future operating activities. We have concluded that the prevailing conditions and ongoing liquidity risks faced by us raise substantial doubt about our ability to continue as a going concern for at least one year following the date these financial statements are issued. The accompanying condensed consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

On January 26, 2024, we filed a new shelf registration statement on Form S-3 (File No. 333-276722) to register \$150.0 million of common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the "2024 Shelf"). The 2024 Shelf was declared effective by the SEC on February 8, 2024.

On March 16, 2018, we entered into a Sales Agreement with Jones Trading Institutional Services LLC (the "Agent").

On January 26, 2024, we filed a prospectus to the 2024 Shelf (the "2024 ATM Prospectus"), pursuant to which we may offer and sell, from time to time, through the Agents, shares of its common stock in ATM sales transactions having an aggregate offering price of up to \$2,605,728. We filed amendments to the 2024 ATM Prospectus on February 26, 2025 and again on April 11, 2025, pursuant to

which we may offer and sell, from time to time through the Agent, shares of our common stock in ATM sales transactions having an additional aggregate offering price of up to \$5,311,508 and \$4,766,105, respectively. Any shares offered and sold in these ATM transactions are issued pursuant to the 2024 Shelf.

During the nine months ended December 31, 2025, we issued 701,729 shares of common stock for net proceeds of approximately \$1.8 million, all of which were sold pursuant to the 2024 Shelf. As of December 31, 2025, we have sold an aggregate of 1,198,134 shares of common stock in ATM offerings under the 2024 ATM Prospectus, with gross proceeds of approximately \$6.9 million and net proceeds of approximately \$6.7 million. As of December 31, 2025, there was approximately \$140.1 million available for future offerings under the 2024 Shelf, and approximately \$3.1 million available for future offerings through our ATM program under the 2024 ATM Prospectus, as amended on April 11, 2025.

In the event that the aggregate market value of our common stock held by non-affiliates (“public float”) is less than \$75.0 million, the amount we can raise through primary public offerings of securities, including sales under the Sales Agreement, in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float. As of the date of filing of this Quarterly Report, our public float was less than \$75.0 million, and therefore we are limited to an aggregate of one-third of our public float in the amount we could raise through primary public offerings of securities in any twelve-month period using shelf registration statements, with such public float recalculated at the time of sale. If our public float meets or exceeds \$75.0 million at any time, we will no longer be subject to the restrictions set forth in General Instruction I.B.6 of Form S-3.

Having insufficient funds may require us to relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could adversely affect our operations. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business. We cannot be sure that additional financing will be available if and when needed, or that, if available, we can obtain financing on terms favorable to our stockholders. Any failure to obtain financing when required will have a material adverse effect on our business, operating results, and financial condition.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We have certain options outstanding but we do not expect to receive sufficient proceeds from the exercise of these instruments unless and until the underlying securities are registered, and/or all restrictions on trading, if any, are removed, and in either case the trading price of our common stock is significantly greater than the applicable exercise prices of the options and warrants.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and this is not required for smaller reporting companies under Item 305(e) of Regulation S-K.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed pursuant to the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of the end of the quarterly period covered by this report were designed and operating effectively.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and our principal financial officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See the information under "Legal Matters" of Note 6 of the Notes to the Unaudited Condensed Consolidated Financial Statements within this Form 10-Q for a discussion of our legal proceedings and contingencies.

ITEM 1A. RISK FACTORS

Investment in our common stock involves a substantial degree of risk and should be regarded as speculative. As a result, the purchase of our common stock should be considered only by persons who can reasonably afford to lose their entire investment. Before you elect to purchase our common stock, you should carefully consider the risk and uncertainties described below in addition to the other information incorporated herein by reference. Additional risks and uncertainties of which we are unaware or which we currently believe are immaterial could also materially adversely affect our business, financial condition or results of operations. If any of the risks or uncertainties discussed in this Quarterly Report on Form 10-Q occur, our business, prospects, liquidity, financial condition and results of operations could be materially and adversely affected, in which case the trading price of our common stock could decline, and you could lose all or part of your investment.

Risk factors marked with an asterisk () below include a substantive change from or an update to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2025, filed with the SEC on June 5, 2025.*

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission before making investment decisions regarding our common stock.

- We will incur substantial additional operating losses over the next several years as our services and research and development activities proceed.*
- Using our platform technology to develop healthy human tissues and disease models to support both external and internal drug discovery and development is new and unproven.*
- We will require access to a constant, steady, reliable supply of human cells to support our services and research and development activities.*
- We may not be successful in retaining, acquiring or in-licensing necessary rights to key technologies underlying our liver toxicology screening and research services platform or technologies relating to any of our other current or future services, product candidates or platforms we may develop.*
- We may require substantial additional funding. Raising additional capital would cause dilution to our existing stockholders and may restrict our operations or require us to relinquish rights to our technologies or to a product candidate.*
- We will be supporting external clinical development by third parties through our services and pursuing our own R&D programs. Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results.*
- The near and long-term viability of our services platform and R&D efforts will depend on our ability to successfully establish strategic relationships.*
- Current and future legislation may increase the difficulty and cost of commercializing drug candidates and may affect the prices that can be charged if drug candidates are approved for commercialization.*
- Management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern. Separately, our independent registered public accounting firm has included in its opinion for the year*

ended March 31, 2025 an explanatory paragraph expressing substantial doubt in our ability to continue as a going concern, which may hinder our ability to obtain future financing.

- *We have a history of operating losses and expect to incur significant additional operating losses.*
- *There is no assurance that an active market in our common stock will continue at present levels or increase in the future.*
- *The price of our common stock may continue to be volatile, which could lead to losses by investors and costly securities litigation.*
- *Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.*
- *We may be involved in lawsuits or other proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.*

Risks Related to our Business

We are a pharmaceutical and biotechnology services company focusing providing testing of drugs and drug candidates in 3D human tissue models, which is an unproven business strategy that may never achieve profitability.

We are a pharmaceutical and biotechnology services company that is focused on providing testing of drugs and drug candidates in three-dimensional ("3D") human tissue models of liver and intestine. We offer our partners liver and intestinal toxicology insights using our new approach methodologies ("NAM") models. We anticipate accelerated adoption of human tissue models following the U.S. Food and Drug Administration ("FDA") announcement on April 10, 2025 to refine animal testing requirements in favor of these non-animal NAM methods. We will also offer bespoke services in the areas of investigational toxicology, mechanism of drug action elucidation, and other applications of these complex human tissue models. These models may not be accepted by our partners. We may not be able to partner or license our drug candidates. We may never achieve profitability, or even if we achieve profitability, we may not be able to maintain or increase our profitability.

We will incur substantial additional operating losses over the next several years as our services and research and development activities proceed.

We will incur substantial additional operating losses over the next several years as our services and research and development activities proceed. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things:

- entering into partnering arrangements with pharmaceutical companies to provide safety and toxicology assessment services;
- successfully developing human tissues and disease models for drug discovery and development that enable us to identify drug candidates;
- successfully outsourcing certain portions of our development efforts;
- entering into partnering or licensing arrangements with pharmaceutical companies to further develop and conduct clinical trials for any drug candidates we identify;
- obtaining any necessary regulatory approval for any drug candidates we identify; and
- raising sufficient funds to finance our activities and long-term business plan.

We might not succeed at any of these undertakings. If we are unsuccessful at one or more of these undertakings, our business, prospects, and results of operations will be materially adversely affected.

Using our platform technology to develop healthy human tissues and disease models to support both external and internal drug discovery and development is new and unproven.

Utilizing our 3D bioprinting platform technology to develop human tissues and disease models to support both internal and external drug discovery and development will involve new and unproven technologies, disease models and approaches, each of which is subject to the risk associated with new and evolving technologies. To date, we have not identified or developed any drug candidates utilizing our business model. We may experience unforeseen technical complications, unrecognized defects and limitations in our technology or our ability to develop disease models or identify viable drug candidates. These complications could materially delay or

substantially increase the anticipated costs and time to identify and develop viable drug candidates, which would have a material adverse effect on our business and financial condition and our ability to continue operations.

We will face intense competition in our services and drug discovery efforts.

The biotechnology and pharmaceutical industry is subject to intense competition and rapid and significant technological change. There are many potential competitors for the services we will provide and our drug discovery efforts, including major drug companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources, experience and expertise in the following areas than we have, including:

- research and technology development;
- development of or access to disease models;
- identification and development of drug candidates;
- regulatory processes and approvals; and
- identifying and entering into agreements with potential collaborators.

Principal competitive factors in our industry include: the quality, scientific and technical support, management and the execution of drug development and regulatory approval strategies; skill and experience of employees, including the ability to recruit and retain skilled, experienced employees; intellectual property portfolio; range of capabilities, including drug identification, development and regulatory approval; and the availability of substantial capital resources to fund these activities.

In order to effectively compete, we may need to make substantial investments in our research and technology development, drug candidate identification and development, testing and regulatory approval and licensing and business development activities. There is no assurance that we will be successful in marketing our services or discovering effective drug candidates using our 3D tissue models or disease models using our 3D tissue models. Our technologies and drug development plans also may be rendered obsolete or noncompetitive as a result of drugs, intellectual property, technologies, products and services introduced by competitors. Any of these risks may prevent us from building a successful services and drug discovery business or entering into a strategic partnership or collaboration.

****We will require access to a constant, steady, reliable supply of human cells to support our services and research and development activities.***

As we pursue providing services and drug development through 3D tissues and disease models, we will require access to a constant, steady, reliable supply of human cells to support our services platform and 3D tissue activities. We purchase human cells from selected third-party suppliers based on quality assurance, cost effectiveness, and regulatory requirements. We need to continue to identify additional sources of qualified human cells and there can be no guarantee that we will be able to access the quantity and quality of raw materials needed at a cost-effective price. Any failure to obtain a reliable supply of sufficient human cells or a supply at cost effective prices would harm our business and our results of operations and could cause us to be unable to support our services platform and drug research and development efforts and could impact our ability to generate revenue.

Our business will be adversely impacted if we are unable to successfully attract, hire and integrate key additional employees or contractors.

Our future success depends in part on our ability to successfully attract and then retain key additional executive officers and other key employees and contractors to support our services platform and drug discovery plans. Recruiting and retaining qualified scientific and clinical personnel is critical to our success. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If we are unable to attract and retain high quality personnel, our ability to pursue our services platform and drug discovery business will be limited, and our business, prospects, financial condition, and results of operations may be adversely affected.

****We may require substantial additional funding. Raising additional capital would cause dilution to our existing stockholders and may restrict our operations or require us to relinquish rights to our technologies or to a product candidate.***

We currently do not have any committed external source of funds and do not expect to generate any meaningful revenue in the foreseeable future. If our board of directors decides that we should pursue further research and development activities than already

proposed, we will require substantial additional funding to operate our proposed business, including expanding our facilities and hiring additional qualified personnel, and we would expect to finance these cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders. Convertible debt 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, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Moreover, we have the ability to sell up to \$3.1 million of additional shares of our common stock to the public through an "at the market" offering pursuant to a Sales Agreement that we entered into with JonesTrading Institutional Services LLC on March 16, 2018 (the "Sales Agreement"). Any shares of common stock issued in the at-the-market ("ATM") offering will result in dilution to our existing stockholders.

We currently have an effective shelf registration statement on Form S-3 filed with the Securities and Exchange Commission (the "SEC"), which we may use to offer from time to time any combination of debt securities, common and preferred stock and warrants. On March 16, 2018, we entered into the Sales Agreement pursuant to which we have the ability to sell shares of our common stock to the public through an ATM offering. As of December 31, 2025, we have issued and sold pursuant to the Sales Agreement an aggregate of 1,530,001 shares of our common stock for gross proceeds of approximately \$52.0 million. However, in the event that the aggregate market value of our common stock held by non-affiliates ("public float") is less than \$75.0 million, the amount we can raise through primary public offerings of securities, including sales under the Sales Agreement, in any twelve-month period using shelf registration statements is limited to an aggregate of one-third of our public float. As of the date of filing this quarterly report, our public float was less than \$75.0 million, and therefore we are limited to an aggregate of one-third of our public float in the amount we could raise through primary public offerings of securities in any twelve-month period using shelf registration statements, with such public float recalculated at the time of sale. If our public float meets or exceeds \$75.0 million at any time, we will no longer be subject to the restrictions set forth in General Instruction I.B.6 of Form S-3. Although we would still maintain the ability to raise funds through other means, such as through the filing of a registration statement on Form S-1 or in private placements, the rules and regulations of the SEC or any other regulatory agencies may restrict our ability to conduct certain types of financing activities, or may affect the timing of and amounts we can raise by undertaking such activities.

Further, additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to curtail or cease our operations. Raising additional funding through debt or equity financing is likely to be difficult or unavailable altogether given the early stage of our technology and any drug candidates we identify. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings.

We will be supporting external clinical development by third parties through our services and pursuing our own R&D programs. Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results.

Before obtaining marketing approval from regulatory authorities for the sale of any drug candidates we identify, any such drug candidates must undergo extensive clinical trials to demonstrate the safety and efficacy of the drug candidates in humans. Human clinical testing is expensive and can take many years to complete, and we cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. We may elect to complete this testing, or some portion thereof, internally or enter into a partnering or development agreement with a pharmaceutical company to complete these trials. Our inability, or the inability of any third party with whom we enter into a partnering or development agreement, to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenues or receive development or milestone payments. Our future success is dependent on our ability, or the ability of any pharmaceutical company with whom we enter into a partnering or development agreement, to successfully develop, obtain regulatory approval for, and then successfully commercialize any drug candidates we identify.

Any drug candidates we identify will require additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in applicable jurisdictions, achieving and maintaining commercial-scale supply, building of a commercial organization, substantial investment and significant marketing efforts. We are not permitted to market or promote any of our drug candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our drug candidates.

We, or any third party with whom we enter into a partnering or development agreement, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to earn development or milestone payments or for any drug candidates to obtain regulatory approval, including:

- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure to obtain sufficient enrollment in clinical trials or participants may fail to complete clinical trials;
- clinical trials of our drug candidates that may produce negative or inconclusive results, and as a result we, or any pharmaceutical company with whom we enter into a partnering or development agreement, may decide, or regulators may require, additional clinical trials;
- suspension or termination of clinical research, either by us, any third party with whom we enter into a partnering or development agreement, regulators or institutional review boards, for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- additional or unanticipated clinical trials required by regulators or institutional review boards to obtain approval or any drug candidates may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving any drug candidates, or such requirements may not be as anticipated;
- the cost of clinical trials for any drug candidates may be greater than anticipated;
- the supply or quality of any drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate or may be delayed;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements may negatively impact the supply chain or cause other disruption; and
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution.

If we, or any third party with whom we enter into a partnering or development agreement, experience delays in the completion of, or termination of, any clinical trial of any drug candidates that we develop, or are unable to achieve clinical endpoints due to unforeseen events, the commercial prospects of our drug candidates will be harmed, and our ability to develop milestones, development fees or product revenues from any of these drug candidates will be delayed.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and potential product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other potential product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our projections of both the number of people who have the diseases that our potential product candidates are intended to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with our potential product candidates, are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our potential product candidates could be significantly diminished and have an adverse material impact on our business. Additionally, the potentially addressable patient population for our potential product candidates may be limited, or may not be amenable to treatment with our potential product candidates. Our spending on current and future research and development programs and potential product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

We will rely upon third-party contractors and service providers for the execution of critical aspects of any future development programs. Failure of these collaborators to provide services of a suitable quality and within acceptable timeframes may cause the delay or failure of any future development programs.

We plan to outsource certain functions, tests and services to CROs, medical institutions and collaborators as well as outsource manufacturing to collaborators and/or contract manufacturers, and we will rely on third parties for quality assurance, clinical monitoring, clinical data management and regulatory expertise. We may elect, in the future, to engage a CRO to run all aspects of a clinical trial on our behalf. There is no assurance that such individuals or organizations will be able to provide the functions, tests, biologic supply or services as agreed upon or in a quality fashion and we could suffer significant delays in the development of our drug candidates or development programs.

In some cases, there may be only one or few providers of such services, including clinical data management or manufacturing services. In addition, the cost of such services could be significantly increased over time. We may rely on third parties and collaborators to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these third parties and collaborators for clinical development activities reduces our control over these activities. Our reliance on these parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with Good Clinical Practice regulations and the investigational plan and protocols contained in the regulatory agency applications. In addition, these third parties may not complete activities on schedule or may not manufacture under Current Good Manufacturing Practice conditions. Preclinical or clinical studies may not be performed or completed in accordance with Good Laboratory Practices regulatory requirements or our trial design. If these third parties or collaborators do not successfully carry out their contractual duties or meet expected deadlines, obtaining regulatory approval for manufacturing and commercialization of our drug candidates may be delayed or prevented. We may rely substantially on third-party data managers for our clinical trial data. There is no assurance that these third parties will not make errors in the design, management or retention of our data or data systems. There is no assurance these third parties will pass FDA or regulatory audits, which could delay or prohibit regulatory approval. In addition, we will exercise limited control over our third-party partners and vendors, which makes us vulnerable to any errors, interruptions or delays in their operations. If these third parties experience any service disruptions, financial distress or other business disruption, or difficulties meeting our requirements or standards, it could make it difficult for us to operate some aspects of our business.

The near and long-term viability of our services platform and R&D efforts will depend on our ability to successfully establish strategic relationships.

The near and long-term viability of our services platform and R&D efforts depend in part on our ability to successfully establish new strategic partnering, collaboration and licensing arrangements with biotechnology companies, pharmaceutical companies, universities, hospitals, insurance companies and or government agencies. Establishing strategic relationships is difficult and time-consuming. Potential partners and collaborators may not enter into relationships with us based upon their assessment of our technology or drug candidates or our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of strategic relationships on acceptable terms, we may not be able to develop and obtain regulatory approval for our drug candidates or generate sufficient revenue to fund further research and development efforts. Even if we establish new strategic relationships, these relationships may never result in the successful development or regulatory approval for any drug candidates we identify or the long-term viability of our services platform for a number of reasons both within and outside of our control.

Our ability to effectively monitor and respond to the rapid and evolving developments and expectations relating to sustainability, including environmental, social and governance factors may impose unexpected costs or results in reputational or other harm that could have a material adverse effect on our business.

There is an increasing focus from certain investors, employees, regulators, listing exchanges and other stakeholders concerning corporate responsibility and sustainability matters, including with regarding environmental, social and governance (“ESG”) factors. Some investors and investor groups may use these factors—either positively or negatively—to guide their investment strategies and, in some cases, investors may choose not to invest in our Company if they believe our policies or practices relating to corporate responsibility and sustainability do not align with their expectations. Currently, a variety of third-party providers of corporate responsibility and sustainability ratings measure the performance of companies on ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers, and major institutional investors have publicly emphasized the importance of ESG measures to their investment decisions. Topics taken into account in such assessments include, among others, companies’ efforts and impacts on climate change, human rights, business ethics and compliance, diversity, equity and inclusion (“DEI”) and the role of companies’ board of directors in overseeing various sustainability-related issues. In light of investors’ increased focus on sustainability matters, if we are, for example, are perceived as lagging in taking steps with respect to ESG initiatives, certain investors may seek to engage with us on improving our ESG disclosures or performance. They may also make voting decisions, or take other actions to hold us and our board of directors accountable.

In addition, there are rapidly and on-going developments and changing expectations relating to sustainability matters. As a result, the criteria by which our corporate responsibility and sustainability practices are assessed may change, which cause us to undertake costly initiatives or actions to satisfy new demands. If we elect not to or are unable to adequately recognize and respond to such developments and changing governmental, societal, investor and/or consumer expectations relating to sustainability matters, we may miss corporate opportunities, become subject to additional scrutiny or incur unexpected costs.

We may face risk of litigation or reputational damage in the event our sustainability policies or practices do not meet the standards set by various constituencies. We may also face reputation damage if we are unable to achieve an acceptable sustainability rating from third-party rating services. A low sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility and sustainability matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

Further, our emphasis on sustainability issues may not maximize short-term financial results and may yield financial results that conflict with the market's expectations. We may in the future make business decisions consistent with our sustainability goals that we believe, based on considered analysis, will create value and improve our financial performance over the long-term. These decisions, however, may not be consistent with the short-term expectations of our stockholders and may not produce the long-term benefits that we expect, in which case our business, financial condition and results of operations could be harmed.

****Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.***

Our business, financial condition and share price could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. There can be no assurances that further deterioration in the credit and financial markets and confidence in economic conditions will not occur. For example, U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States.

Although U.S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, including a suspension of the federal debt ceiling in June 2023, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Absent further quantitative easing by the Federal Reserve, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our results of operations or financial condition. Moreover, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Furthermore, the current U.S. administration has substantially departed from prior U.S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the current U.S. administration has initiated and is continuing to consider imposing additional tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing reciprocal tariffs on certain U.S. goods. It remains unclear what the current U.S. administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, increase the cost of materials purchased to manufacture our potential products, impact our ability to sell our products outside the United States or to sell our products outside the United States at competitive prices and/or to affect the United States or global economy or certain sectors thereof and, thus, could adversely impact our business and financial condition.

Risks Related to Government Regulation

In the past, we have used hazardous chemicals, biological materials and infectious agents in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our product manufacturing, research and development, and testing activities have involved the controlled use of hazardous materials, including chemicals, biological materials and infectious disease agents. We cannot eliminate the risks of accidental contamination or the accidental spread or discharge of these materials, or any resulting injury from such an event. We may be sued for any injury or

contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. We were also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, and the experimental use of animals. Our operations may have required that environmental permits and approvals be issued by applicable government agencies. If we failed to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance.

If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our drug candidates, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for any drug candidate we may develop. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety and tolerability of our potential products in determining whether to approve reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our potential products from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our drug candidates or other potential products.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies.

If the prices for our potential products are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer.

****Current and future legislation may increase the difficulty and cost of commercializing drug candidates and may affect the prices that can be charged if drug candidates are approved for commercialization.***

In the U.S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory approval of drug candidates, restrict or regulate post-marketing activities and affect the ability to profitably sell any drug candidates for which regulatory approval is obtained.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for any of our approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the “PPACA”), was enacted. The PPACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers’ rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of “average manufacturer price”, which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services (“CMS”), which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a discount, equal to 70% off, effective as of 2019, the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the “donut hole.” Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Furthermore, on July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act was signed into law, which reduces funding to federal healthcare programs and imposes additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly in Medicaid programs.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. We also expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our drug candidates, if approved for commercialization.

In Europe, the United Kingdom withdrew from the European Union on January 31, 2020, and entered into a transition period that expired on December 31, 2020. A significant portion of the previous regulatory framework in the United Kingdom was derived from the regulations of the European Union. In 2021, the United Kingdom’s Medicines and Healthcare products Regulatory Agency and the European Medicines Agency released guidance explaining the new regulatory framework. We cannot predict the consequences or impact that the new regulatory framework will have on our future operations, if any, in these jurisdictions.

In addition, on August 16, 2022, former President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which took effect in 2023. Under the Inflation Reduction Act of 2022, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also capped Medicare out-of-pocket drug costs at an estimated \$2,000 a year.

****Disruptions at the FDA, the SEC and other government agencies, caused by funding shortages, government shutdowns or global health concerns, could negatively impact our business, financial condition and results of operations.***

Significant disruptions to the operations of government agencies, including from prolonged or repeated shutdown of the federal government, could adversely affect our business, financial condition and results of operations. Recently, from January 31, 2026 to

February 3, 2026, the U.S. government partially shut down. Additionally, beginning on October 1, 2025, the U.S. government shut down and remained shut down until November 12, 2025, during which time certain regulatory agencies, such as the FDA and the SEC, has furloughed certain employees and stopped certain activities. Additionally, on October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the ongoing federal government shutdown, which has resulted in the suspension or delay of various government-funded programs. The ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, reductions in workforce, ability to hire and retain key personnel and accept the payment of user fees, substantial changes in leadership and shifting policy priorities as a result of changes in the presidential administration and its appointees tasked to oversee the agency, and statutory, regulatory and policy changes. In addition, there may be delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies, including as a result of reductions in force, significant organizational changes, substantial leadership departures, and policy changes, may also slow the time necessary for our potential product candidates to be reviewed or approved by necessary government agencies, which could adversely affect our business, financial condition and results of operations. With the change in presidential administrations in 2025, there is substantial uncertainty as to how the current U.S. administration will continue to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. For example, the current U.S. administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Additionally, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop certain critical activities. The current U.S. administration previously announced plans to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. If funding for the FDA is reduced, if the FDA workforce is reduced, or if the current government shutdown continues, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

Further, a prolonged or future shutdown of the U.S. federal government could materially impact the operations of the SEC. For example, the SEC announced that during the prior U.S. federal government shutdown, it would not declare registration statements effective. In the event of an extended shutdown, the SEC may operate with limited staff or suspend certain functions altogether, which could delay the review or effectiveness of our filings, including registration statements or other financing-related disclosures. Such delays could adversely affect our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

Furthermore, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo*, which overturned the long-standing *Chevron* doctrine that required courts to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes, could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. The *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the agency rule-making process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

Risks Related to Our Capital Requirements, Finances and Operations

Management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern. Separately, our independent registered public accounting firm has included in its opinion for the year ended March 31, 2025 an explanatory paragraph expressing substantial doubt in our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our financial statements as of December 31, 2025 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern. Separately, our independent registered public accounting firm included in its opinion for the year ended March 31, 2025 an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is

dependent upon our ability to obtain additional equity or debt financing, obtain government grants, reduce expenditures and generate significant revenue. Our financial statements as of December 31, 2025 do not include any adjustments that might result from the outcome of this uncertainty. The reaction of investors to the inclusion of a going concern statement by management and our auditors, and our potential inability to continue as a going concern, in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances.

****Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to curtail or cease our operations.***

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. Raising additional funding through debt or equity financing is likely to be difficult or unavailable altogether given the early stage of our therapeutic candidates. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings. In addition, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to our technology or potential future product candidates or otherwise agree to terms unfavorable to us.

****We have a history of operating losses and expect to incur significant additional operating losses.***

As of December 31, 2025, we had total current assets of approximately \$6.0 million and current liabilities of approximately \$2.5 million, resulting in working capital of \$3.5 million. We have generated operating losses each year since we began operations, including \$8.3 million and \$9.5 million for the nine months ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of \$350.2 million. We expect to incur substantial additional operating losses over the next several years as our research and development activities increase.

The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things:

- successfully building a services platform supported by adoption by pharmaceutical and biotech companies to support their development efforts;
- successfully developing human tissues and disease models for drug discovery and development that enable us to identify drug candidates;
- successfully outsourcing certain portions of our development efforts;
- entering into collaboration or licensing arrangements with pharmaceutical companies to further develop and conduct clinical trials for any drug candidates we identify;
- obtaining any necessary regulatory approvals for any drug candidates we identify; and
- raising sufficient funds to finance our activities and long-term business plan.

We might not succeed at any of these undertakings. If we are unsuccessful at one or more of these undertakings, our business, prospects, and results of operations will be materially adversely affected. We may never generate significant revenue, and even if we do generate significant revenue, we may never achieve profitability.

Our quarterly operating results may vary, which could negatively affect the market price of our common stock.

Our results of operations in any quarter may vary from quarter to quarter and are influenced by such factors as expenses related to:

- evaluating and implementing strategic alternatives, technology licensing opportunities, potential collaborations, and other strategic transactions;
- litigation;

- research and development expenditures, including commencement of preclinical studies and clinical trials;
- the timing of the hiring of new employees, which may require payments of signing, retention or similar bonuses; and
- changes in costs related to the general global economy.

We believe that operating results for any particular quarter are not necessarily a meaningful indication of future results. Nonetheless, fluctuations in our quarterly operating results could negatively affect the market price of our common stock.

We may identify material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements.

Our management team is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

We cannot assure you that we will not have material weaknesses or significant deficiencies in our internal control over financial reporting. If we identify any material weaknesses or significant deficiencies that may exist, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

The anticipated benefits of the sale of our FXR program may not be fully realized as we may not receive some or all of the potential milestone payments related to the sale of our FXR program.

On March 25, 2025, we sold our FXR program and related assets to Eli Lilly and Company (the “FXR Asset Sale”). The consideration for the FXR Asset Sale included potential milestone payments by Eli Lilly and Company of up to \$50.0 million in the aggregate, which are contingent upon the achievement of certain development, regulatory and commercial milestones. There can be no assurance that we will be entitled to receive any milestone payments, and there is risk that any or all of the milestone events may not be achieved, that disagreements may occur regarding the achievement of such milestones and that any or all of the payments tied to the achievement of the milestone events might not be received.

Future strategic investments could negatively affect our business, financial condition and results of operations if we fail to achieve the desired returns on our investment.

Our ability to benefit from future external strategic investments depends on our ability to successfully conduct due diligence, evaluate prospective opportunities, and buy the equity of our target investments at acceptable market prices. Our failure in any of these tasks could result in unforeseen losses associated with the strategic investments.

We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance, product liabilities or other undisclosed liabilities that we did not uncover prior to our investment, which could result in us becoming subject asset impairments, including potential loss of our investment capital. In addition, if we do not achieve the anticipated benefits of an external investment as rapidly as expected, or at all, investors or analysts may downgrade our stock.

We also expect to continue to carry out strategic investments that we believe are necessary to expand our business. There are no assurances that such initiatives will yield favorable results for us. Accordingly, if these initiatives are not successful, our business, financial condition and results of operations could be adversely affected. If these risks materialize, our stock price could be materially adversely affected. Any difficulties in such investments could have a material adverse effect on our business, financial condition and results of operations.

Our business could be adversely impacted if we are unable to retain our executive officers and other key personnel.

Our future success will depend to a significant degree upon the continued contributions of our key personnel, especially our executive officers. We do not currently have long-term employment agreements with our executive officers or our other key personnel, and there is no guarantee that our executive officers or key personnel will remain employed with us. Moreover, we have not obtained key man life insurance that would provide us with proceeds in the event of the death, disability or incapacity of any of our executive officers or other key personnel. Further, the process of attracting and retaining suitable replacements for any executive officers and other key personnel we lose in the future would result in transition costs and would divert the attention of other members of our senior

management from our existing operations. Additionally, such a loss could be negatively perceived in the capital markets. Finally, our Executive Chairman also provides services to Viscient Biosciences, Inc. (“Viscient”). He provides services to us and Viscient and does not dedicate all of his time to us, as disclosed in our filings, and we may therefore compete with Viscient for the time commitments of our Executive Chairman from time to time.

We may be subject to security breaches or other cybersecurity incidents that could compromise our information and expose us to liability.

We routinely collect and store sensitive data (such as intellectual property, proprietary business information and personally identifiable information) for ourselves, our employees and our suppliers and customers. We make significant efforts to maintain the security and integrity of our computer systems and networks and to protect this information. However, like other companies in our industry, our networks and infrastructure may be vulnerable to cyber-attacks or intrusions, including by computer hackers, foreign governments, foreign companies or competitors, or may be breached by employee error, malfeasance or other disruption. Any such breach could result in unauthorized access to (or disclosure of) sensitive, proprietary or confidential information of ours, our employees or our suppliers or customers, and/or loss or damage to our data. Any such unauthorized access, disclosure, or loss of information could cause competitive harm, result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and/or cause reputational harm.

****Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition and results of operations.***

The regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation (the “GDPR”), which took effect across all member states of the European Economic Area (the “EEA”) in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal data and/or impose substantial fines for violations of the GDPR, which can be up to four percent of global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

The European Data Protection Board continues to release guidelines for industries and impose fines related to the GDPR, some of which have been very significant, including proposed amendments to the GDPR in November 2025. Meanwhile, there continues to be persistent uncertainty relating to the transfer of personal data from Europe to the U.S., or other non-adequate countries, following the Schrems II decision. On July 10, 2023, the European Commission adopted its adequacy decision on the EU-U.S. Data Privacy Framework (the “DPF”). The decision, which took effect on the day of its adoption, concludes that the United States ensures an adequate level of protection for personal data transferred from the EEA to companies certified to the DPF. However, it remains too soon to tell how the future of the DPF will evolve and what impact it will have on our international activities. At least one challenge to the DPF is pending before the Court of Justice of the European Union.

Further, Brexit has led to, and could continue to lead to legislative and regulatory changes, which may increase our compliance costs. Data processing in the United Kingdom is governed by a United Kingdom version of the GDPR (combining the GDPR and the Data Protection Act 2018), as well as other laws including the Data Use and Access Act and the Privacy and Electronic Communications Regulations exposing us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. The European Commission adopted an Adequacy Decision for the United Kingdom, allowing for the relatively free exchange of personal data between the European Union and the United Kingdom (as the United Kingdom

correspondingly allows transfer back to the EU), which was recently extended through December 27, 2025. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations.

In the EEA, the NIS 2 Directive, or NIS 2, is replacing the cybersecurity legal framework under the current NIS framework. NIS 2 applies to certain in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. To the extent that we are subject to NIS 2 in the future, we may require additional investment of our resources in compliance programs. Under NIS 2, companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection and breach notification laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. All 50 U.S. states and territories and international jurisdictions have varying breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential data experienced by us or our service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify patients or other counterparties of a security breach. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards.

The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. At the federal level, for example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which establishes privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Requirements for compliance under HIPAA are also subject to change, as the U.S. Department of Health and Human Services Office of Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates. The US Department of Justice issued a final rule entitled, "Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," codified at 28 CFR part 202 ("Bulk Transfer Rule"). The Bulk Transfer Rule prohibits and restricts bulk transfers of sensitive personal data (including genetic and health data) to countries of concern, such as China, Russia, and Iran to prevent access by foreign adversaries. It restricts our ability to engage in certain cross-border transactions involving genomic or biological samples and related data, which may increase compliance costs, lead to increased regulatory scrutiny or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition, and operating results.

New laws also are being considered at both the state and federal levels and several states have passed comprehensive privacy laws. For example, the California Consumer Privacy Act (as amended and expanded by the California Privacy Rights Act) (collectively, "CCPA") is creating similar risks and obligations as those created by the GDPR, though the CCPA does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). States have adopted statewide and comprehensive privacy laws and many other states have privacy legislation that is pending. Some state laws minimize what data can be collected from consumers and how businesses may use and disclose it. These state privacy laws also require businesses to make disclosures to consumers about data collection, use and sharing practices. In addition, some of these laws (including the CCPA), along with other standalone health privacy laws, subject health-related information to additional safeguards and disclosures and some specifically regulate consumer health data, such as the Washington My Health My Data Act, which became effective in 2023 and 2024, Nevada's Consumer Health Data Privacy Law, which became effective in 2024, and Connecticut's amendments to its privacy law to address health data, which became effective in 2023. Additionally, a broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal data could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. This is particularly true with respect to data security incidents, and sensitive personal data, including health and biometric data. Even if we are

not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR, new state privacy laws and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal data from our clinical trials, and access to certain data such as the European Health Data Space Regulation, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition and results of operations.

We and our partners may be subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security, and changes in such laws, regulations, policies or how they are interpreted or changes in contractual obligations could adversely affect our business.

There are numerous U.S. federal and state data privacy and protection laws and regulations that apply to the collection, transmission, processing, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

If we are unable to properly protect the privacy and security of health-related information or other sensitive or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents.

We may experience conflicts of interest with Viscient Biosciences, Inc. with respect to business opportunities and other matters.

Keith Murphy, our Executive Chairman, is the Chief Executive Officer, Chairman and principal stockholder of Viscient, a private company that he founded in 2017 that is focused on drug discovery and development utilizing 3D tissue technology and multi-omics (genomics, transcriptomics, metabolomics). In addition, Adam Stern, Douglas Jay Cohen and David Gobel (through the Methuselah Foundation and the Methuselah Fund), members of our board of directors, have invested funds through a convertible promissory note in Viscient, but do not serve as an employee, officer or director of Viscient. Additional members of our Research and Development organization also work at Viscient, and we expect that additional employees or consultants of ours will also be employees of or consultants to Viscient. We use certain Viscient-owned facilities and equipment and allow Viscient to use certain of our facilities and equipment. During fiscal 2026, we provided services to Viscient, and we expect to continue to provide services to Viscient and enter into additional agreements with Viscient in the future.

In addition, we license, as well as cross-license, certain intellectual property to and from Viscient and expect to continue to do so in the future. In particular, pursuant to an Asset Purchase and Non-Exclusive Patent License Agreement with Viscient, dated November 6, 2019, as amended, we have provided a paid up, worldwide, irrevocable, perpetual, non-exclusive license to Viscient under certain of our patents and know-how to (a) make, have made, use, sell, offer to sell, import and otherwise exploit the inventions and subject matter covered by certain patents regarding certain bioprinter devices and bioprinting methods, engineered liver tissues, engineered renal tissues, engineered intestinal tissue and engineered tissue for in vitro research use, (b) to use and internally repair the bioprinters, and (c) to make additional bioprinters for internal use only in connection with drug discovery and development research, target identification and validation, compound screening, preclinical safety, absorption, distribution, metabolism, excretion and toxicology (ADMET) studies, and in vitro research to complement clinical development of a therapeutic compound. Although we have entered, and expect to enter, into agreements and arrangements that we believe appropriately govern the ownership of intellectual property created by joint employees or consultants of Viscient and/or using our or Viscient's facilities or equipment, it is possible that we may disagree with Viscient as to the ownership of intellectual property created by shared employees or consultants, or using shared equipment or facilities.

On December 28, 2020, we entered into an intercompany agreement with Viscient and Organovo, Inc., our wholly-owned subsidiary (the “Intercompany Agreement”). Pursuant to the Intercompany Agreement and subsequent statements of work entered into pursuant thereto, we agreed to provide Viscient certain services related to 3D bioprinting technology, which includes, but is not limited to, histology services, cell isolation, and proliferation of cells, and Viscient agreed to provide us certain services related to 3D bioprinting technology, including bioprinter training, bioprinting services, and qPCR assays, in each case on payment terms specified in the Intercompany Agreement and as may be further determined by the parties. In addition, Viscient and we each agreed to share certain facilities and equipment and, subject to further agreement, to each make certain employees available for specified projects to the other party at prices to be determined in good faith by the parties. During the second quarter of fiscal 2025 and first, second, and third quarters of fiscal 2026, the companies added Statements of Work to the Intercompany Agreement, where Viscient agreed to provide us with certain testing services related to our ongoing research and development. Under the Intercompany Agreement, each party will retain its own prior intellectual property and will obtain new intellectual property rights within their respectively defined fields of use.

Due to the interrelated nature of Viscient with us, conflicts of interest may arise with respect to transactions involving business dealings between us and Viscient, potential acquisitions of businesses or products, the development and ownership of technologies and products, the sale of products, markets and other matters in which our best interests and the best interests of our stockholders may conflict with the best interests of the stockholders of Viscient. In addition, we and Viscient may disagree regarding the interpretation of certain terms of the arrangements we previously entered into with Viscient or may enter into in the future. We cannot guarantee that any conflict of interest will be resolved in our favor, or that, with respect to our transactions with Viscient, we will negotiate terms that are as favorable to us as if such transactions were with another third-party. In addition, an executive that provides services to us and Viscient may not dedicate all of such executive’s time to us and we may therefore compete with Viscient for the time commitments of our executive officer from time to time.

Risks Related to Our Common Stock and Liquidity Risks

****We could fail to maintain the listing of our common stock on the Nasdaq Capital Market, which could seriously harm the liquidity of our stock and our ability to raise capital or complete a strategic transaction.***

The Nasdaq Stock Market LLC (“Nasdaq”) has established continued listing requirements, including a requirement to maintain a minimum closing bid price of at least \$1 per share. If a company trades for 30 consecutive business days below such minimum closing bid price, it will receive a deficiency notice from Nasdaq. Assuming it is in compliance with the other continued listing requirements, Nasdaq would provide such company a period of 180 calendar days in which to regain compliance by maintaining a closing bid price at least \$1 per share for a minimum of ten consecutive business days. There can be no assurance that we will continue to maintain compliance with the minimum bid price requirement or other listing requirements necessary for us to maintain the listing of our common stock on the Nasdaq Capital Market.

As a result of prior non-compliance with the Nasdaq requirement to maintain a minimum of \$2,500,000 in stockholders’ equity, as set forth in Nasdaq Listing Rule 5550(b)(1) (“Rule 5550(b)(1)”), we are subject to a Mandatory Panel Monitor until April 30, 2026. If, within that one-year monitoring period, the Listing Qualifications Staff of Nasdaq (the “Staff”) finds us again out of compliance with Rule 5550(b)(1), we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and the Staff will not be permitted to grant additional time for us to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Nasdaq Listing Rule 5810(c)(3). Instead, the Staff will issue a Delist Determination Letter and we will have an opportunity to request a new hearing with the initial Hearings Panel or a newly convened Hearings Panel if the initial Hearings Panel is unavailable. We will have the opportunity to respond/present to the Hearings Panel as provided by Nasdaq Listing Rule 5815(d)(4)(C). Our securities may be at that time delisted from Nasdaq.

A delisting from the Nasdaq Capital Market and commencement of trading on the Over-the-Counter Bulletin Board would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on stockholders:

- the liquidity of our common stock;
- the market price of our common stock (and the accompanying valuation of our Company);
- our ability to obtain financing or complete a strategic transaction;
- the number of institutional and other investors that will consider investing in shares of our common stock;
- the number of market makers or broker-dealers for our common stock; and
- the availability of information concerning the trading prices and volume of shares of our common stock.

There is no assurance that an active market in our common stock will continue at present levels or increase in the future.

Our common stock is currently traded on the Nasdaq Capital Market, but there is no assurance that an active market in our common stock will continue at present levels or increase in the future. As a result, an investor may find it difficult to dispose of our common

stock on the timeline and at the volumes they desire. This factor limits the liquidity of our common stock and may have a material adverse effect on the market price of our common stock and on our ability to raise additional capital.

The price of our common stock may continue to be volatile, which could lead to losses by investors and costly securities litigation.

The trading price of our common stock is likely to be highly volatile and could fluctuate in response to factors such as:

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- our ability to execute on our new strategic plan;
- reduced government funding for research and development activities;
- actual or anticipated variations in our operating results;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- sales of our common stock or other securities in the open market;
- degree of coverage of securities analysts and reports and recommendations issued by securities analysts regarding our business;
- volume fluctuations in the trading of our common stock; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. The trading price of our common stock is, and is likely to continue to be, volatile. For example, during the quarter ended December 31, 2025, our closing stock price ranged from \$1.81 to \$3.46 per share. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

****Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our capital stock.***

We are authorized to issue 200,000,000 shares of common stock and 25,000,000 shares of preferred stock. As of December 31, 2025, there were an aggregate of 3,499,149 shares of our common stock issued and outstanding and available for issuance on a fully diluted basis and no shares of preferred stock outstanding. That total for our common stock includes 348,419 shares of our common stock that may be issued upon the vesting of restricted stock units, the exercise of outstanding stock options, or is available for issuance under our equity incentive plans, 3,708 shares of common stock that may be issued through our 2023 Employee Stock Purchase Plan ("ESPP"), and 539,060 shares of our common stock that may be issued upon the exercise of outstanding warrants.

In the future, we may issue additional authorized but previously unissued equity securities to raise funds to support our continued operations and to implement our business plan. We may also issue additional shares of our capital stock or other securities that are convertible into or exercisable for our capital stock in connection with hiring or retaining employees, future acquisitions, or for other business purposes. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders may result. In addition, the future issuance of any such additional shares of capital stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently traded on the Nasdaq Capital Market. Moreover, depending on market conditions, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders.

We do not intend to pay dividends for the foreseeable future.

We have paid no dividends on our common stock to date and it is not anticipated that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of our business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock and could significantly affect the value of any investment.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our Certificate of Incorporation, as amended (“Certificate of Incorporation”), and Amended and Restated Bylaws, as amended (“Bylaws”) contain provisions that could delay or prevent a change of control of our Company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by our board of directors without prior stockholder approval, with rights senior to those of the common stock;
- provide for a classified board of directors, with each director serving a staggered three-year term;
- provide that each director may be removed by the stockholders only for cause;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent; and
- require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our Certificate of Incorporation, Bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delaying or impeding a merger, tender offer, or proxy contest involving our Company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Risks Related to Our Intellectual Property

If we are not able to adequately protect our proprietary rights, our business could be harmed.

Our success will depend to a significant extent on our ability to obtain patents and maintain adequate protection for our technologies, intellectual property and products and service offerings in the United States and other countries. If we do not protect our intellectual property adequately, competitors may be able to use our technologies and gain a competitive advantage.

To protect our products and technologies, we, and our collaborators and licensors, must prosecute and maintain existing patents, obtain new patents and pursue other intellectual property protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may also affect the value of our licensed or owned intellectual property or create uncertainty. Moreover, the patent positions of many biotechnology and pharmaceutical companies are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, we cannot guarantee that:

- any patent applications filed by us will issue as patents;
- third parties will not challenge our proprietary rights, and if challenged that a court or an administrative board of a patent office will hold that our patents are valid and enforceable;
- third parties will not independently develop similar or alternative technologies or duplicate any of our technologies by inventing around our claims;
- any patents issued to us will cover our technology and products as ultimately developed;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business; or
- as issued patents expire, we will not lose some competitive advantage.

As previously disclosed, we have recommenced certain historical operations and are now focusing our future efforts on developing highly customized 3D human tissues as living, dynamic models for healthy and diseased human biology for drug development. These tissues will be used to provide testing of drugs and drug candidates to our partners. We offer partners liver and intestinal toxicology insights using our new approach methodologies (“NAM”) models. Previously, we focused our efforts on developing our in vivo liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there were limited treatment options other than organ transplant. We also explored the development of other potential pipeline in vivo tissue constructs. As we focus our business on developing highly customized 3D human tissues as part of a services platform, we may sell, discontinue, adjust

or abandon certain patents and patent applications relating to our historical operations. There can be no assurance that we will be successful at such efforts or sell or otherwise monetize such assets on acceptable terms, if at all. There is also no guarantee that our remaining patents will be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies.

We may not be able to protect our intellectual property rights throughout the world.

Certain foreign jurisdictions have an absolute requirement of novelty that renders any public disclosure of an invention immediately fatal to patentability in such jurisdictions. Therefore, there is a risk that we may not be able to protect some of our intellectual property in the United States or abroad due to disclosures, which we may not be aware of, by our collaborators or licensors. Some foreign jurisdictions prohibit certain types of patent claims, such as “method-of-treatment/use-type” claims; thus, the scope of protection available to us in such jurisdictions is limited.

Moreover, filing, prosecuting and defending patents on all of our potential products and technologies throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not sought or obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our future products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office (the “USPTO”), or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes review* (“IPR”), or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology or products. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

For example, our U.S. Patent Nos. 9,855,369 and 9,149,952, which relate to our bioprinter technology, were the subject of IPR proceedings filed by Cellink AB and its subsidiaries (collectively, “BICO Group AB”), one of our competitors. Likewise, U.S. Patent Nos. 9,149,952, 9,855,369, 8,931,880, 9,227,339, 9,315,043 and 10,967,560 (all assigned to Organovo, Inc.) and U.S. Patent Nos. 7,051,654, 8,241,905, 8,852,932 and 9,752,116 (assigned to Clemson University and the University of Missouri, respectively) were implicated in a declaratory judgment complaint filed against Organovo, Inc., our wholly owned subsidiary, by BICO Group AB and certain of its subsidiaries in the United States District Court for the District of Delaware. All of these matters were eventually settled in February 2022.

Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. We may become involved in lawsuits to protect or enforce our inventions, patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse effect on our business, financial condition, and results of operations.

We may be involved in lawsuits or other proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our collaborators or licensors or our licensors may breach or otherwise prematurely terminate the provisions of our license agreements with them. To counter infringement or unauthorized use, we may be required to file infringement claims or lawsuits, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our collaborators or licensors is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our other patent applications at risk of not issuing. Additionally, our licensors may continue to retain certain rights to use technologies licensed by us for research purposes. Patent disputes can take years to resolve, can be very costly and can result in loss of rights, injunctions or substantial penalties. Moreover, patent disputes and related proceedings can distract management's attention and interfere with running our business.

Furthermore, because of the potential for substantial discovery in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments which could harm our business.

As more companies file patents relating to bioprinters and bioprinted tissues, it is possible that patent claims relating to bioprinters or bioprinted human tissue may be asserted against us. In addition, the drug candidates we pursue may also be pursued by other companies, and it is possible that patent claims relating to such drug candidates may also be asserted against us. Any patent claims asserted against us could harm our business. Moreover, we may face claims from non-practicing entities, which have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Any such claims, with or without merit, could be time-consuming to defend, result in costly litigation and diversion of resources, cause product shipment or delays or require us to enter into royalty or license agreements. These licenses may not be available on acceptable terms, or at all. Even if we are successful in defending such claims, infringement and other intellectual property litigation can be expensive and time-consuming to litigate and divert management's attention from our core business. Any of these events could harm our business significantly.

Our current and future research, development and commercialization activities also must satisfy the obligations under our license agreements. Any disputes arising under our license agreements could be costly and distract our management from the conduct of our business. Moreover, premature termination of a license agreement could have an adverse impact on our business.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine the priority of invention and opposition proceedings outside of the United States. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party.

Third parties may also attempt to initiate reexamination, post grant review or *inter partes review* of our patents or those of our collaborators or licensors in the PTO. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and that may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first to file” system in which the first inventor to file a patent application is typically entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings, including opposition, derivation, reexamination, *inter partes review* or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or the UPC. As the UPC is a relatively new court system, there is little precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the unitary patent system.

We depend on license agreements with University of Missouri for rights to use certain patents, pending applications, and know how. Failure to comply with or maintain obligations under these agreements and any related or other termination of these agreements could materially harm our business and prevent us from developing or commercializing new product candidates.

We are party to license agreements with University of Missouri under which we were granted exclusive rights to patents and patent applications that are important to our business and to our ability to develop and commercialize our 3D tissue products fabricated using our NovoGen Bioprinters. Our rights to use these patents and patent applications and employ the inventions claimed in these licensed patents are subject to the continuation of and our compliance with the terms of our license agreements. If we were to breach the terms of these license agreements and the agreements were terminated as a result, our ability to continue to develop and commercialize our NovoGen Bioprinters and 3D tissue products and to operate our business could be adversely impacted.

****We may not be successful in retaining, acquiring or in-licensing necessary rights to key technologies underlying our liver toxicology screening and research services platform or technologies relating to any of our other current or future services, product candidates or platforms we may develop.***

We currently have rights to intellectual property, through licenses or agreements with third parties, to develop our liver toxicology screening and research services platform, and we expect to seek to expand our intellectual property footprint related to this platform in part by acquiring the rights from Viscient, through licenses or otherwise, to certain key technologies related to this platform. Although we have succeeded in licensing technologies from Viscient and other third parties in past, we can give no assurance that we will be able to in-license or acquire the rights to all technologies or intellectual property relevant to our liver toxicology screening and research services platform from Viscient on acceptable terms, or at all.

Moreover, we expect that the future growth of our business will depend in part on our ability to in-license or acquire the rights to develop additional services, platforms, product candidates and technologies from one or more third parties, and such rights or licenses may not be available on acceptable terms, or at all. The licensing or acquisition of third-party intellectual property rights is a highly competitive area, and other companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. Such companies may have a competitive advantage over us, e.g., due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on

terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we were able to obtain any such license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ or engage individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims.

Risks Related to Litigation

Claims, litigation, government investigations and other proceedings may adversely affect our business, operating results and financial condition.

We are, from time to time, involved in various claims, litigation matters and regulatory proceedings that could have a material adverse effect on us. These matters may include intellectual property disputes, contract disputes, employment and tax matters and other proceedings and litigation, including class action lawsuits. It is not possible to predict the outcome of pending or future litigation and any such claims, with or without merit, could be time consuming and expensive, and may require us to incur substantial costs and divert the resources of management.

For example, on August 27, 2024, H.C. Wainwright & Co., LLC ("H.C. Wainwright") filed a complaint against us in the State of New York alleging that we breached a tail financing provision included in an engagement agreement we entered into with H.C. Wainwright in May 2023. In its complaint, H.C. Wainwright is seeking compensatory and consequential damages and attorneys' fees. On October 18, 2024, we filed an answer to the complaint and on September 2, 2025, we filed an amended answer and counterclaimed for rescission, fraudulent inducement, and breach of contract, alleging that the Court should rescind the engagement agreement and award us damages, interest, costs, and attorneys' fees because H.C. Wainwright misrepresented the services it would provide and breached its duties to us under the engagement agreement. We have briefed H.C. Wainwright's motion to dismiss our counterclaims. We are defending against H.C. Wainwright's claims and pursuing our counterclaims vigorously, but there is no guarantee that we will be successful in these efforts.

Determining legal reserves or possible losses from claims against us involves judgment and may not reflect the full range of uncertainties and unpredictable outcomes. Until the final resolution of such matters, we may be exposed to losses in excess of the amount recorded, and such excess amounts could have a material effect on our business, results of operations and financial condition. In addition, it is possible that a resolution of any claim, including as a result of a settlement, could require us to make substantial future payments or require us to change our business practices each of which could have a material adverse effect on our business, operating results and financial condition.

General Risk Factors

Compliance with the reporting requirements of federal securities laws can be expensive.

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the compliance obligations of the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley Act”). The costs of complying with the reporting requirements of the federal securities laws, including preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders, can be substantial.

If we fail to comply with the rules of Section 404 of the Sarbanes-Oxley Act related to accounting controls and procedures, or, if we discover material weaknesses and deficiencies in our internal control and accounting procedures, we may be subject to sanctions by regulatory authorities and our stock price could decline.

Section 404 of the Sarbanes-Oxley Act (“Section 404”) requires that we evaluate and determine the effectiveness of our internal control over financial reporting. We believe our system and process evaluation and testing comply with the management certification requirements of Section 404. We cannot be certain, however, that we will be able to satisfy the requirements in Section 404 in all future periods. If we are not able to continue to meet the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or Nasdaq. Any such action could adversely affect our financial results or investors’ confidence in us and could cause our stock price to fall. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we identify deficiencies in our internal controls that are deemed to be material weaknesses, we may be required to incur significant additional financial and management resources to achieve compliance.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

During the fiscal quarter ended December 31, 2025, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

The following exhibit index shows those exhibits filed with this report and those incorporated herein by reference:

Exhibit No.	Description
2.1#	Asset Purchase Agreement, dated February 23, 2025, by and between the Company, Eli Lilly and Company and for certain sections therein, Organovo, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed by the Company with the SEC on February 25, 2025).
3.1	Certificate of Incorporation (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.2	Certificate of Amendment of Certificate of Incorporation (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 27, 2018).
3.3	Certificate of Second Amendment of Certificate of Incorporation (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the SEC on August 17, 2020).
3.4	Certificate of Third Amendment of Certificate of Incorporation (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the SEC on March 21, 2025).
3.5	Certificate of Fourth Amendment of Certificate of Incorporation (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the SEC on April 24, 2025).
3.6	Amended and Restated Bylaws (incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K as filed with the SEC on April 24, 2025).
4.1	Form of Common Warrant (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 13, 2024).
31.1*	Certification of Keith Murphy, Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2*	Certification of Norman Staskey, Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1**	Certification of Keith Murphy, Principal Executive Officer, and Norman Staskey, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).*
101.SCH	Inline XBRL Taxonomy Extension Schema.*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).*

Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the Securities and Exchange Commission.

* Filed herewith.

** Furnished herewith.

SIGNATURES

Pursuant to the requirements 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.

VIVOSIM LABS, INC.

Date: February 11, 2026

By: /s/ Keith Murphy
Name: Keith Murphy
Title: Executive Chairman
(Principal Executive Officer)

Date: February 11, 2026

By: /s/ Norman Staskey
Name: Norman Staskey
Title: Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION

I, Keith Murphy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VivoSim Labs, 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

Dated: February 11, 2026

/s/ Keith Murphy

Keith Murphy
Executive Chairman
(Principal Executive Officer)

CERTIFICATION

I, Norman Staskey, certify that:

1. I have reviewed this quarterly report on Form 10-Q of VivoSim Labs, 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

Dated: February 11, 2026

/s/ Norman Staskey

Norman Staskey
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of VivoSim Labs, Inc. (the "Company") for the period ended December 31, 2025, as filed with the Securities and Exchange Commission (the "Report"), I, Keith Murphy, Executive Chairman and I, Norman Staskey, Chief Financial Officer of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 11, 2026

/s/ Keith Murphy

Keith Murphy
Executive Chairman
(Principal Executive Officer)

/s/ Norman Staskey

Norman Staskey
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to VivoSim Labs, Inc. and will be retained by VivoSim Labs, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not to be incorporated by reference into any filing of VivoSim Labs, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.
