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

# FORM 10-K

**(Mark One)**

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

**For the Fiscal Year Ended March 31, 2025**

**OR**

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

**For the Transition Period from _____to**

**Commission File No. 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)* | *(IRS Employer Identification No.)* |
| **11555 Sorrento Valley Rd, Suite 100 San Diego, CA** | **92121** |
| *(Address of principal executive offices)* | *(Zip code)* |

**Registrant's telephone number, including area code: 858-224-1000**

**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, par value $0.001 per share | VIVS | The Nasdaq Stock Market LLC |

**Securities registered pursuant to section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on the closing stock price as reported on the Nasdaq Capital Market on September 30, 2024, the last trading day of the registrant's most recently completed second fiscal quarter, was $7,720,472. For purposes of this computation only, shares of common stock held by each executive officer, director, and 10% or greater stockholders have been excluded in that such persons may be deemed affiliates.

The number of outstanding shares of the registrant's common stock, as of June 1, 2025 was 2,599,797.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required for Part III of this report is incorporated herein by reference to the definitive proxy statement for the 2025 annual meeting of the registrant's stockholders, expected to be filed within 120 days of the end of the registrant's fiscal year.

**VivoSim Labs, Inc.**

**Annual Report on Form 10-K**

**For the Year Ended March 31, 2025**

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**Important Information Regarding Forward-Looking Statements**

Portions of this Annual Report on Form 10-K (including information incorporated by reference) ("Annual Report") include "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995, based on our current beliefs, expectations and projections regarding any strategic transaction process; the ability to advance our research and development activities and pursue development of any of our pipeline products; our technology; our product and service development opportunities and timelines; our business strategies; customer acceptance and the market potential of our technology; products and services; our future capital requirements; our future financial performance; and other matters. This includes, in particular, Item 1. "Business" and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report, as well as other portions of this Annual Report. The words "believe," "expect," "anticipate," "project," "could," "would," and similar expressions, among others, generally identify "forward-looking statements," which speak only as of the date the statements were made. The matters discussed in these forward-looking statements are subject to risks, uncertainties and other factors that could cause our actual results to differ materially from those projected, anticipated or implied in the forward-looking statements. As a result, you should not place undue reliance on any forward-looking statements. The most significant of these risks, uncertainties and other factors are described in Item 1A. "Risk Factors" of this Annual Report. Except to the limited extent required by applicable law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

**Reverse Stock Split**

Except as otherwise indicated, all information in this Annual Report gives effect to the 1-for-12 reverse stock split of the common stock that was effected on March 21, 2025.

## PART I

### Item 1. Business.

#### Overview

VivoSim Labs, Inc., formerly known as Organovo Holdings, Inc. ("VivoSim," "we," "us," "our," the "Company" and "our 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. We offer partners liver and intestinal toxicology insights using our new approach methodologies ("NAM") models. We anticipate accelerated adoption of human tissue models following the U.S. Food and Drug Administration ("FDA") announcement on April 10, 2025 to refine animal testing requirements in favor of these non-animal NAM methods. We will also offer bespoke services in the areas of investigational toxicology, mechanism of drug action elucidation, and other applications of these complex human tissue models.

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. 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.

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

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

We 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 May 2025 Digestive Disease Week scientific conference showing that our liver toxicology platform had a best-in-class predictive power. Our liver predictive power was shown to be 87.5% for a set of challenging liver toxicity cases – inclusive of classic cases of "liver tox misses" drugs with unforeseen liver toxicity found in clinical trials or drugs that were withdrawn from the market after liver toxicity issues emerged later. The platform identified correctly that 87.5% of the known liver-toxic drugs could be seen as liver toxic using NAMkind™ liver. This is known as the sensitivity of the platform, which at 87.5% is a world's best. Importantly, the specificity was 100%, meaning that none of the compounds tested that are not liver toxic were incorrectly identified as having liver toxicity issues by the platform.

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

We have also used these human disease models to identify new molecular targets responsible for driving IBD and to explore the mechanism of action of known drugs including JAK inhibitors and related molecules. A portion of our internal research continues to focus on early stage internal drug discovery programs, validating targets, and testing potentially licensable or transactable external drug compounds to identify drug candidates for partnering and/or internal clinical development.

#### Our Platform Technology

Our 3D human tissue platform is multifaceted. We have expertise in 3D organoids, such as spheroids, and have made significant advances in proprietary cell culture techniques including ratios, components, and conditions that remain protected as our trade secrets. We are developing novel human normal and disease models using high throughput systems, bioprinted and flow/stretch capable 3D systems as appropriate. Our expertise includes important technology such as proprietary bioprinting and related technologies for preparing bio-inks and bioprinting multicellular tissues with complex architecture, grounded in over a decade of peer-reviewed scientific publications. We have a broad portfolio of intellectual property rights covering the principles, enabling instrumentation,

applications, tissue constructs and methods of cell-based printing. We own or exclusively license more than 160 patents and pending applications worldwide covering specific tissue designs, uses, and methods of manufacture.

**Intellectual Property**

We rely on a combination of patents, trademarks, trade secrets, confidential know-how, copyrights, and a variety of contractual mechanisms such as confidentiality, material transfer, licenses, research collaboration, limited technology access, and invention assignment agreements to protect our intellectual property. Our intellectual property portfolio for our core technology was initially built through licenses from University of Missouri-Columbia ("MU") and the Medical University of South Carolina. We subsequently expanded our intellectual property portfolio by filing our own patent and trademark applications worldwide and negotiating additional licenses and purchases.

On an ongoing basis we review and analyze our full intellectual property portfolio to align it with our current business needs, strategies and objectives. Based on that ongoing review, selected patents and patent applications in various countries are or will be abandoned or allowed to lapse. The numbers provided herein are reflective of those changes.

We solely own or hold exclusive licenses to 34 issued U.S. patents and more than 50 issued international patents in foreign jurisdictions including Australia, Canada, China, Denmark, France, Great Britain, Germany, Ireland, Japan, Sweden, the Netherlands and Switzerland. We solely or jointly own or hold exclusive licenses to 9 pending U.S. patent applications, 3 of which are allowed, and more than 5 pending international applications in foreign jurisdictions including Australia, Canada, China, and the European Patent Office. These patent families relate to our bioprinting technology and our engineered tissue products and services, including our various uses in areas of tissue creation, in vitro testing, utilization in drug discovery, and in vivo therapeutics.

In-Licensed Intellectual Property

In 2009 and 2010, we obtained world-wide exclusive licenses to intellectual property owned by MU and the Medical University of South Carolina, which now includes 5 issued U.S. patents and 1 pending U.S. application. Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of Biophysics at MU, was one of the co-inventors of all of these works (collectively, the "Forgacs Intellectual Property"). The Forgacs Intellectual Property provides us with intellectual property rights relating to cellular aggregates, the use of cellular aggregates to create engineered tissues, and the use of cellular aggregates to create engineered tissue with no scaffold present. The intellectual property rights derived from the Forgacs Intellectual Property also enables us to utilize our NovoGen Bioprinter® to create engineered tissues.

The patent rights we obtained through these exclusive licenses are not only foundational within the field of 3D bioprinting but provide us with favorable priority dates. We are required to make ongoing royalty payments under these exclusive licenses based on net sales of products and services that rely on the intellectual property we in-licensed. For additional information regarding our royalty obligations see "Note 6. Collaborative Research, Development, and License Agreements" in the Notes to the Consolidated Financial Statements included in this Annual Report.

Company Owned Intellectual Property

In addition to the intellectual property we have in-licensed, we have historically innovated and grown our intellectual property portfolio.

With respect to our bioprinting platform, we have 11 issued U.S. patents and 15 issued foreign patents directed to our NovoGen Bioprinter® and methods of bioprinting: U.S. Patent Nos. 8,931,880, 9,149,952, 9,227,339, 9,315,043, 9,499,779, 9,855,369, 10,174,276, 10,967,560, 11,577,450, 11,577,451 and 11,413,805; Australia Patent Nos. 2015202836, 2013249569 and 2014296246; Canada Patent Nos. 2,812,766, 2,868,530 and 2,919,734; China Patent Nos. ZL201180050831.4 and ZL201480054148.1; European Patent Nos. 2838985, 2629975, and 3028042; Japan Patent Nos. 6333231, 6566426 and 6842918; and Russian Patent No. 2560393. An additional U.S. continuation application has been allowed. These issued patents and pending patent applications carry remaining patent terms ranging from over 9 years to just over 6 years.

Our NAMkind Human Liver Tissue is protected by U.S. Patent Nos. 9,222,932, 9,442,105, 10,400,219 and 11,127,774; Australia Patent Nos. 2014236780 and 2017200691; Canada Patent No. 2,903,844; and European Patent No. 2970896. We also have a pending U.S. application. Our Human Kidney Tissue is protected by U.S. Patent Nos. 9,481,868, 10,094,821, 10,962,526 and 11,867,689; Australian Patent No. 2015328173; Canadian Patent No. 2,962,778; Chinese Patent No. ZL201580066469.8; European Patent No. 3204488; and Japan Patent No. 7021177. These issued patents and pending patent applications carry remaining patent terms ranging from over 10 years to just over 8 years.

We currently have several patents and pending patent applications in the U.S. and globally that are directed to additional features on bioprinters, additional tissue types, their methods of fabrication, and specific applications.

Our U.S. Patent Nos. 9,855,369 and 9,149,952, which relate to our bioprinter technology, were the subject of *inter partes review* 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 have since been settled in a favorable manner for the Company. Specifically, on February 23, 2022, we announced an agreement of a non-exclusive license for BICO Group AB and its affiliate companies to our foundational patent portfolio in 3D bioprinting.

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 consisted of (i) an upfront cash payment by Lilly to us equal to $10.0 million, of which $9.0 million was paid at closing and the remaining $1.0 million was deposited into escrow for 15 months to satisfy claims for indemnification, (ii) the assumption by Eli Lilly and Company of certain liabilities related to the FXR program, and (iii) 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.

**Employees and Human Capital**

As of June 1, 2025, we had 13 employees, of which 5 are full-time. We have also retained some of our former employees as consultants, in addition to a number of expert consultants in specific scientific and operational areas. Our employees are not represented by labor unions or covered under any collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate select employees, consultants, and directors through the granting of equity-based compensation awards.

**Corporate Information**

We are operating the business of our subsidiaries, including Organovo, Inc., our wholly-owned subsidiary, which we acquired in February 2012 and which was incorporated in Delaware in April 2007 and our wholly-owned subsidiary, VivoSim, Inc., which was incorporated in Delaware in May 2025. Effective April 24, 2025, we changed our corporate name to VivoSim Labs, Inc. Since April 24, 2025, our common stock has traded on the Nasdaq Capital Market under the symbol "VIVS." Between August 8, 2016 and April 24, 2025, our common stock traded on the Nasdaq Capital Market under the symbol "ONVO."

Our principal executive offices are located at 11555 Sorrento Valley Rd, Suite 100, San Diego CA 92121 and our phone number is (858) 224-1000. Our Internet website can be found at https://www.vivosim.ai. The content of our website is not intended to be incorporated by reference into this Annual Report or in any other report or document that we file.

**Available Information**

Our investor relations website is under development and will be live as soon as reasonably practicable and is expected to be located at https://www.vivosim.ai. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Reports filed with the Securities and Exchange Commission (the "SEC") pursuant to the Exchange Act, including annual and quarterly reports, and other reports we file, are expected to be available free of charge, through our website once it is live. The content of our website is not intended to be incorporated by reference into this Annual Report or in any other report or document that we file. We intend to make them available on our website as soon as reasonably possible after we file them with the SEC. The reports we file with the SEC, as well as proxy and information statements and other information that we file electronically with the SEC, are also available on the SEC's website (http://www.sec.gov).

## 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 Annual Report 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 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 Annual Report on Form 10-K 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 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 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 and R&D efforts will depend on our ability to successfully establish strategic relationships.***
- ***Current and future legislation may increase the difficulty and cost of commercializing drug candidates and may affect the prices that can be charged if drug candidates are approved for commercialization.***
- ***Management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern. Separately, our independent registered public accounting firm has included in its opinion for the year ended March 31, 2025 an explanatory paragraph expressing substantial doubt in our ability to continue as a going concern, which may hinder our ability to obtain future financing.***
- ***We have a history of operating losses and expect to incur significant additional operating losses.***
- ***There is no assurance that an active market in our common stock will continue at present levels or increase in the future.***
- ***The price of our common stock may continue to be volatile, which could lead to losses by investors and costly securities litigation.***
- ***Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.***
- ***We may be involved in lawsuits or other proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.***

### Risks Related to our Business

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

We are a pharmaceutical and biotechnology services company that is focused on providing testing of drugs and drug candidates in three-dimensional ("3D") human tissue models of liver and intestine. We offer our partners liver and intestinal toxicology insights

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

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

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

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

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

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

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

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

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

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

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

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

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

As we pursue providing services and drug development through 3D tissues and disease models, we will require access to a constant, steady, reliable supply of human cells to support our 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.

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

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

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

We currently do not have any committed external source of funds and do not expect to generate any meaningful revenue in the foreseeable future. If our board of directors decides that we should pursue further research and development activities than already proposed, we will require substantial additional funding to operate our proposed business, including expanding our facilities and hiring additional qualified personnel, and we would expect to finance these cash needs through a combination of equity offerings, debt financings, government or other third-party funding and licensing or collaboration arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt, the ownership interests of our stockholders will be diluted. In addition, the terms of any equity or convertible debt we agree to issue may include liquidation or other preferences that adversely affect the rights of our stockholders. Convertible debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Moreover, we have the ability to sell up to $3.1 million of additional shares of our common stock to the public through an "at the market offering" pursuant to a Sales Agreement that we entered into with JonesTrading Institutional Services LLC on March 16, 2018 (the "Sales Agreement"). Any shares of common stock issued in the "at the market offering" ("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 March 31, 2025, we have issued and sold pursuant to the Sales Agreement an aggregate of 828,272 shares of our common stock for gross proceeds of approximately $50.1 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 of this Annual 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 results in reputational or other harm that could have a material adverse effect on our business.***

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

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

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

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

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

Our business, financial condition and share price could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our

suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. There can be no assurances that further deterioration in 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. 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 new 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 new U.S. administration has initiated or is considering imposing 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 new U.S. administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, increase the cost of materials purchased to manufacture our potential products, impact our ability to sell our products outside the United States or to sell our products outside the United States at competitive prices and/or to affect the United States or global economy or certain sectors thereof and, thus, could adversely impact our business and financial condition.

**Risks Related to Government Regulation**

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

Our product manufacturing, research and development, and testing activities have involved the controlled use of hazardous materials, including chemicals, biological materials and infectious disease agents. We cannot eliminate the risks of accidental contamination or the accidental spread or discharge of these materials, or any resulting injury from such an event. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. We were also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, and the experimental use of animals. Our operations may have required that environmental permits and approvals be issued by applicable government agencies. If we failed to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance.

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

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

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

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in

product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance.

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

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

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

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

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

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

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

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

Our financial statements as of March 31, 2025 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern. Separately, our independent registered public accounting firm included in its opinion for the year ended March 31, 2025 an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, obtain government grants, reduce expenditures, and generate significant revenue. Our financial statements as of March 31, 2025 do not include any adjustments that might result from the outcome of this uncertainty. The reaction of investors to the inclusion of a going concern statement by management and our auditors, and our potential inability to continue as a going concern, in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances.

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

As of March 31, 2025, we had total current assets of approximately $12.1 million and current liabilities of approximately $3.7 million, resulting in working capital of $8.4 million. We have generated operating losses each year since we began operations, including $12.6 million and $15.1 million for the years ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of $342.2 million. We expect to incur substantial additional operating losses over the next several years as our research and development activities increase.

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

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

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

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

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

- evaluating and implementing strategic alternatives, technology licensing opportunities, potential collaborations, and other strategic transactions;
- litigation;
- research and development expenditures, including commencement of preclinical studies and clinical trials;

- the timing of the hiring of new employees, which may require payments of signing, retention or similar bonuses; and
- changes in costs related to the general global economy.

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

***We may identify material weaknesses in 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. There can be no assurance that we will be entitled to receive any milestone payments, and there is risk that any or all of the milestone events may not be achieved, that disagreements may occur regarding the achievement of such milestones and that any or all of the payments tied to the achievement of the milestone events might not be received.

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

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

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

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

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

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

Executive Chairman also provides services to Viscient Biosciences, Inc. ("Viscient"). He provides services to us and Viscient and does not dedicate all of his time to us, as disclosed in our filings, and we may therefore compete with Viscient for the time commitments of our Executive Chairman from time to time.

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

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

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

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

The European Data Protection Board continues to release guidelines for industries and impose fines related to the GDPR, some of which have been very significant. To improve coordination among EU supervisory authorities, the European Commission has proposed a new regulation that would help to streamline enforcement of the GDPR in cross-border cases. 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. As of January 1, 2021 and the expiry of transitional arrangements agreed to between the United Kingdom and the European Union, 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), exposing us to two parallel regimes, each of which authorizes similar fines and other potentially divergent enforcement actions for certain violations. On June 28, 2021, 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). However, the European Commission may suspend the Adequacy

Decision if it considers that the United Kingdom no longer provides for an adequate level of data protection. A bill to amend the existing UK framework has been reintroduced (in a different form) by the new UK Government and was announced as a bill which will be introduced into Parliament at the King's Speech on July 17, 2024. At this time, there is no specific clarity on the provisions of the bill, or the extent to which it will amend the UK framework, beyond general descriptions on its intended purpose. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations.

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. Each of these laws is subject to varying interpretations and the legislative landscape is constantly evolving and 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.

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 — which went into effect on January 1, 2020 — is creating similar risks and obligations as those created by the GDPR, though the California Consumer Privacy Act 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). As of January 1, 2023, the California Consumer Privacy Act (as amended and expanded by the California Privacy Rights Act) is in full effect, with enforcement by California's dedicated privacy enforcement agency expected to start later in 2023. While California was first among the states in adopting comprehensive data privacy legislation similar to the GDPR, many other states are following suit. Similar laws passed in Virginia, Colorado, Connecticut, and Utah took effect in 2023 while laws in Oregon, Montana, and Texas went into effect in 2024. Additionally, Delaware, Florida, Indiana, Iowa, Kentucky, Maryland, Minnesota, Nebraska, New Hampshire, New Jersey, Rhode Island, and Tennessee have adopted privacy laws, which took or take effect from January 1, 2025 through 2026. Some state laws also 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 California Privacy Rights Act), 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 2025, we provided services to Viscient, and we expect to continue to provide services to Viscient and enter into additional agreements with Viscient in the future.

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

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

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

**Risks Related to Our Common Stock and Liquidity Risks**

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

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

On July 18, 2024, we received a written notice from the Listing Qualifications Staff (the "Staff") of Nasdaq 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) ("Rule 5550(a)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until January 14, 2025, to regain compliance.

On January 16, 2025, the Staff provided a notice to us (the "Nasdaq Notice") that we had not regained compliance with Rule 5550(a)(2) and were not eligible for a second 180 calendar day compliance period as we did not comply with the requirements for initial listing on the Nasdaq Capital Market. The Nasdaq Notice further indicated that, unless we timely requested a hearing before a Hearings Panel (the "Hearings Panel"), our common stock would be subject to delisting. We timely requested a hearing, which automatically stayed any delisting or suspension action pending the hearing and the expiration of any extension period granted by the Hearings Panel following the hearing.

On February 19, 2025, we received a written notice from the Staff of Nasdaq indicating that, since our Quarterly Report on Form 10-Q for the period ended December 31, 2024 reported stockholders' equity of $364,000, and as of February 19, 2025, 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 Nasdaq Listing Rule 5550(b)(1) ("Rule 5550(b)(1)").

On March 21, 2025, we effected a 1-for-12 reverse stock split of our common stock (the "Reverse Stock Split"). On March 27, 2025, the Hearings Panel granted us an exception until April 15, 2025 to demonstrate compliance with Rule 5550(a)(2) and Rule 5550(b)(1). On April 30, 2025, we received a letter from Nasdaq (the "April 30, 2025 Letter") notifying us that we had demonstrated compliance with Rule 5550(a)(2) and Rule 5550(b)(1) as required by the Hearings Panel's March 27, 2025 decision. We will be subject to a Mandatory Panel Monitor for a period of one year from the date of the April 30, 2025 Letter pursuant to Nasdaq Listing Rule 5815(d)(4)(B). If, within that one-year monitoring period, the Staff finds us again out of compliance with Rule 5550(b)(1), notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and the Staff will not be permitted to grant additional time for us to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Nasdaq Listing Rule 5810(c)(3). Instead, the Staff will issue a Delist Determination Letter and we will have an opportunity to request a new hearing with the initial Hearings Panel or a newly convened Hearings Panel if the initial Hearings Panel is unavailable. We will have the opportunity to respond/present to the Hearings Panel as provided by Nasdaq Listing Rule 5815(d)(4)(C). Our securities may be at that time delisted from Nasdaq.

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

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

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

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

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

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

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

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

The stock market is subject to significant price and volume fluctuations. The trading price of our common stock is, and is likely to continue to be, volatile. For example, during the fiscal year ended March 31, 2025, our closing stock price ranged from $2.24 to $16.20 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 March 31, 2025, there were an aggregate of 1,898,068 shares of our common stock issued and outstanding and available for issuance on a fully diluted basis and no shares of preferred stock outstanding. That total for our common stock includes 348,419 shares of our common stock that may be issued upon the vesting of restricted stock units, the exercise of outstanding stock options, or is available for issuance under our equity incentive plans, and 3,708 shares of common stock that may be issued through our 2023 Employee Stock Purchase Plan, and 539,060 shares of our common stock that may be issued upon the exercise of outstanding warrants.

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

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

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

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

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

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

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

**Risks Related to Our Intellectual Property**

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

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

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

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

As previously disclosed, we have recommenced certain historical operations and are now focusing our future efforts on developing highly customized 3D human tissues as living, dynamic models for healthy and diseased human biology for drug development. These tissues will be used to provide testing of drugs and drug candidates to our partners. We offer partners liver and intestinal toxicology insights using our new approach methodologies ("NAM") models. Previously, we focused our efforts on developing our in vivo liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there were limited treatment options other than organ transplant. We also explored the development of other potential pipeline in vivo tissue constructs. As we focus our business on developing highly customized 3D human tissues as part of a services platform, we may sell, discontinue, adjust or abandon certain patents and patent applications relating to our historical operations. There can be no assurance that we will be successful at such efforts or sell or otherwise monetize such assets on acceptable terms, if at all. There is also no guarantee that our

remaining patents will be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies.

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

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

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

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

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

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

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

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

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be

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

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

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

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

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

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

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

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

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and that may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent

application is typically entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings, including opposition, derivation, reexamination, *inter partes review* or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

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

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or the UPC. As the UPC is a new court system, there is no 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 new 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 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. We are defending these claims vigorously, but there is no guarantee that we will be successful in these efforts.

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

**General Risk Factors**

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

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

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

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

**Item 1B. Unresolved Staff Comments.**

None.

**Item 1C. Cybersecurity**

We believe cybersecurity is critical to advancing our technological advancements. As a pharmaceutical and biotechnology services company, we face a multitude of cybersecurity threats that include attacks common in most industries, such as ransomware and denial-of service. Our customers, suppliers, subcontractors, and business partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our operations, performance, and results of operations. These cybersecurity threats and related risks make it imperative that we expend resources on cybersecurity.

Assessing, identifying, and managing cybersecurity related risks are factored into our overall business approach. We have implemented a governance structure and processes to assess, identify, manage, and report cybersecurity risks and have developed our own practices and framework, which we believe enhance our ability to identify and manage cybersecurity risks. Our Audit Committee oversees management's processes for identifying and mitigating risks, including cybersecurity risks, to help align our risk exposure with our strategic objectives. The IT Risk Committee and our cybersecurity consultant, which has extensive information technology and program management experience, regularly brief the Audit Committee on our cybersecurity and information security posture and the Audit Committee is apprised of any cybersecurity incidents deemed to have a moderate or higher business impact, even if immaterial to us. The Audit Committee retains oversight of cybersecurity because of its importance. In the event of any incident, we intend to follow our detailed incident response playbook, which outlines the steps to be followed from incident detection to mitigation, recovery, and notification, including notifying functional areas (e.g., legal), as well as senior leadership and the Audit Committee, as appropriate.

Additionally, we must also comply with extensive regulations, including requirements imposed by the FDA related to adequately safeguarding patient information. We work with our cybersecurity consultant on assessing cybersecurity risk and on policies and practices aimed at mitigating these risks. Third parties also play a role in our cybersecurity. We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges.

We rely heavily on our supply chain to deliver our products and services, and a cybersecurity incident at a supplier, subcontractor or business partner could materially adversely impact us. We will require that our subcontractors report cybersecurity incidents to us so that we can assess the impact of the incident on us.

Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. See "Risk Factors" for a discussion of cybersecurity risks, including, without limitation, the risk factor under the heading "*We may be subject to security breaches or other cybersecurity incidents that could compromise our information and expose us to liability*". Except as set forth therein, risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and are not reasonably likely to materially affect our Company, including our business strategy, results of operations, or financial condition.

**Item 2. Properties.**

In November 2020, we entered into a sixty-two month lease agreement for our long term permanent premises, consisting of approximately 8,051 square feet of lab and office space. In November 2021, we amended the permanent lease agreement to add an additional 2,892 square feet of office space in the same building. In December 2021, we took occupancy of the aforementioned lab and office space, located at 11555 Sorrento Valley Road, San Diego, CA 92121. See "Note 8. Leases" of the Notes to the Consolidated Financial Statements contained within this Annual Report for a further discussion of properties. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

**Item 3. Legal Proceedings.**

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

We assess contingencies to determine the degree of probability and range of possible loss for potential accrual in our 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, we 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 us may be unsupported, exaggerated or unrelated to possible outcomes, and as such are not meaningful indicators of our potential liability.

See “Note 9. Commitments and Contingencies” of the Notes to the Consolidated Financial Statements contained within this Annual Report for a further discussion of potential commitments and contingencies related to legal proceedings.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

**Market Information for Common Stock**

Our common stock is traded on the Nasdaq Capital Market under the symbol "VIVS."

**Holders of Record**

As of May 20, 2025, we had 2,599,797 outstanding shares of common stock and approximately 64 holders of record of our common stock. The number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in "street name."

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

**Recent Sales of Unregistered Securities**

None.

**Issuer Purchases of Equity Securities**

None.

### Item 6. [Reserved]

**Item 7. 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. This management's discussion and analysis contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause our actual results or events to differ materially from those expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in section Item 1A. "Risk Factors" in this Annual Report. Except as required by applicable law we do not undertake any obligation to update our forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.*

**Overview**

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

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. 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.

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

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

We 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 May 2025 Digestive Disease Week scientific conference showing that our liver toxicology platform had a best-in-class predictive power. Our liver predictive power was shown to be 87.5% for a set of challenging liver toxicity cases – inclusive of classic cases of "liver tox misses" drugs with unforeseen liver toxicity found in clinical trials or drugs that were withdrawn from the market after liver toxicity issues emerged later. The platform identified correctly that 87.5% of the known liver-toxic drugs could be seen as liver toxic using NAMkind™ liver. This is known as the sensitivity of the platform, which at 87.5% is a world's best. Importantly, the specificity was 100%, meaning that none of the compounds tested that are not liver toxic were incorrectly identified as having liver toxicity issues by the platform.

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

We have also used these human disease models to identify new molecular targets responsible for driving IBD and to explore the mechanism of action of known drugs including JAK inhibitors and related molecules. A portion of our internal research continues to focus on early stage internal drug discovery programs, validating targets, and testing potentially licensable or transactable external drug compounds to identify drug candidates for partnering and/or internal clinical development.

**Critical Accounting Policies, Estimates, and Judgments**

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles. Any reference in this Annual Report to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates of the Financial Accounting Standards Board. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments used in preparing our financial statements and related disclosures, none of which are considered critical. All estimates affect reported amounts of assets, liabilities, revenues and expenses, as well as disclosures of contingent assets and liabilities. These estimates and judgments are also based on historical experience and other factors that are believed to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

Our significant accounting policies are set forth in "Note 1. Description of Business and Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements contained within this Annual Report. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations. Accounting policies regarding stock-based compensation and revenue are considered critical, as they require significant assumptions. If there is a difference between the assumptions used in determining our stock-based compensation expense and the actual factors that become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

***Stock-based compensation***

For purposes of calculating stock-based compensation, we estimate the fair value of stock options and shares acquirable under our 2022 Equity Incentive Plan ("2022 Plan"), Amended and Restated 2012 Equity Incentive Plan (the "2012 Plan"), our 2023 Employee Stock Purchase Plan (the "ESPP"), or our 2021 Inducement Equity Plan (the "Inducement Plan") using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. Expected volatility is based on the Company-specific historical volatility rate. For certain options granted with vesting criteria contingent on market conditions, we engage with valuation specialists to calculate fair value and requisite service periods using Monte Carlo simulations. For certain options granted with vesting criteria contingent on pre-defined Company performance criteria, we periodically assess and adjust the expense based on the probability of achievement of such performance criteria. For shares acquirable under our ESPP, we use our Company-specific volatility rate. The expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts. If factors change and we employ different assumptions, our stock-based compensation expense may differ significantly from what we have recorded in the past.

For purposes of calculating stock-based compensation, we estimate the fair value of restricted stock units with pre-defined performance criteria, based on the closing stock price on the date of grant. No exercise price or other monetary payment is required for receipt of the shares issued in settlement of the respective award; instead, consideration is furnished in the form of the participant's service to us.

If there is a difference between the assumptions used in determining our stock-based compensation expense and the actual factors that become known over time, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

***Revenue***

*Royalty revenue*

We assess whether our license agreements are considered a contract with a customer under ASC Topic 606, Revenue from Contracts with Customers ("Topic 606") or an arrangement with a collaborator subject to guidance under ASC Topic 808, Collaborative Arrangements. At contract inception, we consider a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether we are a principal or agent, whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and, if applicable, whether any licenses are functional or symbolic. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Typically, non-refundable upfront fees have been considered fixed, while 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.

For agreements that include sales-based royalties, we estimate and recognize revenue in the period the underlying sales occur. Key factors considered in the estimate include sales of products that include the underlying licensed intellectual property ("IP") and the location of customers related to the jurisdictions of the licensed IP. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price. Differences in the allocation of the transaction price between delivered and undelivered performance obligations can impact the timing of revenue recognition but do not change the total revenue recognized under any agreement.

*Product revenue, net*

Our former product-based division, Mosaic Cell Sciences ("Mosaic"), which was established in the fourth quarter of fiscal 2024, produced high-quality cell-based products for use in our R&D and for use by life science customers. We recognized product revenue when the performance obligation was satisfied, which was at the point in time that the customer obtained control of our products, typically upon delivery. Product revenues were recorded at the transaction price under Topic 606. We provided no right of return to our customers except in cases where a customer obtained authorization from us for the return. To date, there have been no product returns. We ended Mosaic's commercial operations during the third quarter of fiscal 2025.

***Sale of 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 consisted of (i) an upfront cash payment by Lilly to us equal to $10.0 million, of which $9.0 million was paid at closing and the remaining $1.0 million was deposited into escrow for 15 months to satisfy claims for indemnification, (ii) the assumption by Eli Lilly and Company of certain liabilities related to the FXR program, and (iii) 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.

We assessed whether this agreement was considered a contract with a customer pursuant to Topic 606 or subject to guidance pursuant to ASC Topic 610, Other Income ("Topic 610"). We considered a variety of factors in determining the appropriate assumptions under this arrangement, such as whether the counterparty was a customer, the nature of our operations, both historically and ongoing, and any contingent consideration constraints. We determined the counterparty was not a customer based on the nature of our ordinary business operations and recorded the transaction within other income under Topic 610. Furthermore, we determined the $1.0 million held in escrow was not constrained due to the terms of the indemnification language and it was therefore recognized as a component of the consideration received at the time of closing; however, we did determine future potential milestone payments that may be made by Eli Lilly were constrained due to the uncertainty of the milestones being met. If and when the future milestone payments are no longer considered constrained, we will record such payments in other income.

**Results of Operations**

***Comparison of the Years Ended March 31, 2025 and 2024***

The following table summarizes our results of operations for the years ended March 31, 2025 and 2024 (in thousands, except percentages):

| | Year Ended March 31, | | Increase (decrease) | |
|---|---|---|---|---|
| | 2025 | 2024 | $ | % |
| Royalty revenue | $ 119 | $ 109 | $ 10 | 9% |
| Product revenue | 25 | — | 25 | 100% |
| Cost of revenues | 5 | — | 5 | 100% |
| Research and development | 5,025 | 5,498 | (473) | (9%) |
| Selling, general and administrative | 7,730 | 9,697 | (1,967) | (20%) |
| Other income | 10,130 | 417 | 9,713 | 2,329% |

**Revenues**

For each of the years ended March 31, 2025 and 2024, total revenue was $0.1 million. Royalty revenue for each of the years ended March 31, 2025 and 2024, was related to the sales-based royalty revenue earned from licensing intellectual property. Product revenue is related to the sale of human cells developed by our former division, Mosaic. As we ended Mosaic's commercial operations during the third quarter of fiscal year 2025, there will be no product revenue from Mosaic going forward.

**Cost of Revenues**

For the years ended March 31, 2025 and 2024, total cost of revenues was less than $0.1 million and zero, respectively, and is related to the sale of finished goods inventory by Mosaic.

**Research and Development Expenses**

The following table summarizes our research and development expenses for the years ended March 31, 2025 and 2024 (in thousands, except percentages):

| | Year Ended March 31, | | Increase (decrease) | |
|---|---|---|---|---|
| | 2025 | 2024 | $ | % |
| Research and development | $ 4,712 | $ 5,133 | $ (421) | (8%) |
| Non-cash stock-based compensation | 86 | 138 | (52) | (38%) |
| Depreciation and amortization | 227 | 227 | — | 0% |
| Total research and development expenses | $ 5,025 | $ 5,498 | $ (473) | (9%) |

Total research and development expenses decreased by $0.5 million, or 9%, from approximately $5.5 million for the year ended March 31, 2024 to approximately $5.0 million for the year ended March 31, 2025. Our full-time research and development staff decreased from an average of sixteen employees for the year ended March 31, 2024 to an average of thirteen employees for the year ended March 31, 2025. The decrease in total research and development activities consisted of a $0.3 million decrease in personnel related costs due to the decrease in headcount, including one executive, and a $0.1 million decrease in facilities and materials cost due to our efforts to reduce spending and extend our cash runway, which was offset by an inventory write-off.

**Selling, General and Administrative Expenses**

The following table summarizes our selling, general and administrative expenses for the years ended March 31, 2025 and 2024 (in thousands, except percentages):

| | Year Ended March 31, | | Increase (decrease) | |
|---|---|---|---|---|
| | 2025 | 2024 | $ | % |
| Selling, general and administrative | $ 7,245 | $ 8,274 | $ (1,029) | (12%) |
| Non-cash stock-based compensation | 446 | 1,370 | (924) | (67%) |
| Depreciation and amortization | 39 | 53 | (14) | (26%) |
| Total selling, general and administrative expenses | $ 7,730 | $ 9,697 | $ (1,967) | (20%) |

Total selling, general and administrative expenses decreased by approximately $2.0 million, or 20%, from $9.7 million for the year ended March 31, 2024 to approximately $7.7 million for the year ended March 31, 2025. The decrease in total selling, general and administrative activities consisted of a $1.3 million decrease in personnel related costs, of which $0.9 million related to a reduction in stock-based compensation expense for forfeitures that occurred during fiscal 2024 and $0.4 million related to severance that was expensed during the prior fiscal year. In addition to the decrease in personnel related costs, we had a $0.6 million decrease in investor relation expenses and a $0.1 million decrease in other corporate costs due to our efforts to reduce spending and extend our cash runway. Our full-time selling, general, and administrative employees remained an average of four employees for each of the years ended March 31, 2024 and March 31, 2025.

**Other Income (Expense)**

Other income was approximately $10.1 million and $0.4 million for the years ended March 31, 2025 and 2024, respectively. The significant increase in other income was related to the sale of our FXR program for $10.0 million, which was offset by a $0.3 million decrease in net interest income.

**Financial Condition, Liquidity and Capital Resources**

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

The accompanying 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 March 31, 2025, we had cash and cash equivalents of approximately $11.3 million and an accumulated deficit of $342.2 million. As of March 31, 2024, we had cash and cash equivalents of $2.9 million and an accumulated deficit of $339.7 million. We had negative cash flows from operations of $9.5 million and $14.7 million for the years ended March 31, 2025 and 2024, respectively.

As of March 31, 2025, we had total current assets of approximately $12.1 million and current liabilities of approximately $3.7 million, resulting in working capital of $8.4 million. At March 31, 2024, we had total current assets of approximately $3.9 million and current liabilities of approximately $1.9 million, resulting in working capital of $2.0 million.

The following table sets forth a summary of the primary sources and uses of cash for the years ended March 31, 2025 and 2024 (in thousands):

| | Year Ended March 31, | |
|---|---|---|
| | 2025 | 2024 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (9,461) | $ (14,653) |
| Investing activities | 9,025 | 816 |
| Financing activities | 8,847 | 1,437 |
| Net increase (decrease) in cash, cash equivalents, and restricted cash | $ 8,411 | $ (12,400) |

*Operating activities*

Net cash used in operating activities was approximately $9.5 million and $14.7 million for the years ended March 31, 2025 and 2024, respectively. The $5.2 million decrease in operating cash usage, for the year ended March 31, 2025, was attributable primarily to the $2.0 million cash payment in fiscal 2024 for acquired in process research and development, in addition to an increase in working capital requirements, including a $3.6 million increase to accounts payable and accrued expenses, offset by a $0.3 million decrease in receivables and prepaid expenses.

*Investing activities*

Net cash provided by investing activities was approximately $9.0 million and $0.8 million for the years ended March 31, 2025 and 2024, respectively. Net cash provided by investing activities for the year ended March 31, 2025 consisted primarily of the sale of our FXR program resulting in $9.0 million of proceeds. Net cash provided by investing activities for the year ended March 31, 2024 consisted of the liquidation of equity securities of $0.7 million and $0.1 million of investment income.

*Financing activities*

Net cash provided by financing activities was approximately $8.8 million and $1.4 million for the years ended March 31, 2025 and 2024, respectively. Financing activities consisted of the sale of common stock through at-the-market (“ATM”) share offerings and a public offering of common stock and accompanying common warrants and pre-funded warrants. Refer to "Operations funding requirements" below for further information regarding financing activities.

*Operations funding requirements*

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

Our ongoing cash requirements include research and development expenses, compensation for personnel, consulting fees, legal and accounting support, insurance premiums, facilities, maintenance of our intellectual property portfolio, license and collaboration agreements, listing on the Nasdaq Capital Market, and other miscellaneous fees to support our operations. We expect our total operating expense for the fiscal year ending March 31, 2026 to be approximately $10.1 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 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 shelf registration statement on Form S-3 (File No. 333-276722) to register $150.0 million of common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the “2024 Shelf”). The 2024 Shelf was declared effective by the SEC on February 8, 2024.

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

On January 26, 2024, we filed a prospectus with the 2024 Shelf (as amended, 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 year ended March 31, 2025, we sold 493,372 shares of common stock in ATM offerings for net proceeds of approximately $4.9 million all of which were sold pursuant to the 2024 Shelf. As of March 31, 2025, we have sold an aggregate of 496,405 shares of common stock in ATM offerings under the 2024 ATM Prospectus, with gross proceeds of approximately $5.0 million. As of March 31, 2025, there was approximately $142.7 million available in future offerings under the 2024 Shelf, and approximately $2.3 million available for future offerings through our ATM program under the 2024 ATM Prospectus. As of June 1, 2025, we had 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 Annual 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 May 8, 2024, we priced a best efforts public offering (the "Offering") of: (i) 130,202 shares of our common stock and accompanying common warrants ("Common Warrants") to purchase up to 130,202 shares of common stock at a combined public offering price of $9.60 per share and accompanying Common Warrant to purchase one share of common stock and (ii) pre-funded warrants ("Pre-Funded Warrants") to purchase 416,666 shares of common stock and accompanying Common Warrants to purchase up to 416,666 shares of common stock at a combined public offering price of $9.588 per Pre-Funded Warrant and accompanying Common Warrant to purchase one share of common stock. The closing of the Offering occurred on May 13, 2024. We received net proceeds of approximately $4.5 million from the Offering, after deducting the offering expenses payable by us including the placement agent fees.

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.

*Nasdaq Deficiency Notices & Reverse Stock Split*

On July 18, 2024, we received a written notice from the Listing Qualifications Staff (the "Staff") of Nasdaq 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) ("Rule 5550(a)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until January 14, 2025, to regain compliance.

On January 16, 2025, the Staff provided a notice to us (the "Nasdaq Notice") that we had not regained compliance with Rule 5550(a)(2) and were not eligible for a second 180 calendar day compliance period as we did not comply with the requirements for initial listing on the Nasdaq Capital Market. The Nasdaq Notice further indicated that, unless we timely requested a hearing before a Hearings Panel (the "Hearings Panel"), our common stock would be subject to delisting. We timely requested a hearing, which automatically stayed any delisting or suspension action pending the hearing and the expiration of any extension period granted by the Hearings Panel following the hearing.

On February 19, 2025, we received a written notice from the Staff of Nasdaq indicating that, since our Quarterly Report on Form 10-Q for the period ended December 31, 2024 reported stockholders' equity of $364,000, and as of February 19, 2025, 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 Nasdaq Listing Rule 5550(b)(1) ("Rule 5550(b)(1)").

On March 21, 2025, we effected a 1-for-12 reverse stock split of our common stock (the "Reverse Stock Split"). On March 27, 2025, the Hearings Panel granted us an exception until April 15, 2025 to demonstrate compliance with Rule 5550(a)(2) and Rule 5550(b)(1). On April 30, 2025, we received a letter from Nasdaq (the "April 30, 2025 Letter") notifying us that we had demonstrated compliance with Rule 5550(a)(2) and Rule 5550(b)(1) as required by the Hearings Panel's March 27, 2025 decision. We will be subject to a Mandatory Panel Monitor for a period of one year from the date of the April 30, 2025 Letter pursuant to Nasdaq Listing Rule 5815(d)(4)(B).

**Contractual Obligations and Commitments**

We enter into contracts in the normal course of business with suppliers, consultants, and service providers. These agreements provide for termination at the request of either party generally with less than six-months notice and are therefore cancellable contracts. We do not currently expect any of these agreements to be terminated and did not have any noncancelable obligations under these agreements as of March 31, 2025.

We have operating lease arrangements for office space in San Diego, California. As of March 31, 2025, we had total undiscounted lease payment obligations of $0.5 million payable in the 12 months following March 31, 2025 and $0.5 million payable thereafter.

See "Note 8. Leases" and "Note 9. Commitments and Contingencies" in the Notes to the Consolidated Financial Statements contained in this Annual Report for additional information.

**Effect of Inflation and Changes in Prices**

Management does not believe that inflation and changes in price will have a material effect on our operations.

**Recent Accounting Pronouncements**

For information regarding recently adopted and issued accounting pronouncements, see "Note 13. Recent Accounting Pronouncements" in the Notes to the Consolidated Financial Statements contained in this Annual Report.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We invest our excess cash in short term, high quality interest bearing securities including U.S. government and U.S. government agency securities and high-grade corporate commercial paper. The primary objective of our investment activities is to preserve our capital for the purpose of funding our operations. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash, cash equivalents, and short-term investments in a variety of securities, including money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are comprised of cash and cash equivalents. We currently do not hedge interest rate exposure. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We have limited foreign currency risk exposure as our business operates primarily in U.S. dollars. We do not have significant foreign currency nor any other derivative financial instruments. As of March 31, 2025, all of our investments that consisted of U.S. Treasury bills matured.

**Item 8. Consolidated Financial Statements.**

**VivoSim Labs, Inc.**
**Index to Consolidated Financial Statements**

## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of:
VivoSim Labs, Inc.

**Opinion on the Financial Statements**

We have audited the accompanying Consolidated Balance Sheet of VivoSim Labs, Inc., formerly known as Organovo Holdings, Inc., (the "Company") as of March 31, 2025 and 2024, and the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended March 31, 2025, and the related notes (collectively referred to as the "Consolidated Financial Statements"). In our opinion, the Consolidated Financial Statements present fairly, in all material respects, the financial position of the Company as of March 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended March 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

**Going Concern Uncertainty**

The accompanying Consolidated Financial Statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the Consolidated Financial Statements, the Company has incurred recurring losses and negative cash flows from operations and is dependent on additional financing to fund operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The Consolidated Financial Statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

**Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

**Presentation of other income**

The Company recognized other income of $10,000,000 during the year ended March 31, 2025. Such amount was a result of the sale of an intangible asset. We identified the recognition of other income as a critical audit matter because of the significance of the account balances and the significant management judgment involved in evaluating the appropriateness of the presentation of other income. The auditing for this transaction required a high degree of audit judgment, including evaluating the reasonableness of the significant judgments made by management in determining the appropriate financial statement presentation.

The primary audit procedures we performed to address this critical audit matter included the following, amongst others:

- Obtaining and examining related documents supporting the sale of the asset.
- Obtaining management's evaluation of the appropriateness of the financial statement presentation of this transaction as other income outside of loss from operations, including a determination that such items did not result from the Company's principal revenue activities during the period.
- Evaluated the accounting treatment for the agreement, under the relevant accounting guidance ASC 610-20, *Gains and Losses from the Derecognition of Nonfinancial Assets*, and ASC 606, *Revenue from Contracts with Customers.*

/s/ Rosenberg Rich Baker Berman, P.A.

We have served as the Company’s auditor since 2023.

Somerset, New Jersey
June 5, 2025

**VIVOSIM LABS, INC.**

**CONSOLIDATED BALANCE SHEETS**
(in thousands except for share and per share data)

| | March 31, 2025 | March 31, 2024 |
|---|---|---|
| **Assets** | | |
| **Current Assets** | | |
| Cash and cash equivalents | $ 11,312 | $ 2,901 |
| Accounts receivable | 30 | 33 |
| Inventory | — | 297 |
| Prepaid expenses and other current assets | 789 | 705 |
| Total current assets | 12,131 | 3,936 |
| Fixed assets, net | 419 | 669 |
| Restricted cash | 143 | 143 |
| Operating lease right-of-use assets | 867 | 1,299 |
| Escrow receivable | 1,000 | — |
| Prepaid expenses and other assets, net | 90 | 302 |
| Total assets | $ 14,650 | $ 6,349 |
| **Liabilities and Stockholders' Equity** | | |
| **Current Liabilities** | | |
| Accounts payable | $ 1,644 | $ 627 |
| Accrued expenses | 1,226 | 727 |
| Insurance premium financing liability | 128 | — |
| Liability to be settled in equity | 218 | — |
| Operating lease liability, current portion | 521 | 506 |
| Total current liabilities | 3,737 | 1,860 |
| Operating lease liability, net of current portion | 421 | 888 |
| Total liabilities | 4,158 | 2,748 |
| **Commitments and Contingencies (Note 9)** | | |
| **Stockholders' Equity** | | |
| Common stock, $0.001 par value; 200,000,000 shares authorized, 1,898,068 and 839,814 shares issued and outstanding at March 31, 2025 and 2024, respectively | 2 | 1 |
| Additional paid-in capital | 352,648 | 343,270 |
| Accumulated deficit | (342,157) | (339,669) |
| Treasury stock, 3 shares at cost | (1) | (1) |
| Total stockholders' equity | 10,492 | 3,601 |
| **Total Liabilities and Stockholders' Equity** | $ 14,650 | $ 6,349 |

*The accompanying notes are an integral part of these Consolidated Financial Statements.*

**VIVOSIM LABS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS**
(in thousands except for share and per share data)

| | Year Ended March 31, 2025 | Year Ended March 31, 2024 |
|---|---|---|
| **Revenues** | | |
| Royalty revenue | $ 119 | $ 109 |
| Product revenue | 25 | — |
| **Total Revenues** | 144 | 109 |
| Cost of revenues | 5 | — |
| Research and development expenses | 5,025 | 5,498 |
| Selling, general, and administrative expenses | 7,730 | 9,697 |
| Total costs and expenses | 12,760 | 15,195 |
| **Loss from Operations** | (12,616) | (15,086) |
| **Other Income (Expense)** | | |
| Gain on investment in equity securities | — | 12 |
| Gain on sale of asset | 10,000 | — |
| Interest income | 140 | 405 |
| Interest expense | (10) | — |
| **Total Other Income** | 10,130 | 417 |
| **Income Tax Expense** | (2) | (2) |
| **Net Loss** | $ (2,488) | $ (14,671) |
| **Other Comprehensive Income:** | | |
| Unrealized loss on available-for-sale debt securities | — | (2) |
| **Comprehensive Loss** | $ (2,488) | $ (14,673) |
| Net loss per common share—basic and diluted | $ (1.70) | $ (19.25) |
| Weighted average shares used in computing net loss per common share—basic and diluted | 1,463,609 | 762,076 |

*The accompanying notes are an integral part of these Consolidated Financial Statements.*

**VIVOSIM LABS, INC.**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(in thousands)

| | Common Stock | | | Treasury Stock | | | | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Additional Paid-in Capital | Shares | Amount | Accumulated Deficit | Accumulated Other Comprehensive Income | Total |
| **Balance at March 31, 2023** | **727** | **$ 1** | **$ 340,325** | **—** | **$ (1)** | **$ (324,998)** | **$ 2** | **$ 15,329** |
| Issuance of common stock under employee and director stock option, RSU and purchase plans | 10 | — | — | — | — | — | — | — |
| Stock-based compensation expense | 5 | — | 1,508 | — | — | — | — | 1,508 |
| Issuance of common stock from public offering, net | 98 | — | 1,437 | — | — | — | — | 1,437 |
| Net loss | — | — | — | — | — | (14,671) | — | (14,671) |
| Unrealized loss on available-for-sale debt securities, net of tax | — | — | — | — | — | — | (2) | (2) |
| **Balance at March 31, 2024** | **840** | **$ 1** | **$ 343,270** | **—** | **$ (1)** | **$ (339,669)** | **$ —** | **$ 3,601** |
| Issuance of common stock under employee and director stock option, RSU and purchase plans | 10 | — | — | — | — | — | — | — |
| Issuance of common stock under warrants exercise | 425 | — | 80 | — | — | — | — | 80 |
| Stock-based compensation expense | — | — | 532 | — | — | — | — | 532 |
| Issuance of common stock from public offering, net | 623 | 1 | 8,766 | — | — | — | — | 8,767 |
| Net loss | — | — | — | — | — | (2,488) | — | (2,488) |
| **Balance at March 31, 2025** | **1,898** | **$ 2** | **$ 352,648** | **—** | **$ (1)** | **$ (342,157)** | **$ —** | **$ 10,492** |

*The accompanying notes are an integral part of these Consolidated Financial Statements.*

**VIVOSIM LABS, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

| | Year Ended March 31, 2025 | Year Ended March 31, 2024 |
|---|---|---|
| **Cash Flows From Operating Activities** | | |
| Net loss | $ (2,488) | $ (14,671) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Gain on investment in equity securities | — | (12) |
| Gain on sale of asset | (10,000) | — |
| Accretion on investments | (38) | (142) |
| Depreciation and amortization | 266 | 280 |
| Stock-based compensation | 532 | 1,508 |
| Non-cash lease expense | 432 | 406 |
| Inventory write-off | 798 | — |
| Increase (decrease) in cash resulting from changes in: | | |
| Accounts receivable | 3 | 119 |
| Inventory | (501) | (297) |
| Prepaid expenses and other assets | 253 | 392 |
| Accounts payable | 1,017 | 296 |
| Accrued expenses | 717 | (2,121) |
| Operating lease liability | (452) | (411) |
| **Net cash used in operating activities** | (9,461) | (14,653) |
| **Cash Flows From Investing Activities** | | |
| Purchases of fixed assets | (13) | (42) |
| Proceeds from sale of asset | 9,000 | — |
| Purchases of investments | (2,962) | (10,860) |
| Maturities of investments | 3,000 | 11,000 |
| Liquidation of equity securities | — | 718 |
| **Net cash provided by investing activities** | 9,025 | 816 |
| **Cash Flows From Financing Activities** | | |
| Proceeds from issuance of common stock, net | 8,847 | 1,437 |
| **Net cash provided by financing activities** | 8,847 | 1,437 |
| **Net Increase (Decrease) in Cash, Cash Equivalents, and Restricted Cash** | 8,411 | (12,400) |
| **Cash, cash equivalents, and restricted cash at beginning of period** | 3,044 | 15,444 |
| **Cash, cash equivalents, and restricted cash at end of period** | $ 11,455 | $ 3,044 |
| **Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets** | | |
| Cash and cash equivalents | $ 11,312 | $ 2,901 |
| Restricted cash | 143 | 143 |
| **Total cash, cash equivalents and restricted cash** | $ 11,455 | $ 3,044 |
| **Supplemental Disclosure of Cash Flow Information:** | | |
| Escrow receivable | $ 1,000 | $ — |
| Income taxes paid | $ 2 | $ 2 |
| Interest paid | $ 10 | $ — |
| Liability to be settled in equity | $ 218 | $ — |
| Financed insurance premium exchanged for prepaid insurance | $ 128 | $ — |

*The accompanying notes are an integral part of these Consolidated Financial Statements.*

**VivoSim Labs, Inc.**

**Notes to Consolidated Financial Statements**

**Note 1. Description of Business and Summary of Significant Accounting Policies**

***Nature of Operations***

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

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. 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.

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 lead asset, FXR314, hits key development, regulatory and commercial milestones.

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

The Company 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'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 May 2025 Digestive Disease Week scientific conference showing that the liver toxicology platform had a best-in-class predictive power. VivoSim's liver predictive power was shown to be 87.5% for a set of challenging liver toxicity cases – inclusive of classic cases of "liver tox misses" drugs with unforeseen liver toxicity found in clinical trials or drugs that were withdrawn from the market after liver toxicity issues emerged later. The platform identified correctly that 87.5% of the known liver-toxic drugs could be seen as liver toxic using NAMkind™ liver. This is known as the sensitivity of the platform, which at 87.5% is a world's best. Importantly, the specificity was 100%, meaning that none of the compounds tested that are not liver toxic were incorrectly identified as having liver toxicity issues by the platform.

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

The Company has also used these human disease models to identify new molecular targets responsible for driving IBD and to explore the mechanism of action of known drugs including JAK inhibitors and related molecules. A portion of its internal research continues to focus on early stage internal drug discovery programs, validating targets, and testing potentially licensable or transactable external drug compounds to identify drug candidates for partnering and/or internal clinical development.

In February 2024, the Company formed its Mosaic Cell Sciences division ("Mosaic") that was intended to serve as a key source of certain primary human cells that the Company utilizes in its research and development efforts. Mosaic provided the Company with qualified human cells for use in its clinical research and development programs. In addition to supplying the Company with primary human cells, Mosaic offered human cells for sale to life science customers, both directly and through distribution partners, which the Company expected to offset costs and over time become a profit center that offset overall research and development ("R&D") spending by the Company. The Company ended Mosaic's commercial sales operations in the third quarter of fiscal 2025, and any remaining saleable inventory was internally transferred to R&D at that time.

***Liquidity and Going Concern***

The accompanying 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 March 31, 2025, the Company had cash and cash equivalents of approximately $11.3 million, restricted cash of approximately $0.1 million and an accumulated deficit of approximately $342.2 million. 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 $9.5 million during the year ended March 31, 2025. As of March 31, 2025, the Company had total current assets of approximately $12.1 million and current liabilities of approximately $3.7 million, resulting in working capital of $8.4 million.

Through March 31, 2025, the Company has financed its operations primarily through the sale of common stock through public and at-the-market ("ATM") offerings, the private placement of equity securities, from revenue derived from the licensing of intellectual property, products and research-based services, grants, and collaborative research agreements, the sale of the Company's FXR program, and from the sale of convertible notes. During the year ended March 31, 2025, the Company issued 493,372 shares of its common stock through its ATM facility, for net proceeds of approximately $4.9 million.

On March 25, 2025, the Company sold its FXR program for $10.0 million, with $9.0 million paid at closing and $1.0 million held in escrow for a period of 15 months, with future milestones of up to $50.0 million to be paid if the lead asset, FXR314, hits key regulatory and commercial milestones.

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 Consolidated Financial Statements are issued. The accompanying 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.

***Nasdaq Deficiency Notices***

On July 18, 2024, the Company received a written notice from the Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the last 30 consecutive business days, the Company no longer meets the requirement to maintain a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided an initial period of 180 calendar days, or until January 14, 2025, to regain compliance.

On January 16, 2025, the Staff provided a notice to the Company (the "Nasdaq Notice") that it had not regained compliance with Rule 5550(a)(2) and was not eligible for a second 180 calendar day compliance period as it did not comply with the requirements for initial listing on the Nasdaq Capital Market. The Nasdaq Notice further indicated that, unless the Company timely requested a hearing before a Hearings Panel (the "Hearings Panel"), the Company's common stock would be subject to delisting. The Company timely requested a hearing, which automatically stayed any delisting or suspension action pending the hearing and the expiration of any extension period granted by the Hearings Panel following the hearing.

On February 19, 2025, the Company received a written notice from the Staff of Nasdaq indicating that, since the Company's Quarterly Report on Form 10-Q for the period ended December 31, 2024 reported stockholders' equity of $364,000, and as of February 19, 2025, the Company did not meet the alternatives of market value of listed securities or net income from continuing operations, the Company no longer met the requirement to maintain a minimum of $2,500,000 in stockholders' equity, as set forth in Nasdaq Listing Rule 5550(b)(1) ("Rule 5550(b)(1)").

On March 31, 2025, the Company effected a 1-for-12 reverse stock split of its common stock (the "Reverse Stock Split"). On March 27, 2025, the Hearings Panel granted the Company an exception until April 15, 2025 to demonstrate compliance with Rule 5550(a)(2) and Rule 5550(b)(1). On April 30, 2025, the Company received a letter from Nasdaq notifying it that it has demonstrated compliance with Rule 5550(a)(2) and Rule 5550(b)(1) as required by the Hearings Panel's March 27, 2025 decision. Pursuant to Nasdaq Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor for a period of one year from the date of Nasdaq's letter.

***Reverse Stock Split***

The par value per share and the number of authorized shares were not adjusted as a result of the Reverse Stock Split. The shares of common stock underlying outstanding stock options, common stock warrants and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the shares available for grants under the Company's incentive plans were adjusted as a result of the Reverse Stock Split. All references to common stock, options to purchase common stock, outstanding common stock warrants, common stock share data, per share data, and related information contained in the consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

***Basis of Presentation and Principles of Consolidation***

The accompanying Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates promulgated by the Financial Accounting Standards Board ("FASB").

The Consolidated Financial Statements include the accounts of VivoSim and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of the Consolidated 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.

***Financial Instruments***

For certain of the Company's financial instruments, including cash and cash equivalents, prepaid expenses and other assets, accounts payable, accrued expenses, the carrying amounts are generally considered to be representative of their respective fair values because of the short-term nature of those instruments.

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents.

***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 have been derived from a relatively small number of customers and third parties. 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 uncollectable 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 March 31, 2025.

***Restricted Cash***

As of March 31, 2025 and 2024, the Company had approximately $0.1 million of restricted cash, deposited with a financial institution. The entire amount was held in certificates of deposit to support a letter of credit agreement related to the Company's facility leases entered into in November 2020 and amended in November 2021.

***Investments***

Investments consist of investments in debt securities.

Investments in debt securities consist of investments in U.S. Treasury bills. Any investments that have original maturities of three months or less are classified as cash equivalents on the Consolidated Balance Sheets. As of March 31, 2025, all Company investments, which consisted of U.S. Treasury bills, matured. As of March 31, 2024, all investments were classified as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies. Available-for-sale debt securities are recorded at fair value. Any unrealized gains and losses are included in accumulated other comprehensive income as a component of stockholders' equity until realized. As U.S. Treasury bills are risk-free, any declines in fair value are considered temporary.

***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 2024, the Company entered into an insurance premium financing agreement for $0.4 million, with a term of nine months and an annual interest rate of 8.57%. The Company made a down payment of 10% and is required to make monthly principal and interest payments of $44,281 over the term of the agreement, which matures in June 2025. The insurance premium financing liability was approximately $0.1 million as of March 31, 2025. Related prepaid insurance at March 31, 2025 of $0.2 million is included in prepaid expenses and other current assets on the accompanying Consolidated Balance Sheets.

***Inventory***

Inventories are stated at the lower of cost or net realizable value. Inventory as of March 31, 2024 consisted of approximately $0.3 million in finished goods, which was related to the Company's former division, Mosaic. There was no inventory as of March 31, 2025. The Company ended Mosaic's commercial operations in the third quarter of fiscal 2025. At that time, all remaining inventory was internally transferred to R&D and written off to research and development expenses.

***Fixed Assets and Depreciation***

Fixed assets are carried at cost less accumulated depreciation. Expenditures that extend the life of the asset are capitalized and depreciated. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets or, in the case of leasehold improvements, over the lesser of the useful life of the related asset or the remaining lease term. The estimated useful lives of the fixed assets range between one and seven years.

***Impairment of Long-Lived Assets***

In accordance with authoritative guidance, the Company reviews its long-lived assets, including fixed assets and other assets, for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be fully recoverable. To determine recoverability of its long-lived assets, the Company evaluates whether future undiscounted net cash flows will be less than the carrying amount of the assets and adjusts the carrying amount of its assets to fair value. Management has determined that no impairment of long-lived assets occurred as of March 31, 2025 and 2024.

***Research and Development***

Research and development expenses, including direct and allocated expenses, consist of independent research and development costs, as well as costs associated with sponsored research and development. Research and development costs are expensed as incurred.

***Acquired In-Process Research and Development***

*FXR Program*

In March 2023, the Company acquired Metacrine's FXR program for $4.0 million. The FXR program was determined to have no alternative future use, and therefore was considered acquired in-process research and development and fully expensed. Acquired in-process research and development expenses were included in total research and development expenses on the Consolidated Statements of Operations and Other Comprehensive Loss. In the year ended March 31, 2023, the Company paid a $2.0 million upfront payment, and the remaining $2.0 million was paid in the year ended March 31, 2024, upon the final transfer of the drug compounds, related data, and IP.

On March 25, 2025, the Company sold its FXR program and related assets to Eli Lilly and Company (the “FXR Asset Sale”). The consideration for the FXR Asset Sale consisted of (i) an upfront cash payment by Lilly to the Company equal to $10.0 million, of which $9.0 million was paid at closing and the remaining $1.0 million was deposited into escrow for 15 months to satisfy any claims for indemnification during such period, (ii) the assumption by Eli Lilly and Company of certain liabilities related to the FXR program, and (iii) 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.

The Company assessed whether this agreement was considered a contract with a customer pursuant to Topic 606 or subject to guidance pursuant to ASC Topic 610, Other Income ("Topic 610"). The Company considered a variety of factors in determining the appropriate assumptions under this arrangement, such as whether the counterparty was a customer, the nature of its operations, both historically and ongoing, and any contingent consideration constraints. The Company determined the counterparty was not a customer based on the nature of its ordinary business operations and recorded the transaction within other income under Topic 610. Furthermore, the Company determined the $1.0 million held in escrow was not constrained due to the terms of the indemnification language and it was therefore recognized as a component of the consideration received at the time of closing; however, the Company did determine future potential milestone payments that may be made by Eli Lilly and Company were constrained due to the uncertainty of the milestones being met. If and when the future milestone payments are no longer considered constrained, the Company will record such payments in other income.

***Segment Reporting***

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 in deciding how to allocate resources to an individual segment and in assessing performance. As of March 31, 2025, the Company identified only one operating segment. Please refer to "Note 15. Business Segment Information" for further information.

***Income Taxes***

Deferred income taxes are recognized for the tax consequences in future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the combination of the tax payable for the year and the change during the year in deferred tax assets and liabilities. The Company’s policy regarding uncertainty in income taxes is pursuant to ASC Topic 740-10. Interest and penalties that would be assessed in relation to the settlement value of unrecognized tax benefits is recognized as a component of income tax expense.

***Revenue Recognition***

*Royalty revenue*

The Company has entered into a license agreement with a company that includes the following: (i) non-refundable upfront fees and (ii) royalties based on specified percentages of net product sales, if any. At the initiation of the agreement, the Company has analyzed whether it results in a contract with a customer under Topic 606.

The Company has considered a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the Company is a principal or 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 has evaluated each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, non-refundable upfront fees have been considered fixed, while sales-based royalty payments have been identified as variable consideration which must be evaluated to determine if it has been constrained and, therefore, excluded from the transaction price. Please refer to "Note 6. Collaborative Research, Development, and License Agreements" for further information.

*Product revenue, net*

The Company's former product-based division, Mosaic, which was established in the fourth quarter of fiscal 2024, produced high-quality cell-based products for use in its R&D and for use by life science customers. The Company recognized product revenue when the performance obligation is satisfied, which was at the point in time the customer obtained control of the Company's product, typically upon delivery. Product revenues were recorded at the transaction price under Topic 606. The Company provided no right of return to its customers except in cases where a customer obtained authorization from the Company for the return. To date, there have been no product returns. The Company ended Mosaic's commercial operations during the third quarter of fiscal 2025.

***Stock-Based Compensation***

The Company accounts for stock-based compensation in accordance with the ASC Topic 718, *Compensation — Stock Compensation,* which establishes accounting for equity instruments exchanged for employee and non-employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award (determined using either the Black-Scholes or Monte Carlo option-pricing models, depending on the complexity of the equity grant), and is recognized as an expense, under the straight-line method, over the employee or non-employee's requisite service period (generally the vesting period of the equity grant). The assumed dividend yield is based on the Company's expectation of not paying dividends in the foreseeable future. The Company uses its Company-specific historical volatility rate. The risk-free interest rate assumption is based on U.S. Treasury rates. The weighted average expected life of options is estimated using the average of the contractual term and the weighted average vesting term of the options. Option forfeitures are treated as a reduction of stock-based compensation expense and accounted for as they occur.

***Comprehensive Income (Loss)***

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive income (loss) in the consolidated financial statements in the period in which they are recognized. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss).

***Net Loss Per Share***

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

Common stock equivalents excluded from computing diluted net loss per share due to their anti-dilutive effect were approximately 0.7 million shares and less than 0.1 million shares for the years ended March 31, 2025 and 2024, respectively.

**Note 2. Investments and fair value measurement**

*Investments in debt securities*

As of March 31, 2025, all Company investments that consisted of U.S. Treasury bills matured. For the year ended March 31, 2025, there was approximately $0.1 million of interest income related to the investments in debt securities. As the investments in debt securities consist of U.S. Treasury bills from active markets, the fair value is measured using level 1 inputs.

The Company did not have any investments in debt securities as of March 31, 2025. The following table summarizes the Company's investments in debt securities that are measured at fair value as of March 31, 2024 (in thousands):

| | Amortized costs basis | Gross unrealized gains | Gross unrealized losses | Fair value |
|---|---|---|---|---|
| **As of March 31, 2024** | | | | |
| Investments in debt securities | $ 996 | $ 2 | $ — | $ 998 |

**Note 3. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following (in thousands):

| | March 31, 2025 | March 31, 2024 |
|---|---|---|
| Prepaid insurance | $ 417 | $ 445 |
| Prepaid expenses | 360 | 256 |
| Other current assets | 12 | 4 |
| Total prepaid expenses and other current assets | $ 789 | $ 705 |

Prepaid expenses and other current assets for the years ended March 31, 2025 and 2024 was approximately $0.8 million and $0.7 million, respectively.

**Note 4. Fixed Assets**

Fixed assets consisted of the following (in thousands):

| | March 31, 2025 | March 31, 2024 |
|---|---|---|
| Laboratory equipment | $ 1,630 | $ 1,617 |
| Furniture and fixtures | 66 | 66 |
| Computer software and equipment | 244 | 244 |
| Fixed Assets, gross | 1,940 | 1,927 |
| Less accumulated depreciation | (1,521) | (1,258) |
| Fixed Assets, net | $ 419 | $ 669 |

As of March 31, 2025 and 2024, all of the Company's fixed assets were active and in use. Depreciation expense for each of the years ended March 31, 2025 and 2024 was approximately $0.3 million.

**Note 5. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

| | March 31, 2025 | March 31, 2024 |
|---|---|---|
| Accrued payroll and other employee benefits | $ 652 | $ 536 |
| Accrued legal and professional fees | 515 | 93 |
| Other accrued expenses | 59 | 98 |
| Total accrued expenses | $ 1,226 | $ 727 |

**Note 6. 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 was 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 years ended March 31, 2025 and 2024, the Company recorded $119,000 and $109,000, respectively, of royalty revenue based on sales-based royalties from the license agreement.

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

*University of Missouri*

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

On December 5, 2022, the Company amended the license agreement with the University of Missouri, whereby the Company agreed to pay a single, upfront payment of $50,000 to the University of Missouri in exchange for the aforementioned licensed intellectual property to be fully paid up by the Company. As a result, the Company will continue to have rights to the licensed intellectual property until its expiration in June 2028, but will no longer owe minimum annual royalty payments, royalty payments based on net sales, or any other payments (other than patent annuities and any prosecution costs) in the future.

*Clemson University*

In May 2011, the Company entered into a license agreement with Clemson University Research Foundation ("CURF") to in-license certain technology and intellectual property relating to ink-jet printing of viable cells. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company was required to pay the university royalties ranging from 1.5% to 3% of net sales of covered tissue products and the fair market value of covered tissues transferred internally for use in the Company's commercial service business, depending on the level of net sales reached each year. The license agreement terminated in May 2024 upon expiration of the patents licensed and was subject to certain conditions as defined in the license agreement. Minimum annual royalty payments of $40,000 per year were due beginning in calendar 2016. Royalty payments of $40,000 were made for the years ended March 31, 2025 and 2024. The annual minimum royalty was creditable against royalties owed during the same calendar year.

In addition to the annual royalty noted above, CURF was owed 40% of all payments including but not limited to, upfront payments, license fees, issue fees, maintenance fees, and milestone payments received from third parties, including sublicensees, in consideration for sublicensing rights to licensed products. However, per the agreement, in the event that the Company defended the technology by litigation, it could offset any royalties due by legal expenses incurred. As of the expiration of the license agreement in May 2024, the Company's legal expenses exceeded royalties owed from the upfront payment and sales-based royalties related to the BICO Group AB license agreement. Therefore, no royalty expense to CURF was recorded for the year ended March 31, 2025 and no royalty expense related to sales-based royalties was ever recorded under the agreement.

*Capitalized License Fees*

Capitalized license fees consisted of the following (in thousands):

| | March 31, 2025 | March 31, 2024 |
|---|---|---|
| License fees | $ 44 | $ 109 |
| Less accumulated amortization | (39) | (101) |
| License fees, net | $ 5 | $ 8 |

The above license fees, net of accumulated amortization, are included in prepaid expenses and other assets in the accompanying Consolidated Balance Sheets and are being amortized over the life of the related patents. Amortization expense of licenses was approximately $3,000 and $5,000 for the years ended March 31, 2025 and 2024, respectively, which are included in selling, general,

and administrative expenses. At March 31, 2025, the weighted average remaining amortization period for all licenses was approximately 2 years. The annual amortization expense of licenses for the next three years is estimated to be approximately $2,000 per year.

*The Salk Institute for Biological Studies*

In March 2023, the Company acquired the FXR Agonist program from Metacrine. All patent rights related to this program were assigned to the Company in connection with the acquisition. In addition, the Company assumed and was assigned a license agreement with the Salk Institute for Biological Studies (hereafter "Salk") that provided for certain payments to Salk upon the successful development and commercialization of the lead compound, FXR314. The Company was required to pay Salk royalties ranging from 1% to 1.125% of net sales of therapeutics based on FXR314. In addition, the Company was required to make certain milestone payments based on the successful initiation and/or completion of certain development milestones, including $500,000 within 45 days of the dosing of the first patient in a phase III clinical trial, $1,000,000 within 45 days of FDA approval of the first Licensed Product and $1,500,000 within 45 days of the first commercial sale of a Licensed Product in the Territory. There were also reduced milestone payments application to a second or third licensed product, if any. In March 2025, the Company closed the sale of its FXR program under which the license agreement was assigned to the buyer thereof. Pursuant to the license agreement with Salk, the Company paid $100,000 to Salk following the closing of the sale of the FXR program, which was recorded as selling, general, and administrative royalty expense.

**Note 7. Stockholders' Equity**

***Preferred stock***

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

***Common stock***

In January 2012, the Company's Board of Directors ("Board") approved the 2012 Amended and Restated Equity Incentive Plan ("2012 Plan"). The 2012 Plan initially authorized the issuance of up to 27,308 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, RSUs, performance units, performance shares, and other stock or cash awards, and the number of shares issuable pursuant thereto was increased several times to an aggregate of 193,974 shares.

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

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

The Company previously had an effective shelf registration statement on Form S-3 (File No. 333-252224), declared effective by the SEC on January 29, 2021 (the "2021 Shelf"), which registered $150.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that expired on January 29, 2024. On January 26, 2024, the Company filed a new 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 and replaced the 2021 Shelf at that time.

On March 16, 2018, the Company entered into a Sales Agreement with Jones Trading Institutional Services LLC (the “Agent”). On January 29, 2021, the Company filed a prospectus supplement to the 2021 Shelf, 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 $50.0 million. Any shares offered and sold were issued pursuant to the 2021 Shelf until it was replaced by the 2024 Shelf.

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 year ended March 31, 2025, the Company issued 493,372 shares of common stock in ATM offerings, pursuant to the 2024 Shelf. As of March 31, 2025, the Company has sold an aggregate of 496,405 shares of common stock in ATM offerings under the 2024 ATM Prospectus, with gross proceeds of approximately $5.0 million. As of March 31, 2025, there was approximately $142.7 million unallocated and available for future offerings under the 2024 Shelf, and approximately $2.3 million available for future offerings through the Company’s ATM program under the 2024 ATM Prospectus.

In the event that the aggregate market value of the Company’s common stock held by non-affiliates (“public float”) is less than $75.0 million, the amount the Company 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 its public float. As of the date of filing of this Annual Report, the Company’s public float was less than $75.0 million, and therefore it is limited to an aggregate of one-third of its public float in the amount it 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 the Company’s public float meets or exceeds $75.0 million at any time, the Company will no longer be subject to the restrictions set forth in General Instruction I.B.6 of Form S-3.

***May 2024 Best Efforts Public Offering***

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

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

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

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

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

The Company sold (i) 130,202 shares of its common stock and Common Warrants to purchase up to 130,202 shares of common stock and (ii) Pre-Funded Warrants to purchase 416,666 shares of common stock and accompanying Common Warrants to purchase up to 416,666 shares of common stock. As of March 31, 2025, all of the Pre-Funded Warrants had been exercised and 7,810 shares of common stock had been issued upon exercise of Common Warrants.

***Restricted stock units***

The following table summarizes the Company's RSUs activity for the year ended March 31, 2025:

| | Number of Shares | | Weighted Average Price |
|---|---|---|---|
| Unvested at March 31, 2024 | 10,214 | $ | 21.02 |
| Granted | 9,798 | $ | 6.57 |
| Vested | (10,214) | $ | 21.02 |
| Cancelled / forfeited | (1,633) | $ | 6.57 |
| Unvested at March 31, 2025 | 8,165 | $ | 6.57 |

***Stock options***

During the year ended March 31, 2025, under the A&R 2022 Plan, 96,169 stock options were granted at various exercise prices.

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 stock options 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 March 31, 2025, no performance conditions have been met. The grant date fair value of the performance based awards is $118,000 in the aggregate, which will be recognized when the performance condition is satisfied.

The following table summarizes stock option activity for the year ended March 31, 2025:

| | Options Outstanding | | Weighted-Average Exercise Price | | Aggregate Intrinsic Value |
|---|---|---|---|---|---|
| Outstanding at March 31, 2024 | 58,140 | $ | 51.14 | $ | — |
| Options granted | 96,169 | $ | 7.11 | $ | — |
| Options canceled | (12,912) | $ | 35.08 | $ | — |
| Outstanding at March 31, 2025 | 141,397 | $ | 22.66 | $ | — |
| Vested and Exercisable at March 31, 2025 | 40,292 | $ | 57.61 | $ | — |

The weighted-average remaining contractual term of stock options exercisable and outstanding at March 31, 2025 was approximately 8.3 years.

***Warrants***

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

The following table summarizes the Company's Common Warrant activity from March 31, 2024 to March 31, 2025:

| | Number of Warrants | Exercise Price |
|---|---|---|
| Outstanding at March 31, 2024 | — | — |
| Issued | 546,870 | $9.60 |
| Exercised | (7,810) | $9.60 |
| Outstanding at March 31, 2025 | 539,060 | $9.60 |

During the year ended March 31, 2025, all 416,666 Pre-Funded Warrants were exercised. The following table summarizes the Company's Pre-Funded Warrants activity from March 31, 2024 to March 31, 2025:

| | Number of Warrants | Exercise Price |
|---|---|---|
| Outstanding at March 31, 2024 | — | — |
| Issued | 416,666 | $ 0.001 |
| Exercised | (416,666) | $ 0.001 |
| Outstanding at March 31, 2025 | — | — |

***Employee Stock Purchase Plan***

In July 2023, the Board adopted, and subsequently on October 31, 2023, the Company's stockholders approved, the 2023 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 year ended March 31, 2025, 42 shares were issued under the ESPP. At March 31, 2025, there were 3,708 shares remaining available for purchase under the ESPP.

***Common stock reserved for future issuance***

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

| | |
|---|---|
| Common stock issuable pursuant to options outstanding and reserved under the 2012 Plan | 31,292 |
| Common stock reserved under the 2012 Plan | — |
| Common stock issuable pursuant to options outstanding and reserved under the A&R 2022 Plan | 105,939 |
| Common stock reserved under the A&R 2022 Plan | 198,774 |
| Common stock reserved under the ESPP | 3,708 |
| Common stock reserved under the 2021 Inducement Equity Plan | 83 |
| Common stock issuable pursuant to restricted stock units outstanding under the 2012 Plan | — |
| Common stock issuable pursuant to restricted stock units outstanding under the A&R 2022 Plan | 8,165 |
| Common stock issuable pursuant to options outstanding and reserved under the Inducement Plan | 4,166 |
| Common stock issuable pursuant to outstanding Pre-Funded Warrants | — |
| Common stock issuable pursuant to outstanding Common Warrants | 539,060 |
| Total at March 31, 2025 | 891,187 |

***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 awards, performance-based RSUs under an Incentive Award Performance-Based Restricted Stock Unit Agreement, the 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):

| | Year Ended March 31, 2025 | Year Ended March 31, 2024 |
|---|---|---|
| Research and development | $ 86 | $ 138 |
| General and administrative | 446 | 1,370 |
| Total | $ 532 | $ 1,508 |

The total unrecognized compensation cost related to unvested stock option grants as of March 31, 2025 was approximately $0.6 million and the weighted average period over which these grants are expected to vest is 2.51 years.

The total unrecognized stock-based compensation cost related to unvested RSUs as of March 31, 2025 was less than $0.1 million, which will be recognized over a weighted average period of 0.35 years.

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

| | Year Ended March 31, 2025 | Year Ended March 31, 2024 |
|---|---|---|
| Dividend yield | — | — |
| Volatility | 99.38% | 99.04% |
| Risk-free interest rate | 3.75% | 4.11% |
| Expected life of options | 5.75 years | 6 years |
| Weighted average grant date fair value | $ 5.67 | $ 1.34 |

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

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

| | Year Ended March 31, 2025 | Year Ended March 31, 2024 |
|---|---|---|
| Dividend yield | — | — |
| Volatility | 95.20% | 95.20% |
| Risk-free interest rate | 5.27% | 5.27% |
| Expected term | 6 months | 6 months |
| Grant date fair value | $ 0.39 | $ 0.39 |

The assumed dividend yield was 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 was based on U.S. Treasury rates. The expected life is the 6-month purchase period.

**Note 8. Leases**

After the initial adoption of ASC Topic 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 identified asset in exchange for consideration over a period of time. If a lease is identified, the Company will apply the guidance from ASC Topic 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 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 are approximately $40,800 with 3% annual escalators.

The Company determined that the Permanent Lease is considered an operating lease under ASC Topic 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 March 31, 2025 (in thousands):

| | March 31, 2025 |
|---|---|
| **ASSETS** | |
| Operating lease right-of-use assets | $ 867 |
| Total lease right-of-use assets | $ 867 |
| | |
| **LIABILITIES** | |
| Current | |
| Operating lease liability | 521 |
| Noncurrent | |
| Operating lease liability, net of current portion | 421 |
| Total lease liabilities | $ 942 |
| | |
| Weighted average remaining lease term: | 1.83 years |
| Weighted average discount rate: | 6% |

Variable lease expense was approximately $93,000 and $153,000 for the years ended March 31, 2025 and 2024, respectively. Operating lease expense was approximately $503,000 for the years ended March 31, 2025 and 2024, respectively.

Cash outflows associated with the Company's operating lease for the years ended March 31, 2025 and 2024 were $524,000 and $509,000, respectively.

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

| | |
|---|---|
| Fiscal year ending March 31, 2026 | 538 |
| Fiscal year ending March 31, 2027 | 460 |
| Total future lease payments | 998 |
| Less: Imputed Interest | (56) |
| Total lease obligations | 942 |
| Less: Current obligations | (521) |
| Noncurrent lease obligations | $ 421 |

**Note 9. 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 Supreme Court of the State of New York, County 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. The Company is defending these claims vigorously, but there is no guarantee that it 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 Consolidated Financial Statements. Accruals are recognized when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. Gain contingencies are not recognized until realized. Legal fees are expensed as incurred. 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. During fiscal 2025, the Company recorded an accrual of $0.6 million (which was considered a financing fee related to the Offering discussed in Note 7. Stockholders' Equity) for the loss contingencies associated with the above described H.C. Wainwright complaint. Of the $0.6 million loss contingency accrual, $0.4 million is included in accrued expenses on the accompanying 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 Consolidated Balance Sheets. The liability to be settled in equity relates to a fixed number of warrants that were included in the complaint as part of the sought compensatory damages. The Company recorded the loss contingency accrual as it determined that an unfavorable outcome is probable or reasonably possible and believed that the amount or range of any possible loss was reasonably estimable. However, amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions including timing of related payments, and the outcome of legal proceedings and claims brought against the Company is subject to significant uncertainty. If one or more legal matters were resolved against the Company in a reporting period, the Company’s Consolidated Financial Statements for that reporting period could be materially adversely affected.

**Note 10. Income Taxes**

A reconciliation of the statutory federal rate and the effective rate, for operations, is as follows for the years ended March 31, 2025 and 2024 (in thousands, except percentages):

| | March 31, 2025 | | March 31, 2024 | |
|---|---|---|---|---|
| Tax computed at federal statutory rate | $ (522) | 21.0% | $ (3,081) | 21.0% |
| State income tax, net of federal benefit | (35) | 1.4% | (110) | 0.7% |
| Stock-based compensation | 75 | -3.0% | 721 | -4.9% |
| Research credits | — | 0.0% | — | 0.0% |
| Change in tax rate | (32) | 1.3% | (62) | 0.4% |
| Removal of net operating losses and research development credits | 615 | -24.7% | 1,910 | -13.0% |
| Uncertain tax positions | 96 | -3.9% | 111 | -0.8% |
| Other | (18) | 0.7% | (14) | 0.1% |
| Valuation allowance | (177) | 7.1% | 527 | -3.6% |
| Provision (benefit) for income taxes | $ 2 | -0.1% | $ 2 | 0.0% |

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets are as follows as of March 31, 2025 and 2024 (in thousands, except percentages):

| | March 31, 2025 | March 31, 2024 |
|---|---|---|
| **Deferred tax assets:** | | |
| Amortization | $ 1 | $ 593 |
| Section 174 R&D capitalization | 2,380 | 1,793 |
| Accrued expenses and reserves | 132 | 105 |
| Operating lease liability | 207 | 307 |
| Stock-based compensation | 336 | 315 |
| Inventory | — | 259 |
| Other, net | 5 | 4 |
| Total deferred tax assets | 3,061 | 3,376 |
| Valuation allowance | (2,807) | (2,983) |
| Net deferred tax assets | $ 254 | $ 393 |
| **Deferred tax liabilities:** | | |
| Operating lease right-of-use assets | (191) | (286) |
| Depreciation | (63) | (107) |
| Total deferred tax liabilities | $ (254) | $ (393) |
| | $ — | $ — |

A full valuation allowance has been established to offset the deferred tax assets as management cannot conclude that realization of such assets is more likely than not. Under the Internal Revenue Code Sections 382 and 383, annual use of the Company's net operating loss and research tax credit carryforwards to offset taxable income may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such limitations have been triggered as of March 31, 2025. Until this analysis is completed, the Company has removed the deferred tax assets related to net operating losses from its deferred tax asset schedule. Further, until a study is completed and any limitation known, approximately $1.8 million and $1.7 million for the years ended March 31, 2025 and 2024, respectively, would be considered as an uncertain tax position if netted against the deferred tax asset. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. The valuation allowance decreased by approximately $177,000 and increased by approximately $525,000 for the years ended March 31, 2025 and 2024, respectively.

The Company had federal and state net operating loss carryforwards of approximately $222.2 million and $44.3 million, respectively, as of March 31, 2025. Federal net operating loss carryforwards of approximately $78.6 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year subject to revisions made by the Coronavirus Aid, Relief, and Economic Security Act. The remaining federal net operating losses will begin to expire in 2028, unless previously utilized. The state net operating loss carryforwards will begin to expire in 2028, unless previously utilized.

The Company had federal and state research tax credit carryforwards of approximately $5.3 million and $4.8 million at March 31, 2025, respectively. The federal research tax credit carryforwards begin expiring in 2028. The state research tax credit carryforwards do not expire.

The Company did not record any accruals for income tax accounting uncertainties for the year ended March 31, 2025.

The Company did not accrue either interest or penalties from inception through March 31, 2025.

The Company does not expect its unrecognized tax benefits to significantly increase or decrease within the next 12 months.

The Company is subject to tax in the United States and in California. As of March 31, 2025, the Company's tax years from inception are subject to examination by the tax authorities due to the generation of net operating losses. The Company is not currently under examination by any jurisdiction.

**Note 11. Related Parties**

From time to time, the Company enters into agreements with one or more related parties 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”) is an entity for which Keith Murphy, the Company’s Executive Chairman, serves as the Chief Executive Officer and President.

On December 28, 2020, the Company entered into an intercompany agreement (the “Intercompany Agreement”) with Viscient and Organovo, Inc., the Company’s wholly-owned subsidiary, which included an asset purchase agreement for certain lab equipment. Pursuant to the Intercompany Agreement, the Company agreed to provide Viscient certain services related to 3D bioprinting technology, which includes, but is not limited to, histology services, cell isolation, and proliferation of cells and Viscient agreed to provide the Company certain services related to 3D bioprinting technology, including bioprinter training, bioprinting services, and qPCR assays, in each case on payment terms specified in the Intercompany Agreement and as may be further determined by the parties. In addition, the Company and Viscient each agreed to share certain facilities and equipment and, subject to further agreement, to each make certain employees available for specified projects for the other party at prices to be determined in good faith by the parties. During the second quarter of fiscal 2025 and first quarter of fiscal 2026, the companies added Statements of Work to the Intercompany Agreement, where Viscient agreed to provide the Company with certain testing services related to the Company's ongoing R&D. The Company evaluated the accounting for the Intercompany Agreement and concluded that any services provided by Viscient to the Company will be expensed as incurred, and any compensation for services provided by the Company to Viscient will be considered a reduction of personnel related expenses. Any services provided to Viscient do not fall under Topic 606 as the Intercompany Agreement is not a contract with a customer. For the fiscal year ended March 31, 2025, the Company incurred $118,000 in R&D consulting expenses from Viscient. The Company did not incur any consulting expenses during the fiscal year ended March 31, 2024. Additionally, for the fiscal years ended March 31, 2025 and 2024, the Company provided approximately $3,000 and $14,000 of histology services to Viscient, respectively.

**Note 12. Defined Contribution Plan**

The Company has a defined contribution 401(k) plan covering substantially all employees. During the year ended March 31, 2015, the 401(k) plan was amended (the “Amended Plan”) to include an employer matching provision. Under the terms of the Amended Plan, the Company will make matching contributions on up to the first 6% of compensation contributed by its employees. Amounts expensed under the Company’s 401(k) plan for the years ended March 31, 2025 and 2024 were approximately $66,000 and $61,000, respectively.

**Note 13. Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the 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 November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the Chief Operating Decision Maker (“CODM”) and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment’s profit or loss in assessing segment performance and deciding how to allocate resources. The ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The adoption of this guidance did not have a material impact on the Company’s Consolidated Financial Statements. Please refer to "Note 16. Business Segment Information" for further information.

*Recently Issued 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 Company has not yet completed its assessment of the impact of ASU 2023-09 on the Company’s Consolidated Financial Statements.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which is intended to improve the disclosures of expenses by providing more detailed information about the types of expenses in commonly presented expense captions. The standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December

15, 2027, with early adoption permitted. The standard can be applied either prospectively or retrospectively. The Company has not yet completed its assessment of the impact of ASU 2024-03 on the Company's Consolidated Financial Statements.

**Note 14. Restructuring**

On August 18, 2023, the Company announced to its employees a plan to reduce the Company's workforce, effective August 25, 2023, by approximately six employees, which represented approximately 24% of its employees as of August 18, 2023. The Company refocused operations on FXR314, its clinical drug candidate. This decision to reduce the Company's workforce was made in order to focus spending on the Company's clinical program for FXR314, reduce ongoing operating expenses not related to clinical expenses, and extend the Company's cash runway. The Company incurred approximately $0.4 million of cash expenditures for the year ended March 31, 2024, in connection with the reduction in force, which related to severance pay. As of March 31, 2024, all restructuring costs were paid in full. The Company's annual cost savings for the fiscal year ended March 31, 2025 was approximately $1.4 million resulting from the reduction in force.

**Note 15. 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 CODM in deciding how to allocate resources to an individual segment and in assessing performance. The Company identified two operating segments in fiscal 2024, which did not impact prior periods, and during fiscal 2025 had a change in the operating segments from two to one operating segment. During fiscal 2024, the Company's operating segments were as follows:

***Research & Development***

The R&D segment consisted of the Company's drug development efforts. The Company's clinical focus was in advancing FXR314 in IBD, including ulcerative colitis and Crohn's disease. In March 2025, the Company sold its FXR program. The Company now focuses on providing testing of drugs and drug candidates in 3D human tissue models of liver and intestine, offering partners liver and intestinal toxicology insights using its NAM models. The Company plans to work with pharmaceutical and biotech companies at all stages of drug development to reduce the significant risk and cost of bringing therapeutics to market through the regulatory process and offer bespoke services in the areas of investigational toxicology, mechanism of drug action elucidation, and other applications of these complex human tissue models.

***Mosaic Cell Sciences***

The Mosaic segment, which began operations in February 2024, consisted of the Company's Mosaic Cell Sciences division, which served as a key source of certain of the primary human cells that the Company utilized in its research and development efforts. Mosaic provided the Company with qualified human cells for use in its clinical research and development programs. In addition to supplying the Company with primary human cells, Mosaic offered human cells for sale to life science customers, both directly and through distribution partners, which the Company expected to offset costs and over time become a profit center that offset overall R&D spending by the Company. However, the Company ended Mosaic's operations in the third quarter of fiscal 2025.

***Change to Reportable Segments***

The Company had a change in reportable segments in the fourth quarter of fiscal 2025, due to Mosaic ending its operations during the third quarter of fiscal 2025. As a result, there was an update to the financial information that is evaluated on a regular basis by the CODM for purposes of allocating resources and assessing performance, where the chief operating decision maker now regularly reviews the entity-wide operating results and performance. As a result, the Company's single operating segment constitutes all of the consolidated entity. The change in reportable segments does not affect prior period segment reporting.

The Company analyzed whether the closing of the Mosaic business segment qualified for reporting as a discontinued operation under ASC Topic 205. The Company's main operations are its R&D activities. Mosaic was initially formed to generate primary human cells for use by R&D rather than purchasing from third parties, while also selling excess inventory commercially to external customers, as a way to offset costs. However, the Company did not achieve significant revenues from Mosaic as initially expected. Therefore, Mosaic's remaining saleable inventory was internally transferred to R&D and Mosaic ended its commercial operations. The Company concluded that the closing of the Mosaic business segment does not qualify for reporting as a discontinued operation because the closing of the segment does not represent a strategic shift that will have a major effect on the Company's operations and financial results.

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

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

| | Year Ended March 31, 2025 | Year Ended March 31, 2024 |
|---|---|---|
| Revenue | | |
| Royalty revenue | $ 119 | $ 109 |
| Product revenue | 25 | — |
| Total revenue | 144 | 109 |
| Operating expenses | | |
| Cost of revenues | 5 | — |
| Research and development (a) (b) | 4,712 | 5,133 |
| Selling, general, and administrative expenses (a)(b) | 7,245 | 8,274 |
| Non-cash stock-based compensation (see Note 7) | 532 | 1,508 |
| Depreciation and amortization (see Note 4) | 266 | 280 |
| Total operating expenses | $ 12,760 | $ 15,195 |
| Consolidated operating loss | $ (12,616) | $ (15,086) |

(a) Stock-based compensation expense of $86,000 and $138,000 related to research and development and $446,000 and $1,370,000, related to selling, general, and administration have been excluded for the years ended March 31, 2025 and 2024, respectively.
(b) Depreciation and amortization expense of $227,000 related to research and development for each of the years ended March 31, 2025 and 2024. Depreciation and amortization expense of $39,000 and $53,000 related to selling, general, and administration have been excluded for the years ended March 31, 2025 and 2024, respectively.

**Note 16. Subsequent Events**

Between April 1, 2025 and the date of the filing of this Annual Report on Form 10-K, the Company issued 701,729 shares of common stock in ATM offerings under the 2024 ATM Prospectus for net proceeds of approximately $1.8 million.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. 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 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 Executive Chairman and Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively), as appropriate, to allow timely decisions regarding required disclosure.

Under the supervision of our Executive Chairman and our Chief Financial Officer, and with the participation of all members of management, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on this evaluation, our Executive Chairman and our Chief Financial Officer concluded that our disclosure controls and procedures were designed and operating effectively as of the end of the period covered by this Annual Report.

**Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our system of internal control over financial reporting is designed to provide reasonable assurance to our management and the board of directors regarding the preparation and fair presentation of our Consolidated Financial Statements for external purposes in accordance with generally accepted accounting principles.

Our management, under the supervision of our Executive Chairman and our Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of March 31, 2025. In making this assessment, we used the framework included in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the criteria set forth in *Internal Control — Integrated Framework* (2013), our management concluded that our internal control over financial reporting was effective as of March 31, 2025.

**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) and 15d-15(f) of the Exchange Act) that occurred during the fourth quarter of the fiscal year ended March 31, 2025, 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 Executive Chairman and our Chief Financial Officer, does 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.

**Item 9B. Other Information**.

During the fiscal quarter ended March 31, 2025, none of our directors or officers (as defined in Section 16 of the Exchange Act) 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 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

Information relating to our directors, executive officers and corporate governance, including our Code of Business Conduct and Insider Trading Policy, will be included in the proxy statement for our 2025 annual meeting of stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference. Our Code of Business Conduct, which is the code of ethics that applies to all of our officers, directors and employees, is filed as an exhibit to this Annual Report.

### Item 11. Executive Compensation.

Information relating to executive compensation will be included in the proxy statement for our 2025 annual meeting of stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table summarizes information about our equity compensation plans by type as of March 31, 2025:

| Plan category | (A) Number of securities to be issued upon exercise/vesting of outstanding options, warrants, units and rights | (B) Weighted-average exercise price of outstanding options, warrants, units and rights | (C) Number of securities available for future issuance under Equity Compensation Plans (excluding securities reflected in column (A)) |
|---|---|---|---|
| Equity compensation plans approved by security holders (1) | 145,396 (2) | $ 22.34 | 202,482 (3) |
| Equity compensation plans not approved by security holders (4) | 4.166 (5) | $ 33.00 | 83 (6) |

(1) Includes the 2012 Plan, the A&R 2022 Plan, and the ESPP.
(2) Includes stock options to purchase 137,231 shares of common stock with a per share weighted-average exercise price of $22.34. Also includes 8,165 restricted stock units with no exercise price.
(3) Includes 198,774 shares of common stock reserved for issuance pursuant to the 2012 Plan and A&R 2022 Plan and 3,708 shares of common stock available for purchase under the ESPP as of March 31, 2025.
(4) Includes the Inducement Plan.
(5) Includes 4,166 stock options with a per share exercise price of $33.00 granted pursuant to the Inducement Plan.
(6) Includes 83 shares of common stock reserved for issuance pursuant to the Inducement Plan.

Information relating to the beneficial ownership of our common stock will be included in the proxy statement for our 2025 annual meeting of stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference.

### Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information relating to certain relationships and related transactions and director independence will be included in the proxy statement for our 2025 annual meeting of stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference.

### Item 14. Principal Accountant Fees and Services.

Information relating to principal accountant fees and services will be included in the proxy statement for our 2025 annual meeting of stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference.

## PART IV

**Item 15. Exhibits, Financial Statement Schedules.**

(a) The following documents have been filed as part of this Annual Report:

1. Consolidated Financial Statements: The information required by this item is included in Item 8 of Part II of this Annual Report.

2. Financial Statement Schedules: Financial statement schedules required under the related instructions are not applicable for the years ended March 31, 2025 and 2024 and have therefore been omitted.

3. Exhibits: The exhibits listed in the Exhibit Index attached to this report are filed or incorporated by reference as part of this Annual Report.

(b) The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report.

## EXHIBIT INDEX

| 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* | Description of Securities. |
| 10.1+* | VivoSim Labs, Inc. Amended and Restated 2012 Equity Incentive Plan. |
| 10.2+ | Form of Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.16 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012). |
| 10.3+ | Form of Non-Employee Director Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 9, 2015). |
| 10.4+ | Form of Executive Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 9, 2015). |
| 10.5+ | Form of Indemnification Agreement (incorporated by reference from Exhibit 10.17 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012). |
| 10.6#* | License Agreement, dated March 24, 2009, by and between Organovo, Inc. and the Curators of the University of Missouri. |
| 10.7#* | License Agreement, dated March 12, 2010, by and between Organovo, Inc. and the Curators of the University of Missouri. |
| 10.8+ | Severance and Change in Control Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2015). |
| 10.9+ | Amendment No. 1 to Severance and Change in Control Plan, dated May 19, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 20, 2020). |
| 10.10+ | Form of Severance and Change in Control Plan Participation Agreement (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2015). |

| Exhibit No. | Description |
|---|---|
| 10.11+ | Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement (Retention Form) under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016). |
| 10.12+ | Form of Employee Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016). |
| 10.13+ | Form of Non-Employee Director Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016). |
| 10.14+ | Consulting Agreement, dated September 15, 2020, by and between Organovo, Inc. and Multi Dimensional Bio Insight LLC (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 5, 2020). |
| 10.15+ | Consulting Agreement, dated August 25, 2020, by and between Organovo, Inc. and Danforth Advisors (incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 5, 2020). |
| 10.16+ | Amendment No. 5, dated October 4, 2021, to Consulting Agreement, dated August 25, 2020, by and between Organovo, Inc. and Danforth Advisors LLC (incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on October 6, 2021). |
| 10.17+ | Amendment No. 6, dated December 30, 2024, to Consulting Agreement, dated August 25, 2020, by and between Organovo, Inc. and Danforth Advisors, LLC (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on December 31, 2024). |
| 10.18 | Lease Agreement, dated November 23, 2020, between VivoSim Labs, Inc. and San Diego Inspire 2, LLC (Permanent Lease Agreement 176640186.8) (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on November 25, 2020). |
| 10.19 | Amended and Restated Lease Agreement, dated November 23, 2020, between Organovo, Inc., as Tenant, and San Diego Inspire 2, LLC, as Landlord, as amended by First Amendment to Amended & Restated Lease, dated November 17, 2021, between Organovo, Inc., as Tenant and San Diego Inspire 2, LLC, as Landlord (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 19, 2021). |
| 10.20 | Intercompany Agreement, dated December 28, 2020, by and among VivoSim Labs, Inc., Organovo, Inc. and Viscient Biosciences, Inc. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 31, 2020). |
| 10.21 | Sales Agreement, dated March 16, 2018, by and between VivoSim Labs, Inc. and Jones Trading Institutional Services LLC (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 16, 2018). |
| 10.22+* | VivoSim Labs, Inc. Amended and Restated 2021 Inducement Equity Incentive Plan. |
| 10.23+* | Form of Stock Option Agreement under the VivoSim Labs, Inc. 2021 Inducement Equity Incentive Plan. |
| 10.24+* | Form of Restricted Stock Unit Agreement under the VivoSim Labs, Inc. 2021 Inducement Equity Incentive Plan. |
| 10.25 | Settlement and Patent License Agreement, dated February 22, 2022, by and between Organovo, Inc. and BICO Group AB (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 10, 2022). |
| 10.26+* | VivoSim Labs, Inc. Amended and Restated 2022 Equity Incentive Plan. |
| 10.27+* | Form of Global Stock Option Award Agreement under the VivoSim Labs, Inc. Amended and Restated 2022 Equity Incentive Plan. |
| 10.28+* | Form of Global Restricted Stock Unit Award Agreement under the VivoSim Labs, Inc. Amended and Restated 2022 Equity Incentive Plan. |
| 10.29+* | VivoSim Labs, Inc. Amended and Restated 2023 Employee Stock Purchase Plan. |
| 14.1* | VivoSim Labs, Inc. Code of Business Conduct. |
| 19.1* | VivoSim Labs, Inc. Insider Trading Policy. |
| 21.1* | Subsidiaries of VivoSim Labs, Inc. |
| 23.1* | Consent of Independent Registered Public Accounting Firm. |

| Exhibit No. | Description |
|---|---|
| 24.1* | Power of Attorney (included on signature page hereto). |
| 31.1* | Certification of Chief Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended. |
| 31.2* | Certification of Chief Financial Officer a Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended. |
| 32.1** | Certifications Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and to 18 U.S.C. Section 1350. |
| 97 | VivoSim Labs, Inc. Clawback Policy (incorporated by reference from Exhibit 97 to the Company's Annual Report on Form 10-K, as filed with the SEC on May 31, 2024). |
| 101.INS* | Inline XBRL Instance Document |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

# Portions of this exhibit (indicated by [* * *]) have been omitted because the Company has determined that the information is both (i) not material and (ii) of the type that the Company treats as private and confidential. In addition, schedules have been omitted from this filing pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule to the SEC upon its request; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any schedule so furnished.

* Filed herewith.

** Furnished herewith.

+ Designates management contracts and compensation plans.

**SIGNATURES**

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

VIVOSIM LABS, INC.

By: /s/ Keith Murphy
Keith Murphy
Executive Chairman

Date: June 5, 2025

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Keith Murphy and Norman Staskey, and each of them individually, as the undersigned's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their respective substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Keith Murphy<br>Keith Murphy | Executive Chairman<br>(Principal Executive Officer) | June 5, 2025 |
| /s/ Norman Staskey<br>Norman Staskey | Chief Financial Officer<br>(Principal Financial and Principal Accounting Officer) | June 5, 2025 |
| /s/ Adam Stern<br>Adam Stern | Director | June 5, 2025 |
| /s/ Douglas Cohen<br>Douglas Cohen | Director | June 5, 2025 |
| /s/ David Gobel<br>David Gobel | Director | June 5, 2025 |
| /s/ Alison Milhous<br>Alison Milhous | Director | June 5, 2025 |