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 September 30, 2026

OR

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

For the transition period from _____ to

Commission File Number 001-35996

VivoSim Labs, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**27-1488943**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11555 Sorrento Valley Rd, Suite 100, San Diego, CA 92121	**(858) 224-1000**
(Address of principal executive offices and zip code)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of November 1, 2026, a total of 20,281,495 shares of the registrant's Common Stock, $0.001 par value, were outstanding.

VIVOSIM LABS, INC.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2026 (Unaudited)	March 31, 2026
Assets		
Current Assets		
Cash and cash equivalents	$ 8,564	$ 5,024
Accounts receivable	56	32
Work in progress	30	—
Escrow receivable	—	1,014
Prepaid expenses and other current assets	747	557
Total current assets	9,397	6,627
Fixed assets, net	217	206
Restricted cash	143	143
Operating lease right-of-use assets	165	407
Prepaid expenses and other assets, net	2	3
Total assets	$ 9,924	$ 7,386
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities		
Accounts payable	$ 953	1,021
Accrued expenses	991	981
Deferred revenue	8	—
Insurance premium financing liability	330	118
Liability to be settled in equity	218	218
Operating lease liability, current portion	182	447
Total current liabilities	2,682	2,785
Common stock warrant liabilities	—	5,700
Total liabilities	2,682	8,485
Commitments and Contingencies (Note 6)		
Stockholders' Equity (Deficit)		
Common stock, $0.001 par value; 200,000,000 shares authorized, 18,067,495 and 2,894,519 shares issued and outstanding at September 30, 2026 and March 31, 2026, respectively	18	3
Additional paid-in capital	365,037	354,898
Accumulated deficit	(357,813)	(356,000)
Total stockholders' equity (deficit)	7,242	(1,099)
Total Liabilities and Stockholders' Equity (Deficit)	$ 9,924	$ 7,386

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 September 30, 2026	Three Months Ended September 30, 2025	Six Months Ended September 30, 2026	Six Months Ended September 30, 2025
Revenues				
Service revenue	$ 22	$ —	$ 22	$ —
Royalty revenue	29	28	47	65
Total Revenues	51	28	69	65
Cost of services provided	56	—	56	—
Research and development expenses	1,096	923	2,228	1,924
Selling, general and administrative expenses	2,215	1,740	3,860	3,691
Total costs and expenses	3,367	2,663	6,144	5,615
Loss from Operations	(3,316)	(2,635)	(6,075)	(5,550)
Other Income (Expense)				
Loss on change in fair value of common stock warrant liabilities	(2,213)	—	(813)	—
Gain on milestone payment related to sale of asset	5,000	—	5,000	—
Interest income	54	92	82	168
Interest expense	—	—	(4)	(4)
Total Other Income	2,841	92	4,265	164
Income Tax Expense	—	(2)	(3)	(2)
Net Loss	$ (475)	$ (2,545)	$ (1,813)	$ (5,388)
Comprehensive Loss	$ (475)	$ (2,545)	$ (1,813)	$ (5,388)
Net loss per common share—basic and diluted	$ (0.03)	$ (0.98)	$ (0.17)	$ (2.11)
Weighted average shares used in computing net loss per common share—basic and diluted	16,445,249	2,604,950	10,872,972	2,554,419

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

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

	Three and Six Months Ended September 30, 2026						
	Common Stock			Treasury Stock			
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulated Deficit	Total
Balance at March 31, 2026	**2,895**	**$ 3**	**$ 354,898**	**—**	**$ —**	**$ (356,000)**	**$ (1,099)**
Issuance of common stock under pre-funded warrants exercise	299	—	—	—	—	—	—
Stock-based compensation expense	—	—	91	—	—	—	91
Net loss	—	—	—	—	—	(1,338)	(1,338)
Balance at June 30, 2026	**3,194**	**$ 3**	**$ 354,989**	**—**	**$ —**	**$ (357,338)**	**$ (2,346)**
Issuance of common stock under employee and director stock option, RSU, and purchase plans	75	—	—	—	—	—	—
Issuance of common stock under pre-funded warrants exercise	5,186	5	(2)	—	—	—	3
Issuance of common stock under common warrants exercise	9,613	10	6,503	—	—	—	6,513
Issuance of common stock from private placement, net	—	—	3,417	—	—	—	3,417
Stock-based compensation expense	—	—	130	—	—	—	130
Net loss	—	—	—	—	—	(475)	(475)
Balance at September 30, 2026	**18,068**	**$ 18**	**$ 365,037**	**—**	**$ —**	**$ (357,813)**	**$ 7,242**

	Three and Six Months Ended September 30, 2025						
	Common Stock			Treasury Stock			
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulated Deficit	Total
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	**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	**2,608**	**$ 3**	**$ 354,607**	**—**	**$ —**	**$ (347,545)**	**$ 7,065**

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)

	Six Months Ended September 30, 2026	Six Months Ended September 30, 2025
Cash Flows From Operating Activities		
Net loss	$ (1,813)	$ (5,388)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on change in fair value of common stock warrant liabilities	813	—
Interest accretion on escrow receivable	—	(8)
Gain on milestone payment related to sale of asset	(5,000)	—
Depreciation and amortization	75	120
Stock-based compensation	326	150
Non-cash lease expense	242	226
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(16)	(2)
Work in progress	(30)	—
Prepaid expenses and other assets	140	345
Accounts payable	(68)	(1,064)
Accrued expenses	(95)	(455)
Operating lease liability	(265)	(242)
Net cash used in operating activities	(5,691)	(6,318)
Cash Flows From Investing Activities		
Purchases of fixed assets	(85)	—
Release of escrow receivable	1,014	—
Proceeds from milestone payment related to sale of asset	5,000	—
Net cash provided by investing activities	5,929	—
Cash Flows From Financing Activities		
Proceeds from issuance of common stock, net	3	1,811
Proceeds from private placement, net	3,417	—
Repayment of insurance premium financing liability	(118)	(128)
Net cash provided by financing activities	3,302	1,683
Net increase (decrease) in cash, cash equivalents, and restricted cash	3,540	(4,635)
Cash, cash equivalents, and restricted cash at beginning of period	5,167	11,455
Cash, cash equivalents, and restricted cash at end of period	$ 8,707	$ 6,820
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 8,564	$ 6,677
Restricted cash	143	143
Total cash, cash equivalents, and restricted cash	$ 8,707	$ 6,820
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	$ 3	$ 2
Financed insurance premium exchanged for prepaid insurance	$ 330	$ 352
Reclassification of common stock warrant liabilities to equity upon cashless exercise	$ 6,513	$ —
Interest paid	$ 4	$ 4

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 also offers bespoke services in the areas of investigational toxicology, mechanism of drug action elucidation, and other applications of these complex human tissue models.

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 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. The Company presented findings at the June 2026 European Toxicology Meeting scientific conference showing that the liver toxicology platform had a best-in-class predictive power. VivoSim's liver predictive power was shown to be >90% sensitivity 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 many of the missed cases could be seen as liver toxic using NAMkind™ liver. This is known as the sensitivity of the platform, which at >90%, the Company believes is the world's best. The specificity was >95%, meaning that few of the compounds tested that are not liver toxic were incorrectly identified as having liver toxicity issues by the platform. The Company has obtained an exclusive license to the NAMKind Liver Model platform from Viscient (as defined below) within the field of non-animal toxicity and normal liver-tissue safety screening services pursuant to the Viscient License Agreement. See "Note 9. Related Parties" and "Note 11. Subsequent Events" for further details.

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.

Prior to March 2025, the Company was a clinical stage biotechnology company that was focused on developing FXR314 in inflammatory bowel disease ("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 had 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 at that time also focused 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.

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. In July 2026, the Company received a milestone payment in the amount of $5.0 million upon the achievement of a certain development milestone related to FXR314 which was recorded within other income on the consolidated statements of operations and comprehensive loss. Additionally, in July 2026, the $1.0 million held in escrow was released to the Company. The current remaining total potential for additional milestone payments includes up to $45 million in milestones, including a $15 million milestone which is to be paid upon Eli Lilly first dosing a patient in a Phase 3 clinical trial.

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.

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, 2026 is derived from the Company’s audited consolidated balance sheet as filed with the Securities and Exchange Commission ("SEC") on July 14, 2026.

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, 2026, 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, 2027 (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 September 30, 2026, the Company had cash and cash equivalents of approximately $8.6 million, restricted cash of approximately $0.1 million and an accumulated deficit of approximately $357.8 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 $5.7 million during the six months ended September 30, 2026. As of September 30, 2026, the Company had total current assets of approximately $9.4 million and current liabilities of approximately $2.7 million, resulting in working capital of $6.7 million. The Company also had significant cash inflows received in July 2026, which include the milestone payment and escrow release discussed in "Note 1. Description of Business", as well as a private placement transaction, discussed below.

Through September 30, 2026, 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, the sale of FXR314 and related milestone payments, grants, and collaborative research agreements, and from the sale of convertible notes.

July 2026 PIPE

On July 16, 2026, the Company entered into a Securities Purchase Agreement with an accredited institutional investor, pursuant to which, among other things, the Company agreed to issue and sell, in a private placement transaction (the “2026 PIPE”), (i) pre-funded warrants (the “2026 PIPE Pre-Funded Warrants”) to purchase up to an aggregate of 4,705,883 shares of the Company’s common stock, par value $0.001 per share, and (ii) accompanying warrants to purchase up to an aggregate of 4,705,883 shares of Common Stock (the “2026 PIPE Common Warrants”), at the combined purchase price of $0.85 per share of Common Stock for gross proceeds of approximately $4.0 million and net proceeds of approximately $3.4 million, after deducting offering expenses. See “Note 4. Stockholders’ Equity” for additional information.

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 2026, the Company entered into an insurance premium financing agreement for $0.3 million, with a term of nine months and an annual interest rate of 7.32%. The Company made a down payment of 10% and is required to make monthly principal and interest payments of $37,780 over the term of the agreement, which will mature in June 2027. The insurance premium financing liability was approximately $0.3 million and $0.1 million as of September 30, 2026, and March 31, 2026, respectively. The balance as of March 31, 2026 related to the prior year's insurance premium financing agreement, which was fully repaid as of September 30, 2026. Related prepaid insurance at September 30, 2026, and March 31, 2026 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 basic loss per share includes the assumed exercise of any outstanding pre-funded warrants. 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 three and six months ended September 30, 2026 and 2025 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 5.6 million shares and 0.7 million shares at September 30, 2026 and 2025, 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. Revenue is recognized when the underlying sales occur and the related performance obligation has been satisfied. Estimates relate to sales occurring within the reporting period. Please refer to "Note 5. Collaborative Research, Development, and License Agreements" for further information.

Service revenue, net

The Company markets and offers liver and intestinal toxicology and disease (or efficacy, used interchangeably) predictive screening research services using new approach methodologies ("NAM") to pharmaceutical and biotech companies at all stages of drug development. These contracts with customers contain a single performance obligation, which is transferring a comprehensive report to customers. Therefore, the Company recognizes revenue when the promised services are performed and a single comprehensive report is transferred to customers. The customer does not have access or control of the deliverable until the final comprehensive report is transferred. Accordingly, the Company's service-based business utilizes point-in-time recognition under ASC Topic 606. For the service contracts, the Company allocates the transaction price to the single performance obligation, and the transaction price is a fixed consideration.

Accounts Receivable

The Company records accounts receivable, net of an allowance for credit losses. An allowance for credit losses is established based on historical collection information, which is limited at this time as the Company began recognizing service revenue in fiscal 2027. The Company also considers a review of major client accounts receivable balances, current economic conditions in the geographies in which it operates, and the Company's expectations of future economic conditions that may affect the collectability of the recorded amounts. Amounts determined to be uncollectible are charged or written off against the allowance.

Deferred Revenue

The Company records deferred revenue when it has the right to issue advanced billings or upfront payments from its contracts with customers. Deferred revenue was less than $0.1 million and zero as of September 30, 2026 and March 31, 2026, respectively.

Cost of Services Provided

The Company reported approximately $0.1 million of cost of services provided for each of the three and six months ended September 30, 2026. Cost of services provided consists of costs related to producing service revenue, which includes direct materials, costs of personnel directly involved in performing the service, and an allocation of facility costs.

Work in Progress

The Company reported approximately less than $0.1 million of work in progress as of September 30, 2026. Work in progress represents costs incurred related to providing services that are not completed as of the end of a reporting period. The Company records the total costs incurred, which include direct materials, costs of personnel directly involved in performing the service, and an allocation of facility costs. The costs will be recognized as cost of services provided when the service is completed and the related service revenue is recognized.

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.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued 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 are included in the Company's Form 10-K for fiscal year ending March 31, 2026, and were applied on a retrospective basis.

Recently Issued Accounting Pronouncements

On July 4, 2025, the U.S. government enacted comprehensive legislation commonly referred to as the One Big Beautiful Bill Act, or the 2025 Act. The 2025 Act makes changes to U.S. corporate income taxes including reinstating the option to claim 100% accelerated depreciation deductions on qualified property, with prospective application beginning January 20, 2025 and immediate expensing of domestic research and development costs, with prospective application beginning January 1, 2025. The impact of this legislation was not material to the Company's consolidated financial position and results of operations for the three and six months ended September 30, 2026.

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 within annual 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 disclosures.

Note 3. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2026	March 31, 2026
Accrued payroll and other employee benefits	$ 340	$ 422
Accrued legal and professional fees	577	523
Other accrued expenses	74	36
	$ 991	$ 981

As of September 30, 2026 there was approximately $0.1 million of share-based compensation expense included within accrued legal and professional fees. The equity was not issued as of September 30, 2026, and was considered an accrued expense as the compensation was a fixed amount with a variable number of shares to be issued based on market price of the Company's common stock on the issuance date. See “Note 4. Stockholders' Equity” for more information regarding share-based compensation expense.

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

Common Stock

On September 30, 2026, the Company’s stockholders approved the amendment and restatement of the 2022 Equity Incentive Plan (the “A&R 2022 Plan”) to increase the number of shares reserved for issuance thereunder by 3,165,000 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 JonesTrading 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 six months ended September 30, 2026, the Company issued zero shares of common stock in ATM offerings pursuant to the 2024 Shelf. As of September 30, 2026, 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 September 30, 2026, 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.

March 2026 Best Efforts Public Offering

On March 31, 2026, the Company priced the 2026 Offering which consisted of: (i) 286,557 shares of its common stock and 429,836 accompanying common warrants ("2026 Common Warrants") to purchase up to 429,836 shares of common stock at a combined public offering price of $1.14 per share and accompanying one and a half common warrants to purchase one share common stock and (ii) 2,345,022 pre-funded warrants ("2026 Pre-Funded Warrants") to purchase 2,345,022 shares of common stock and 3,517,533 accompanying 2026 Common Warrants to purchase up to 3,517,533 shares of common stock at a combined public offering price of $1.139 per pre-funded warrant and accompanying one and a half common warrants to purchase one share of common stock. Each 2026 Common Warrant had an exercise price of $1.71 per share of common stock.

The per share exercise price for the 2026 Pre-Funded Warrants was $0.001, subject to adjustment as provided therein. The 2026 Pre-Funded Warrants were immediately exercisable, subject to certain beneficial ownership limitations, and were to expire when exercised in full. The holder could exercise the 2026 Pre-Funded Warrants by means of a "cashless exercise."

The per share exercise price for the 2026 Common Warrants was $1.71, subject to adjustment as provided therein. The 2026 Common Warrants were immediately exercisable, subject to certain beneficial ownership limitations, and were to expire on the date that is five years following the original issuance date. The 2026 Common Warrants had price protection against subsequent dilutive issuances of shares of common stock, options, warrants and convertible securities, subject to a $0.01 per share of common stock floor, as further described in the 2026 Common Warrants. The holders of the 2026 Common Warrants could exchange the 2026 Common Warrants on a cashless basis for a number of shares of common stock determined by multiplying the total number of shares of common stock with respect to which the 2026 Common Warrant is then being exercised by the Black Scholes Value (as defined in the 2026 Common Warrant) divided by the lower of the two closing bid prices of the common stock in the two days prior to the time of such exercise, but in any event not less than $0.01.

In connection with the 2026 Offering, the Company paid Joseph Gunnar & Co. LLC (the "Placement Agent"), which acted as the placement agent in connection with the 2026 Offering, a cash fee of 7.5% of the aggregate gross proceeds raised in the 2026 Offering. Additionally, in connection with the 2026 Offering, the Company issued to the Placement Agent 131,579 warrants to purchase 131,579 shares of common stock ("Placement Agent Warrants") with an exercise price of $1.425 per share of common stock.

The closing of the 2026 Offering occurred on March 31, 2026. The Company received gross proceeds of approximately $3.0 million and net proceeds of approximately $2.4 million from the 2026 Offering, after deducting the offering expenses payable by the Company, including the Placement Agent fees.

July 2026 PIPE

On July 16, 2026, the Company entered into a Securities Purchase Agreement with an accredited institutional investor, pursuant to which, among other things, the Company sold in a private placement transaction that closed on July 17, 2026 (the "2026 PIPE"), (i) pre-funded warrants (the "2026 PIPE Pre-Funded Warrants") to purchase up to an aggregate of 4,705,883 shares of the Company's common stock, par value $0.001 per share, and (ii) accompanying warrants to purchase up to an aggregate of 4,705,883 shares of common stock (the "2026 PIPE Common Warrants"), at the combined purchase price of $0.85 per share of common stock for gross proceeds of approximately $4.0 million and net proceeds of approximately $3.4 million, after deducting offering expenses.

Each 2026 PIPE Pre-Funded Warrant has an exercise price of $0.001 per share of common stock, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, is exercisable immediately upon issuance and will survive until it is exercised in full. Each 2026 PIPE Pre-Funded Warrant is exercisable on a cash or cashless exercise basis.

Each 2026 PIPE Common Warrant has an exercise price of $0.85 per share of common stock, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions, are exercisable at any time on or after September 30, 2026 (the date the Company obtained stockholder approval with respect to the 2026 PIPE Common Warrants) until September 30, 2031. Each 2026 PIPE Common Warrant is exercisable on a cash basis unless, at the time of such exercise, the shares of common stock underlying such

2026 PIPE Common Warrant cannot be immediately resold pursuant to an effective registration statement, in which case such 2026 PIPE Common Warrant will also be exercisable on a cashless exercise basis.

In connection with the 2026 PIPE, on July 16, 2026, the Company also entered into a placement agency agreement (the "Placement Agency Agreement") with A.G.P./Alliance Global Partners (the "Placement Agent"). Pursuant to the Placement Agency Agreement, the Company agreed to pay to the Placement Agent a cash fee equal to 6.50% of the gross proceeds of the Private Placement.

In connection with the 2026 PIPE, on July 16, 2026, the Company also entered into an amendment (the "Armistice Warrant Amendment") to the 2024 Common Warrants (defined below), which included 520,833 of the 2024 Common Warrants issued by the Company to Armistice Capital Master Fund Ltd. (the "Armistice Warrants"), to, among other things, amend the date of termination and the exercise price of the Armistice Warrants to be September 30, 2031 (5 years after the date the Company obtained stockholder approval with respect to the Armistice Warrants) and underlying shares of common stock and $0.85 per share of common stock, respectively, and amend certain provisions relating to the treatment of the warrants upon a Fundamental Transaction, (such as removing a Black-Scholes repurchase provision, as defined in the Armistice Warrants). The Armistice Warrant Amendment was accounted for as a noncash equity issuance cost, with an offsetting credit to additional paid-in-capital related to the warrants. Accordingly, the modification had no net effect on total stockholders' equity or net income.

Warrants issued in connection with the 2026 PIPE contain provisions such as the requirements for the registration of shares and the right for the holder to retain the warrants upon a fundamental transaction.

Restricted Stock Units

The following table summarizes the Company's RSUs activity for the six months ended September 30, 2026:

	Number of Shares	Weighted Average Grant-Date Fair Value
Unvested at March 31, 2026	75,000	$ 1.73
Granted	—	$ —
Vested	(75,000)	$ 1.73
Cancelled / forfeited	—	$ —
Unvested at September 30, 2026	—	$ —

Stock Options

During the three and six months ended September 30, 2026, under the A&R 2022 Plan, the Company granted at various exercise prices 1,209 and 10,039 stock options, 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 September 30, 2026, 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, 2026 to September 30, 2026:

	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2026	261,084	$ 12.40	$ —
Options granted	10,039	$ 1.19	$ —
Options cancelled / forfeited	(596)	$ 4.23	$ —
Options expired	—	$ —	$ —
Outstanding at September 30, 2026	270,527	$ 12.00	$ —
Vested and Exercisable at September 30, 2026	89,921	$ 28.91	$ —

The weighted average remaining contractual term of stock options exercisable and outstanding at September 30, 2026, was approximately 8.09 years.

Warrants

2024 Offering

In connection with a best efforts public offering that occurred in May 2024 ("2024 Offering"), the Company issued (i) common warrants ("2024 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 ("2024 Pre-Funded Warrants") to purchase 416,666 shares of common stock and accompanying 2024 Common Warrants to purchase up to 416,666 shares of common stock at a combined public offering price of $9.588 per 2024 Pre-Funded Warrant and accompanying 2024 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 as they are adjusted proportionately for any stock dividends or stock splits. As of September 30, 2026, all 2024 Pre-Funded Warrants associated with the 2024 Offering were fully exercised. In connection with the 2026 PIPE that occurred in July 2026, the Company entered into the Armistice Warrant Amendment to amend 520,833 of the outstanding 2024 Common Warrants, which included the date of termination and the exercise price to be 5 years and $0.85, respectively, effective upon the date of stockholder approval. The Company's stockholders approved the Armistice Warrant Amendment on September 30, 2026.

The following table summarizes the Company's activity under the 2024 Common Warrants from March 31, 2026 to September 30, 2026 which includes 520,833 of the amended warrants as discussed above:

	Number of Warrants	Exercise Price
Outstanding at March 31, 2026	539,060	$ 9.60
Issued	—	—
Exercised	—	—
Warrant amendment - exercise price	520,833	$ 0.85
Warrants not subject to amendment	18,227	$ 9.60
Total outstanding at September 30, 2026	539,060	

2026 Offering

In connection with the 2026 Offering, the Company issued (i) 286,557 shares of its common stock and 429,836 accompanying 2026 Common Warrants to purchase up to 429,836 shares of common stock at a combined public offering price of $1.14 per share and accompanying one and a half 2026 Common Warrants to purchase one share common stock and (ii) 2,345,022 2026 Pre-Funded Warrants to purchase 2,345,022 shares of common stock and 3,517,533 accompanying 2026 Common Warrants to purchase up to 3,517,533 shares of common stock at a combined public offering price of $1.139 per 2026 Pre-Funded Warrant and accompanying one and a half 2026 Common Warrants to purchase one share of common stock. The Company has determined that the 2026 Pre-Funded 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. Each 2026 Common Warrant has an exercise price of $1.71 per share of common stock. The Company has determined that the 2026 Common Warrants should be classified as a common stock warrant liability as the instrument contains a leverage factor and therefore is not considered indexed to

the Company's own stock. During the three months ended September 30, 2026, 2,045,022 2026 Pre-Funded Warrants were exercised at an exercise price of $0.001. The 2026 Pre-Funded Warrants were fully exercised as of September 30, 2026.

During the three months ended September 30, 2026, 3,947,369 2026 Common Warrants were exercised via an alternative cashless exercise provision. As a result of the exercise, 9,612,823 shares of common stock were issued. As of September 30, 2026, all 2026 Common Warrants were exercised, and the related common stock warrant liability was zero.

In connection with the 2026 Offering, the Company issued 131,579 Placement Agent Warrants to purchase 131,579 shares of common stock with an exercise price of $1.425 per share of common stock.

The following table summarizes the Company's activity under the 2026 Pre-Funded Warrants, the 2026 Common Warrants, and the Placement Agent Warrants from March 31, 2026 to September 30, 2026:

	2026 Pre-Funded Warrants	Exercise Price	2026 Common Warrants	Exercise Price	Placement Agent Warrants	Exercise Price
Outstanding at March 31, 2026	2,345,022	$ 0.001	3,947,369	$ 1.71	131,579	$ 1.43
Issued	—	$ —	—	$ —	—	$ —
Exercised	(2,345,022)	$ 0.001	(3,947,369)	$ 1.71	—	$ —
Outstanding at September 30, 2026	—	$ —	—	$ —	131,579	$ 1.43

The following table summarizes the Company’s common stock warrant liability change from March 31, 2026, to September 30, 2026 (in thousands). The fair value as of March 31, 2026 represents a recurring measurement that is classified with Level 3 of the fair value hierarchy wherein the fair value is estimated using significant unobservable inputs. The fair value of the common stock warrant liability as of March 31, 2026 was measured using a Monte Carlo model and was remeasured each reporting period, and the change in fair value was recorded in earnings. The fair value of the 2026 Common Warrants is inherently sensitive to changes in the Company's stock price and related volatility assumptions. During the three months ended September 30, 2026, all of the outstanding 2026 Common Warrants were exercised. Immediately prior to exercise, the 2026 Common Warrants were remeasured to fair value using the Company's closing stock price, with changes in fair value recorded in earnings. As of September 30, 2026, the common stock warrant liability was zero.

Beginning common stock warrant liability at March 31, 2026	$ 5,700
Common warrants issued	—
Common warrants exercised	—
Change in fair value	(1,400)
Ending common stock warrant liability at June 30, 2026	$ 4,300
Common warrants issued	—
Change in fair value	2,213
Common warrants exercised	(6,513)
Ending common stock warrant liability at September 30, 2026	$ —

2026 PIPE

In connection with the 2026 PIPE, the Company issued (i) 2026 PIPE Pre-Funded Warrants to purchase up to an aggregate of 4,705,883 shares of the Company’s common stock, par value $0.001 per share, and (ii) accompanying 2026 PIPE Common Warrants to purchase up to an aggregate of 4,705,883 shares of Common Stock, at the combined purchase price of $0.85 per share of Common Stock. Each 2026 PIPE Pre-Funded Warrant has an exercise price of $0.001 per share, was exercisable immediately upon issuance and will remain exercisable until exercised in full. Each 2026 PIPE Common Warrant has an exercise price of $0.85 per share and became exercisable upon the Company’s receipt of stockholder approval in accordance with Nasdaq Listing Rule 5635(d) on September 30, 2026, and will expire on September 30, 2031. The exercise prices of the 2026 PIPE warrants are subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions. 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, . During the three months ended September 30, 2026, 3,141,883 Pre-funded Warrants were exercised. Proceeds from the 2026 PIPE were allocated evenly between the 2026 PIPE Pre-Funded Warrants and the 2026 PIPE Common Warrants.

The following table summarizes the Company's activity under the 2026 PIPE Pre-Funded Warrants and 2026 PIPE Common Warrants from March 31, 2026 to September 30, 2026:

	2026 PIPE Pre-Funded Warrants	Exercise Price	2026 PIPE Common Warrants	Exercise Price
Outstanding at March 31, 2026	—	$ —	—	$ —
Issued	4,705,883	$ 0.001	4,705,883	$ 0.85
Exercised	(3,141,883)	$ 0.001	—	$ —
Outstanding at September 30, 2026	1,564,000	$ 0.001	4,705,883	$ 0.85

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 six months ended September 30, 2026 there were no shares issued under the ESPP. At September 30, 2026, 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 September 30, 2026:

Common stock issuable pursuant to options outstanding and reserved under the 2012 Plan	27,565
Common stock issuable pursuant to options outstanding and reserved under the A&R 2022 Plan	238,796
Common stock reserved under the A&R 2022 Plan	3,167,809
Common stock reserved under the ESPP	3,708
Common stock reserved under the 2021 Inducement Equity Plan	83
Common stock issuable pursuant to options outstanding and reserved under the 2021 Inducement Equity Plan	4,166
Common stock issuable pursuant to outstanding 2024 Common Warrants	539,060
Common stock issuable pursuant to outstanding 2026 PIPE Pre-Funded Warrants	1,564,000
Common stock issuable pursuant to outstanding 2026 PIPE Common Warrants	4,705,883
Common stock issuable pursuant to outstanding Placement Agent Warrants	131,579
Total at September 30, 2026	10,382,649

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 September 30, 2026	Three Months Ended September 30, 2025	Six Months Ended September 30, 2026	Six Months Ended September 30, 2025
Research and development	$ 14	$ 13	$ 28	$ 26
General and administrative	221	59	298	124
Total	$ 235	$ 72	$ 326	$ 150

As discussed in "Note 3. Accrued Expenses", as of September 30, 2026, there was approximately $0.1 million of stock-based compensation expense included within accrued legal and professional fees. The equity was not issued as of September 30, 2026, and therefore it is not included in the stock-based compensation expense amount presented on the consolidated statements of stockholders' equity.

The total unrecognized compensation cost related to unvested stock option grants as of September 30, 2026 was approximately $0.4 million and the weighted average period over which these grants are expected to vest is 2.47 years.

The total unrecognized compensation cost related to unvested RSUs as of September 30, 2026 was zero.

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 September 30, 2026	Three Months Ended September 30, 2025	Six Months Ended September 30, 2026	Six Months Ended September 30, 2025
Dividend yield	—	—	—	—
Volatility	111.00%	111.00%	112.00%	112.30%
Risk-free interest rate	4.38%	3.83%	4.15%	3.87%
Expected life of options	6 years	6 years	6 years	6 years
Weighted average grant date fair value	$ 0.25	$ 1.50	$ 1.01	$ 1.53

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 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. There were no participants in the ESPP for the purchase periods that commenced on September 1, 2026.

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 six months ended September 30, 2026, the Company recorded $29,000 and $47,000 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 $28,000 and $65,000 for the three and six months ended September 30, 2025, respectively.

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 counterclaims for rescission, fraudulent inducement, and breach of contract against H.C. Wainwright. H.C. Wainwright moved to dismiss the Company's counterclaims in November 2025, and the Court granted that motion in July 2026. The Company is defending against H.C. Wainwright’s claims and pursuing its own 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 September 30, 2026, 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 and reasonably estimable 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 September 30, 2026, (in thousands except the year and percentage):

	September 30, 2026
ASSETS	
Operating lease right-of-use assets	$ 165
Total lease right-of-use assets	$ 165
LIABILITIES	
Current	
Operating lease liability	$ 182
Total lease liabilities	$ 182
Weighted average remaining lease term (years):	0.33
Weighted average discount rate:	6%

Variable lease expense was approximately $37,000 and $73,000 for the three and six months ended September 30, 2026, respectively, and approximately $34,000 and $73,000 for the three and six months ended September 30, 2025, respectively. Operating lease expense was approximately $126,000 and $252,000 for the three and six months ended September 30, 2026, and September 30, 2025 respectively.

Cash outflows associated with the Company's operating lease for the three and six months ended September 30, 2026, were approximately $138,000 and $275,000, respectively, and approximately $134,000 and $267,000 for the three and six months ended September 30, 2025, respectively.

Future lease payments relating to the Company's operating lease liabilities as of September 30, 2026 are as follows (in thousands):

Fiscal year ending March 31, 2027	185
Total future lease payments	185
Less: Imputed interest	(3)
Total lease obligations	182
Less: Current obligations	(182)
Noncurrent lease obligations	$ —

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's receivables related to service revenue have been derived from a small amount of customers, and there has been no indicators of credit risk to date. 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 September 30, 2026.

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 fiscal 2026 and fiscal 2027, the companies added Statements of Work to the Intercompany Agreement, where Viscient agreed to provide the Company with certain consulting and testing services related to the Company's ongoing R&D and commercial services. The Company evaluated the accounting for the Intercompany Agreement and concluded that any R&D 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 Statements of Work where Viscient provides commercial services for the Company's service customers are considered cost of services performed by the Company. 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 six months ended September 30, 2026, the Company incurred $185,000 and $383,000 in R&D consulting expenses from Viscient, respectively. For each of the three and six months ended September 30, 2026, the Company incurred $58,000 in commercial service expenses from Viscient. Of the $58,000 in commercial service expenses, approximately $35,000 was included within cost of services provided on the consolidated statement of operations, and $23,000 was included within work in progress costs on the consolidated balance sheets as of September 30, 2026. As of September 30, 2026, the accounts payable balance to Viscient was approximately $69,000 and there was approximately $79,000 in accrued expenses. As of March 31, 2026, the accounts payable balance to Viscient was approximately $56,000 and there was zero accrued expenses. For the three and six months ended September 30, 2025, the Company incurred $144,000 and $216,000 in R&D consulting expenses from Viscient, respectively. Additionally, for the three and six months ended September 30, 2026 and 2025, the Company provided zero and $5,000 of histology services to Viscient, respectively.

On October 29, 2026, VivoSim Inc., the Company's wholly-owned subsidiary, entered into a Technology License and Tech-Transfer Agreement with Viscient. Please refer to "Note 11. Subsequent Events" for further details.

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 2027, and thus one reportable segment.

For purposes of evaluating performance and allocating resources, the Company's CODM, its Executive Chairman, regularly reviews Consolidated Operating 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.

The operating 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 works 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.

In addition to the significant expense categories included within Consolidated Operating 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 six months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Six Months Ended September 30, 2026	Six Months Ended September 30, 2025
Revenue				
Services revenue	$ 22	$ —	$ 22	$ —
Royalty revenue	29	28	47	65
Total revenue	51	28	69	65
Operating expenses				
Cost of services provided	56	—	56	—
Research and development expenses (a)(b)	1,051	855	2,133	1,787
Selling, general, and administrative expenses (a)(b)	1,990	1,677	3,554	3,558
Non-cash stock-based compensation (see Note 4)	235	72	326	150
Depreciation and amortization	35	59	75	120
Total operating expense	$ 3,367	$ 2,663	$ 6,144	$ 5,615
Consolidated operating loss	$ (3,316)	$ (2,635)	$ (6,075)	$ (5,550)

(a) Stock-based compensation expense of $14,000 and $28,000 related to research and development and $221,000 and $298,000, related to selling, general, and administration have been excluded for the three and six months ended September 30, 2026, respectively. Stock-based compensation expense of $13,000 and $26,000 related to research and development and $59,000 and $124,000, related to selling, general, and administration have been excluded for the three and six months ended September 30, 2025, respectively.
(b) Depreciation and amortization expense of $31,000 and $67,000 related to research and development as well as $4,000 and $8,000 related to selling, general, and administration have been excluded for the three and six months ended September 30, 2026, respectively. Depreciation and amortization expense of $55,000 and $111,000 related to research and development as well as $4,000 and $9,000 related to selling, general, and administration have been excluded for the three and six months ended September 30, 2025, respectively.

Note 11. Subsequent Events

Lease Amendment

On October 13, 2026, Organovo, Inc., a wholly owned subsidiary of the Company, entered into a Second Amendment to Amended and Restated Lease with San Diego Inspire 2, LLC, which, among other things, (i) requires the Company to vacate and surrender Suite 202 on or before February 28, 2027, (ii) extends the term with respect to Suite 100 from March 1, 2027 through April 30, 2028, (iii) adjusts the monthly base rent to $43,072.85 and (iv) provides for a rental abatement of $21,536.43 per month for the period from March 1, 2027 through June 30, 2027, for an aggregate rental abatement of $86,145.70.

Viscient License Agreement

On October 29, 2026, VivoSim Inc., the Company's wholly-owned subsidiary, entered into a Technology License and Tech-Transfer Agreement (the "Viscient License Agreement") with Viscient. Pursuant to the Viscient License Agreement, Viscient granted VivoSim Inc. an exclusive (subject to rights reserved by Viscient), worldwide, non-transferable license, sublicensable to the Company's affiliates and, with Viscient's consent, to third parties, under Viscient's NAMKind Liver Model platform, including related know-how, protocols, standard operating procedures, reagent specifications and patents and patent applications (the "Licensed Technology"), to commercialize services in the field of non-animal toxicity and normal liver-tissue safety screening services and to use the Licensed Technology for internal research and development. Viscient also agreed to provide training, documentation and validation materials to transfer the Licensed Technology to the Company, and to use reasonable efforts to complete such technology transfer within 90 to 120 days after the effective date. In consideration, the Company agreed to pay Viscient (i) a non-refundable upfront license fee of $100,000, (ii) a technology transfer fee of $150,000, payable in three $50,000 tranches upon commencement of the technology transfer, delivery of materials and completion of training, and the first successful validation run, which payment may be deferred until the Company has recorded $337,079 of revenue from services covered by the agreement, (iii) tiered royalties of 11%, 9% and 7% on annual net services revenue generated using the Licensed Technology of up to $5.0 million, between $5.0 million and $15.0 million, and above $15.0 million, respectively, (iv) a royalty of 7% on net services revenue generated using in silico, machine learning, artificial intelligence or other models developed primarily using data generated from assays performed using the Licensed Technology, (v) beginning in the second year of the term, an annual minimum royalty of $75,000, which is creditable against earned

royalties for the same year, and (vi) 35% of any sublicense income. The Company granted Viscient a non-exclusive, royalty-free license to improvements the Company makes to the Licensed Technology, with any use in the Company's field limited to non-competitive internal research and development. The Viscient License Agreement has an initial term of eight years, which may be extended for successive two-year terms by mutual agreement, and may be terminated by the Company for convenience upon 180 days' prior written notice (subject to payment of a pro rata portion of the annual minimum royalty), or by either party for uncured material breach or upon specified bankruptcy events. The Viscient License Agreement was approved by the Audit Committee in accordance with the Company's related party transaction policy.

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, 2026. 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, 2026, filed with the Securities and Exchange Commission on July 14, 2026, 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, 2026, filed with the SEC on Form 10-K on July 14, 2026, 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 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 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. 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 June 2026 European Toxicology Meeting scientific conference showing that our liver toxicology platform had a best-in-class predictive power. Our liver predictive power was shown to be >90% sensitivity 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 many of the missed cases could be seen as liver toxic using NAMkind™ liver. This is known as the sensitivity of the platform, which at >90% we believe is a world's best. The specificity was >95%, meaning that few of the compounds tested that are not liver toxic were incorrectly identified as having liver toxicity issues by the platform. We have obtained an exclusive license to the NAMKind Liver Model platform from Viscient Biosciences, Inc. within the field of non-animal toxicity and normal liver-tissue safety screening services pursuant to a Technology License and Tech-Transfer Agreement with Viscient. See "Note 9. Related Parties" and "Note 11. Subsequent Events" to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for further details.

Prior to March 2025, we were a clinical stage biotechnology company that was focused on developing FXR314 in inflammatory bowel disease ("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 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 at that time also focused 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.

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. In July 2026, we received a milestone payment in the amount of $5.0 million upon the achievement of a certain development milestone related to FXR314. Additionally, in July 2026, the $1.0 million held in escrow was released to us. The current remaining total potential for additional milestone payments includes up to $45M in milestones, including a $15M milestone which is to be paid upon Eli Lilly first dosing a patient in a Phase 3 clinical trial.

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 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.

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. 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.

During the three months ended September 30, 2026, the Company adopted new accounting policies regarding service revenue recognition, and related work in progress, cost of services provided, and allowance for credit losses. Service revenue utilizes point-in-time recognition when a single performance obligation is fulfilled. Costs of services provided relates to costs incurred to produce service revenue, which includes direct materials, direct labor, and facility overhead costs. Work in progress represents costs incurred related to service contracts that is not completed as of the end of a reporting period. These accounting policies represent significant changes to our critical accounting policies since March 31, 2026. 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, 2026, filed with the SEC on July 14, 2026.

Results of Operations

Comparison of the three months ended September 30, 2026 and 2025:

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025 (in thousands, except %):

	Three Months Ended September 30,		Increase (decrease)	

	2026	2025	$	%
Service revenue	$ 22	$ —	$ 22	—
Royalty revenue	$ 29	$ 28	$ 1	4%
Cost of services provided	$ 56	$ —	$ 56	—
Research and development expenses	$ 1,096	$ 923	$ 173	19%
Selling, general and administrative	$ 2,215	$ 1,740	$ 475	27%
Other income	$ 2,841	$ 92	$ 2,749	2,988%

Revenues

For the three months ended September 30, 2026 and 2025, total revenue was less than $0.1 million. Service revenue is related to the Company's liver and intestinal toxicology and disease predictive screening research services. The second quarter of fiscal 2027 was the first quarter that we generated service revenue. Going forward, our main focus is to grow service revenue, and we expect service revenue to increase in the coming quarters.

Royalty revenue is related to sales-based royalties from licensing intellectual property. We expect royalty revenue to remain consistent with the current quarter going forward.

Cost of Services Provided

For the three months ended September 30, 2026, cost of services provided was approximately $0.1 million. Cost of services provided directly relates to service revenue generated. Cost of services provided include materials, labor, and overhead expenses to perform our liver and intestinal toxicology and disease predictive screening research services for customers. The second quarter of fiscal 2027 was the first quarter that we generated service revenue, and we offered significant discounts for our initial pilot contracts. Going forward, as we grow service revenue and improve efficiencies, we expect our gross margins to improve and cost of services provided to increase at a slower pace relative to increases in service revenue.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2026 and 2025 (in thousands, except %):

	Three Months Ended September 30, 2026	% of total	Three Months Ended September 30, 2025	% of total	Increase (decrease) $	Increase (decrease) %
Research and development expenses	$ 1,051	96%	$ 855	93%	$ 196	23%
Non-cash stock-based compensation	14	1%	13	1%	1	8%
Depreciation and amortization	31	3%	55	6%	(24)	(44%)
Total research and development expenses	**$ 1,096**	**100%**	**$ 923**	**100%**	**$ 173**	**19%**

For the three months ended September 30, 2026, total research and development expenses were $1.1 million, an increase of approximately $0.2 million, or 19%, from the prior year period. Our average full-time research and development staff increased from an average of nine full-time employees for the three months ended September 30, 2025, to an average of twelve full-time employees for the three months ended September 30, 2026. Our operations for the three months ended September 30, 2026 as compared to the three months ended September 30, 2025 resulted in a $0.2 million increase in personnel related expenses, which includes stock-based compensation, due to the increase in headcount. Going forward, we expect personnel related expenses to increase due to an increase in headcount. We expect research and development expenses to remain consistent or decrease with the current quarter, as we expect a relative shift from research and development expenses to cost of services provided as our service revenue operations continue to grow in the upcoming quarters.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended September 30, 2026 and 2025 (in thousands, except %):

	Three Months Ended September 30, 2026	% of total	Three Months Ended September 30, 2025	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 1,990	90%	$ 1,677	96%	$ 313	19%
Non-cash stock-based compensation	221	10%	59	3%	162	275%
Depreciation and amortization	4	0%	4	1%	—	0%
Total selling, general and administrative expenses	**$ 2,215**	**100%**	**$ 1,740**	**100%**	**$ 475**	**27%**

For the three months ended September 30, 2026, total selling, general and administrative expenses were approximately $2.2 million, an increase of approximately $0.5 million, or 27%, from the prior year period. Our average full-time selling, general and administrative staff remained flat with four full-time employees for the three months ended September 30, 2026 and September 30, 2025, respectively. Our operations for the three months ended September 30, 2026 as compared to the three months ended September 30, 2025 resulted in a $0.2 million increase in personnel related expenses, which is due to an increase in stock-based compensation costs. The increase was offset by a decrease in recruiting expenses of $0.2 million related to the prior year. Other increased costs in the current year included a $0.1 million increase in consulting costs, a $0.1 million increase in facility costs, and a $0.3 million increase in other general corporate costs. The increase in general corporate costs is attributed to legal and investor relation costs due to our annual meeting held during the three months ended September 30, 2026, whereas in prior year the meeting occurred in the following quarter. Going forward, we expect selling, general and administrative expenses to remain consistent with the current quarter.

Other Income

Other income was approximately $2.8 million for the three months ended September 30, 2026 due to a $5.0 million gain upon the achievement of a milestone related to the sale of the FXR314 asset in a prior year. The $5.0 million milestone payment was collected in July 2026. The $5.0 million gain was offset by a $2.2 million loss due to the change in fair value of common stock warrant liabilities. During the three months ended September 30, 2026, all of the underlying common warrants were exercised, and therefore the common stock warrant liability was zero as of September 30, 2026. Other income was $0.1 million for the three months ended September 30, 2025, mainly due to interest income.

Comparison of the six months ended September 30, 2026 and 2025:

The following table summarizes our results of operations for the six months ended September 30, 2026 and 2025 (in thousands, except %):

	Six Months Ended September 30, 2026	Six Months Ended September 30, 2025	Increase (decrease) $	Increase (decrease) %
Service revenue	$ 22	$ —	$ 22	—
Royalty revenue	$ 47	$ 65	$ (18)	(28%)
Cost of services provided	$ 56	$ —	$ 56	—
Research and development expenses	$ 2,228	$ 1,924	$ 304	16%
Selling, general and administrative	$ 3,860	$ 3,691	$ 169	5%
Other income	$ 4,265	$ 164	$ 4,101	2,501%

Revenues

For the six months ended September 30, 2026 and 2025, total revenue was $0.1 million. Service revenue is related to the Company's liver and intestinal toxicology and disease predictive screening research services. The second quarter of fiscal 2027 was the first quarter that we generated service revenue. Going forward, our main focus is to grow service revenue, and we expect service revenue to increase in the coming quarters.

Royalty revenue is related to sales-based royalties from licensing intellectual property. We expect royalty revenue to remain consistent with the current quarter going forward.

Cost of Services Provided

For the six months ended September 30, 2026, cost of services provided was approximately $0.1 million. Cost of services provided directly relates to service revenue generated. Cost of services provided include materials, labor, and overhead expenses to perform our liver and intestinal toxicology and disease predictive screening research services for customers. The second quarter of fiscal 2027 was the first quarter that we generated service revenue, and we offered significant discounts for our initial pilot contracts. Going forward, as we grow service revenue and improve efficiencies, we expect our gross margins to improve and cost of services provided to increase at a slower pace relative to increases in service revenue.

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended September 30, 2026 and 2025 (in thousands, except %):

	Six Months Ended September 30, 2026	% of total	Six Months Ended September 30, 2025	% of total	Increase (decrease) $	Increase (decrease) %
Research and development expenses	$ 2,133	96%	$ 1,787	93%	$ 346	19%
Non-cash stock-based compensation	28	1%	26	1%	2	8%
Depreciation and amortization	67	3%	111	6%	(44)	(40%)
Total research and development expenses	**$ 2,228**	**100%**	**$ 1,924**	**100%**	**$ 304**	**16%**

For the six months ended September 30, 2026, total research and development expenses were $2.2 million, an increase of approximately $0.3 million, or 16%, from the prior year period. Our average full-time research and development staff increased from an average of nine full-time employees for the six months ended September 30, 2025, to an average of eleven full-time employees for the six months ended September 30, 2026. Our operations for the six months ended September 30, 2026 as compared to the six months ended September 30, 2025 resulted in a $0.2 million increase in personnel related expenses, which includes stock-based compensation, due to the increase in headcount. There was also a $0.1 million increase in consulting costs, mainly related to improving offerings for the service operations. Going forward, we expect personnel related expenses to increase due to an increase in headcount. We expect research and development expenses to remain consistent or decrease with the current quarter, as we expect a relative shift from research and development expenses to cost of services provided as our service revenue operations continue to grow in the upcoming quarters.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the six months ended September 30, 2026 and 2025 (in thousands, except %):

	Six Months Ended September 30, 2026	% of total	Six Months Ended September 30, 2025	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 3,554	92%	$ 3,558	96%	$ (4)	0%
Non-cash stock-based compensation	298	8%	124	4%	174	140%
Depreciation and amortization	8	0%	9	0%	(1)	(11%)
Total selling, general and administrative expenses	**$ 3,860**	**100%**	**$ 3,691**	**100%**	**$ 169**	**5%**

For the six months ended September 30, 2026, total selling, general and administrative expenses were approximately $3.9 million, an increase of approximately $0.2 million, or 5%, from the prior year period. Our average full-time selling, general and administrative staff remained flat at four full-time employees for the six months ended September 30, 2026 and September 30, 2025, respectively. Our operations for the six months ended September 30, 2026 as compared to the six months ended September 30, 2025 resulted in a $0.3 million increase in personnel related expenses, which includes stock-based compensation. The increase was offset by a decrease in recruiting expenses of $0.2 million related to the prior year. Other increased costs in the current year included a $0.1 million increase in consulting costs and a $0.1 million increase in facility costs, which were offset by a $0.1 million decrease in other general corporate costs. Going forward, we expect selling, general and administrative expenses to remain consistent with the current quarter.

Other Income

Other income was approximately $4.3 million for the six months ended September 30, 2026, due to a $5.0 million gain upon the achievement of a milestone related to the sale of the FXR314 asset in a prior year. The $5.0 million milestone payment was collected in July 2026. The $5.0 million gain was offset by a $0.8 million loss due to the change in fair value of common stock warrant liabilities. The remaining $0.1 million was due to interest income. During the six months ended September 30, 2026, all of the underlying common warrants were exercised, and therefore the common stock warrant liability was zero as of September 30, 2026. Other income was $0.2 million for the six months ended September 30, 2025, mainly due 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 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 September 30, 2026, we had cash and cash equivalents of approximately $8.6 million, restricted cash of approximately $0.1 million and an accumulated deficit of $357.8 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 $5.7 million during the six months ended September 30, 2026. At March 31, 2026, we had cash and cash equivalents of approximately $5.0 million, restricted cash of approximately $0.1 million and an accumulated deficit of approximately $356.0 million.

At September 30, 2026, we had total current assets of approximately $9.4 million and current liabilities of approximately $2.7 million, resulting in working capital of $6.7 million. At March 31, 2026, we had total current assets of approximately $6.6 million and current liabilities of approximately $2.8 million, resulting in working capital of $3.8 million.

In July 2026, we received a milestone payment of $5.0 million in connection with the FXR Asset Sale upon the achievement of a certain development milestone. Additionally, in July 2026, the $1.0 million held in escrow as part of the FXR Asset Sale was released to us.

On July 16, 2026, we entered into a Securities Purchase Agreement with an accredited institutional investor (the “Purchaser”), pursuant to which, among other things, we issued and sold to the Purchaser, in a private placement transaction that closed on July 17, 2026, (i) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to an aggregate of 4,705,883 shares of the Company’s common stock, par value $0.001 per share (the “Common Stock”), and (ii) accompanying warrants to purchase up to an aggregate of 4,705,883 shares of Common Stock (the “Common Warrants”), at the combined purchase price of $0.85 per share of Common Stock subject to the Pre-Funded Warrants and accompanying Common Warrants, for gross proceeds to us of approximately $4.0 million and net proceeds of approximately $3.4 million, after deducting offering expenses. In connection with the private placement, we also amended certain outstanding warrants held by the Purchaser to reduce the exercise price to $0.85 per share, which became effective upon stockholder approval on September 30, 2026, and to extend the term to September 30, 2031.

The following table summarizes the primary sources and uses of cash for the six months ended September 30, 2026 and 2025 (in thousands):

	Six Months Ended September 30,	
	2026	2025
Net cash (used in) provided by:		
Operating activities	$ (5,691)	$ (6,318)
Investing activities	5,929	—
Financing activities	3,302	1,683
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 3,540	$ (4,635)

Operating activities

Net cash used in operating activities for the six months ended September 30, 2026 was approximately $5.7 million as compared to $6.3 million used in operating activities for the six months ended September 30, 2025. This $0.6 million decrease in operating cash usage can be attributed primarily to the timing of payables.

Investing activities

Net cash provided by investing activities for the six months ended September 30, 2026 was approximately $5.9 million and is attributed to a development milestone payment of $5.0 million related to the asset sale of FXR314 in a prior year. As well as the $1.0 million released to us from escrow account related to the sale of FXR314.

Financing activities

Net cash provided by financing activities for the six months ended September 30, 2026 was $3.3 million and consisted of net proceeds of approximately $3.4 million from a private placement transaction in July 2026. This was offset by approximately $0.1 million of repayments of the insurance premium financing liability. Net cash provided by financing activities was $1.7 million for the six months ended September 30, 2025, and 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 $0.1 million.

Operations funding requirements

Through September 30, 2026, we have financed our operations primarily through the sale of common stock through private placement, 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 related developmental milestone payments, 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. Our license and collaboration obligations include payments under the Viscient License Agreement, consisting of a $100,000 upfront license fee, a $150,000 technology transfer fee, royalties on net services revenue and, beginning in the second year of the term, an annual minimum royalty. We expect our total operating expense for the fiscal year ending March 31, 2027 to be $10.7 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 JonesTrading 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 Agent, shares of our 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 six months ended September 30, 2026, we did not issue any shares of common stock pursuant to the 2024 Shelf. As of September 30, 2026, 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 September 30, 2026, 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.

On March 31, 2026, we priced the 2026 Offering, which consisted of: (i) 286,557 shares of our common stock and 429,836 accompanying common warrants ("2026 Common Warrants") to purchase up to 429,836 shares of common stock at a combined public offering price of $1.14 per share and accompanying one and a half 2026 Common Warrants to purchase one share common stock and (ii) 2,345,022 pre-funded warrants ("2026 Pre-Funded Warrants") to purchase 2,345,022 shares of common stock and 3,517,533 accompanying 2026 Common Warrants to purchase up to 3,517,533 shares of common stock at a combined public offering price of $1.139 per 2026 Pre-Funded Warrant and accompanying one and a half 2026 Common Warrants to purchase one share of common stock. Each 2026 Common Warrant will have an exercise price of $1.71 per share of common stock. The closing of the Offering occurred on March 31, 2026. We received gross proceeds of approximately $3.0 million and net proceeds of approximately $2.4 million from the 2026 Offering, after deducting the offering expenses payable by us, including the placement agent fees. The fair value of the placement agent warrants was approximately $0.1 million and was also considered an offering expense. All offering expenses were included within selling, general, and administrative expenses in the consolidated statement of operations and comprehensive loss during the year ended March 31, 2026. As the fair value of the common stock warrant liability of $5.7 million exceeded the gross proceeds from the offering, we recognized a $2.7 million loss on issuance of common stock during the year ended March 31, 2026. The common stock warrant liability is remeasured to its fair value at the end of each reporting period, with a change in fair value recorded in other income. As of September 30, 2026, all 2026 Pre-Funded Warrants were fully exercised.

During the three months ended September 30, 2026, 3,947,369 2026 Common Warrants were exercised via an alternative cashless exercise provision. As a result of the exercise, 9,612,823 shares of common stock were issued. As of September 30, 2026, all 2026 Common Warrants were exercised, and the related common stock warrant liability was zero.

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, 2026, filed with the SEC on July 14, 2026.

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, 2026 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 on 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 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 have only recently begun generating service revenue, have a limited operating history as a services company and may not be able to grow our services business as we expect.***

We began generating service revenue from our liver and intestinal toxicology and disease predictive screening research services during the quarter ended September 30, 2026, and we recognized approximately $22,000 of service revenue and approximately $56,000 of cost of services provided for the three months ended September 30, 2026. Our services business is therefore at an early stage, and we have a limited operating history upon which investors can evaluate our ability to market and sell our services, price our services profitably, perform our contracts on time and within budget and scale our operations. There can be no assurance that we will achieve the revenue growth we anticipate, that our gross margins will improve as we expect or that our services business will ever generate revenue sufficient to fund our operations. Because our service contracts generally contain a single performance obligation and we recognize revenue at the point in time when we transfer a final report to the customer, our revenue may fluctuate significantly from quarter to quarter based on when projects are completed, and delays in completing projects, including delays caused by customers, suppliers or third parties that perform services on our behalf, could shift revenue between periods. If we are unable to grow our services business, our business, financial condition and results of operations would be materially adversely affected.

****We rely on a limited number of key customers, the importance of which may vary significantly from period to period, and the loss of one or more of these key customers, or the cancellation, delay or reduction in scope of their projects, could adversely affect our results of operations.***

We began generating service revenue during the quarter ended September 30, 2026, and our service revenue to date has been derived from a small number of customers. The loss of a significant amount of business from one or more of our customers would materially and adversely affect our results of operations until such time, if ever, as we are able to replace the lost business. Significant customers or projects in any one period may not continue to be significant customers or projects in other periods. In any given period, there is a possibility that a single customer may account for a significant percentage of our total service revenue or that our business may depend o*n one or* more large projects. Since we do not have long-term contracts with our customers, the importance of a single customer may vary dramatically from period to period as projects end and new projects begin. To the extent that we are meaningfully

dependent on any single customer, we are indirectly subject to risks related to that customer, including if such risks impede the customer's ability to stay in business, to fund its research and development programs or otherwise to make timely payments to us.

We rely on Viscient, a related party, to perform certain services that we provide to our customers, and any failure by Viscient to perform could harm our services business and reputation.

We have entered into statements of work under our intercompany agreement with Viscient Biosciences, Inc. ("Viscient"), an entity for which our Executive Chairman serves as Chief Executive Officer, pursuant to which Viscient provides certain commercial services that we use in performing our service contracts for our customers, in addition to research and development consulting and testing services. During the three months ended September 30, 2026, we incurred approximately $58,000 of commercial service expenses from Viscient. As a result, our ability to timely and accurately deliver our services to customers depends in part on Viscient's personnel, facilities, equipment and performance. Under our Technology License and Tech-Transfer Agreement with Viscient (the "Viscient License Agreement"), Viscient has agreed to transfer its NAMKind Liver Model platform to us so that we can perform these services ourselves, and to use reasonable efforts to complete the technology transfer within 90 to 120 days after the effective date of that agreement. The technology transfer may take longer than expected, may require additional resources, or may not be completed successfully, including if we are unable to meet the validation acceptance criteria, and until it is completed we will continue to depend on Viscient. If Viscient fails to perform these services or the technology transfer in a timely manner or in accordance with required quality standards, ceases to provide these services, increases the price of these services or experiences financial, operational or other difficulties, we may be unable to meet our obligations to our customers, our reputation could be harmed and we may be required to obtain these services from another provider, which could result in delays and increased costs. Moreover, because Viscient is a related party, the terms of these arrangements may not be as favorable to us as those we could obtain from an unaffiliated third party, and conflicts of interest may arise as described under "We may experience conflicts of interest with Viscient Biosciences, Inc. with respect to business opportunities and other matters" below.

If our testing services do not perform as expected, contain errors or are not accepted by customers or regulators, we could suffer reputational harm, lose customers and be subject to liability claims.

Our customers may use the data and reports we deliver to inform decisions regarding the development of their drug candidates, including decisions regarding which candidates to advance into clinical trials. Our 3D human tissue models and new approach methodologies are relatively new, and the predictive performance we have observed in prior studies, including the sensitivity and specificity results we have presented, may not be replicated across a broader set of compounds or in customer programs. If our models fail to identify a toxicity or other adverse effect, incorrectly identify a toxicity that does not exist, or if our reports contain errors, customers could lose confidence in our services, we could lose customers or be required to re-perform services at our expense, and we could be subject to claims for damages. In addition, although the FDA has announced plans to reduce animal testing requirements in favor of non-animal methods, regulatory acceptance of new approach methodologies remains uncertain and evolving, and if regulators do not accept data generated using our models, or if the anticipated shift away from animal testing occurs more slowly than we expect or not at all, demand for our services may not grow as we anticipate. We may not maintain insurance sufficient to cover any liability claims, and the limitations of liability in our customer contracts may not be enforceable or sufficient to protect us.

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 while we began generating service revenue during the quarter ended September 30, 2026, we do not expect our revenue to be sufficient to fund our operations for 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 September 30, 2026, 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 who 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 potential 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 result 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 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, 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.

Our use of generative artificial intelligence tools in our operations may expose us to risks related to confidentiality, accuracy, regulatory compliance and intellectual property ownership or rights.

We may utilize generative artificial intelligence ("AI") tools in certain aspects of our operations, including drafting, analysis, administrative functions and other business processes. While these technologies may enhance efficiency, their use involves risks and

challenges that could adversely affect our business and reputation, including with regard to cybersecurity, data privacy, IT, confidentiality, regulatory, legal, operational, competitive, reputational and intellectual property, among others.

Generative AI platforms are typically operated by third-party providers and may process information through external systems. Although we maintain internal policies governing the use of such tools, there can be no assurance that confidential, proprietary or sensitive information will not be inadvertently disclosed, misused or accessed by unauthorized parties. Any such disclosure could result in reputational harm, competitive disadvantage, regulatory scrutiny or potential legal liability.

In addition, AI-generated outputs may contain inaccuracies, incomplete information, outdated data or unintended biases. If such outputs are relied upon without appropriate review and validation, they could impair internal decision-making or result in errors in communications or disclosures.

The legal and regulatory landscape surrounding artificial intelligence technologies is evolving. Future laws, regulations or regulatory interpretations could impose additional requirements or restrictions on the use of AI tools, increase compliance costs or limit our ability to utilize such technologies effectively.

Further, uncertainty regarding intellectual property ownership or rights associated with AI-generated materials may create additional legal risk. Any failure to appropriately manage the risks associated with our use of generative AI tools could adversely affect our operations, financial condition or results of operations.

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.

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.

Changes in government funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent our potential product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business, financial condition and results of operations.

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 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 that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. In addition, government shutdowns, if prolonged, could significantly impact the ability of government agencies upon which we rely, such as the FDA and SEC, to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In December 2016, the 21st Century Cures Act was signed into law. This legislation is designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. However, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform its roles, including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources.

Disruptions at the FDA and other agencies 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. For example, over the past decade, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, 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. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

Finally, with the change in U.S. presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our potential product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our potential product candidates. If we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our potential product candidates, the commercial prospects for our potential product candidates may be harmed and our ability to generate revenue will be materially impaired.

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, 2026 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 September 30, 2026 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, 2026 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 September 30, 2026 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 September 30, 2026, we had total current assets of approximately $9.4 million and current liabilities of approximately $2.7 million, resulting in working capital of $6.7 million. We have generated operating losses each year since we began operations, including $6.1 million and $5.6 million for the six months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $357.8 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 the number, size and timing of service contracts and 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 our internal control over financial reporting 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. In July 2026, we received a milestone payment in the amount of $5.0 million upon the achievement of a certain development milestone related to the FXR314 Asset sale; however, there can be no assurance that we will be entitled to receive any additional milestone payments, and there is risk that any or all of the additional 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 additional 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 to 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. 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 extended through December 27, 2031. 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 during fiscal 2027, Viscient has provided us with research and development consulting services as well as commercial services that we use in performing services for our customers. We expect to continue to provide services to and receive services from Viscient and to 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 fiscal 2027 and fiscal 2026, the companies added Statements of Work to the Intercompany Agreement, where Viscient agreed to provide us with certain consulting and testing services related to our ongoing research and development and, during fiscal 2027, certain commercial services that we use in performing services for our customers. 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.

On July 20, 2026, we received a written notice from the Listing Qualifications Staff of Nasdaq (the "Staff") indicating that, since our Annual Report on Form 10-K for the period ended March 31, 2026, reported stockholders' equity of $(1,099,000), and as of July 20, 2026, we did not meet the alternatives of market value of listed securities or net income from continuing operations, we no longer met the requirement to maintain a minimum of $2,500,000 in stockholders' equity, as set forth in Rule 5550(b)(1). On August 4, 2026, we received a notice from the Staff indicating that we regained compliance with Nasdaq Listing Rule 5550(b)(1).

On August 17, 2026, we received a written notice from the Staff indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer met the requirement to maintain a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided with an initial period of 180 calendar days, or until February 16, 2027, to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least $1 per share for a minimum of ten consecutive business days during this 180-day period. If we do not regain compliance with Rule 5550(a)(2) by February 16, 2027, we may be eligible for an additional compliance period of 180 calendar days. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice to Nasdaq of our intention to cure the bid price deficiency during the second compliance period. However, if it appears to the Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq would notify us that our securities will be subject to delisting. In the event of such a notification, we may appeal the Staff's determination to delist its securities, but there can be no assurance the Staff would grant any request for continued listing. On September 30, 2026, our stockholders approved an amendment to our Certificate of Incorporation to effect a reverse stock split at a ratio to be determined by our Board of Directors within a range of 1-for-5 to 1-for-20, at any time on or before September 30, 2027. There can be no assurance that we will regain compliance with the minimum bid price requirement, that we will effect a reverse stock split or that we will maintain our compliance with the other listing requirements necessary for us to maintain the listing of our common stock on the Nasdaq Capital Market.

Additionally, Nasdaq has adopted Listing Rules 5450(a)(3) and 5550(a)(6), which would require issuers to maintain a minimum Market Value of Listed Securities ("MVLS") of at least $5 million (the "MVLS Requirement"). On July 22, 2026, the staff of the SEC's Division of Trading and Markets, acting pursuant to delegated authority, approved the Nasdaq rule change. Under the rule as approved, an issuer whose MVLS remains below $5 million for 30 consecutive business days would be subject to immediate suspension and delisting without a cure or compliance period, and a request for review by a Nasdaq Hearings Panel would not stay the suspension of trading. However, on July 29, 2026, the SEC received notices of intention to petition for review of the delegated action and, pursuant to Rule 431(e) of the SEC's Rules of Practice, the July 22, 2026 approval order was automatically stayed pending review by the full SEC. As a result, the MVLS Requirement and the related immediate suspension and delisting provisions are not currently in effect and will remain stayed unless and until the SEC orders otherwise. The SEC may ultimately affirm, modify or set aside the delegated action, and there can be no assurance as to the outcome or timing of the SEC's review, whether the MVLS Requirement will take effect in its current form, a modified form or at all, or if the MVLS Requirement or a modification thereof takes effect, that we will be compliant, or maintain compliance, with such.

A delisting from the Nasdaq Capital Market and commencement of trading on over-the-counter market, such as those operated by OTC Markets Group Inc., 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 current 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 September 30, 2026, our closing stock price ranged from $0.20 to $1.06 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 September 30, 2026, there were an aggregate of 28,450,144 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 18,067,495 shares issued and outstanding, 3,438,419 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 6,940,522 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 recently expanded our intellectual property footprint related to this platform in part by acquiring the rights from Viscient through a license to certain key technologies related to this platform.

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 counterclaims for rescission, fraudulent inducement, and breach of contract against H.C. Wainwright. H.C. Wainwright moved to dismiss our counterclaims in November 2025, and the Court granted that motion in July 2026. We are defending against H.C. Wainwright's claims, 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 DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

During the fiscal quarter ended September 30, 2026, 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).
4.2	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1 (File No. 333-294716) filed with the Securities and Exchange Commission on March 27, 2026).
4.3	Form of Pre-Funded Warrant to Purchase Shares of Common Stock (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 17, 2026).
4.4	Form of Common Stock Purchase Warrant to Purchase Shares of Common Stock (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the SEC on July 17, 2026).
4.5	Amendment to Common Stock Purchase Warrants, dated July 16, 2026, between the Company and Armistice Capital Master Fund Ltd. (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on July 17, 2026).
10.1	Securities Purchase Agreement, dated July 16, 2026, between the Company and the purchaser identified on the signature page thereto (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 17, 2026).
10.2	Placement Agency Agreement, dated July 16, 2026, between the Company and A.G.P./Alliance Global Partners (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on July 17, 2026).
10.3†	VivoSim Labs, Inc. Amended and Restated 2022 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 6, 2026).
31.1*	Certification of Keith Murphy, Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Norman Staskey, Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Keith Murphy, Principal Executive Officer, and Norman Staskey, Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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).*

Exhibit No.	Description
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).*

Certain identified information has been omitted pursuant to Item 601(b)(2)(ii) of Regulation S-K because such information is both (i) not material and (ii) the type that the Registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the Securities and Exchange Commission.

* Filed herewith.

** Furnished herewith.

† Indicates management contract or compensatory plan.

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: November 12, 2026

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

Date: November 12, 2026

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

Exhibit 31.1

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: November 12, 2026

/s/ Keith Murphy
Keith Murphy
Executive Chairman
(Principal Executive Officer)

Exhibit 31.2

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: November 12, 2026

/s/ Norman Staskey

Norman Staskey
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of VivoSim Labs, Inc. (the "Company") for the period ended September 30, 2026, 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: November 12, 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.