

Explanatory Note

On May 10, 2024, the registrant previously filed this prospectus (the “Original Filing”) with the Securities and Exchange Commission. The registrant hereby refiles this prospectus for the sole purpose of correcting disclosure regarding the periods during which the registrant agreed not to enter into variable rate transactions and not to enter into any equity financings, each of which were inadvertently misstated in the Plan of Distribution and the Risk Factors sections of the Original Filing. No other changes have been made to the Original Filing.

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-278668

PROSPECTUS



1,562,500 Shares of Common Stock
Pre-Funded Warrants to Purchase up to 5,000,000 Shares of Common Stock
Common Warrants to Purchase up to 6,562,500 Shares of Common Stock
Up to 11,562,500 Shares of Common Stock Underlying the Pre-Funded Warrants and Common Warrants

We are offering 1,562,500 shares of common stock together with common warrants to purchase up to 6,562,000 shares of common stock at a public offering price for each share of common stock and accompanying common warrant of \$0.80. Each share of common stock, or pre-funded warrant in lieu thereof, is being sold together with a common warrant to purchase one share of common stock. The shares of common stock, or pre-funded warrants in lieu thereof, and common warrants are immediately separable and will be issued separately in this offering, but must be purchased together in this offering. Each common warrant will have an exercise price of \$0.80, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date.

We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded warrants to purchase up to 5,000,000 shares of common stock, in lieu of shares of common stock that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. The public offering price of each pre-funded warrant to purchase one share of common stock and accompanying common warrant to purchase one share of common stock will be equal to the price at which one share of common stock and accompanying common warrant to purchase one share of common stock is sold to the public in this offering, minus \$0.001, and the exercise price of each pre-funded warrant will be \$0.001 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full.

Our shares of common stock are listed on the Nasdaq Capital Market under the symbol “ONVO.” On May 7, 2024, the last reported sale price of our common stock was \$0.91.

There is no established public trading market for the common warrants or pre-funded warrants and we do not expect a market to develop. Without an active trading market, the liquidity of the common warrants and pre-funded warrants will be limited. In addition, we do not intend to list the common warrants or pre-funded warrants on the Nasdaq Capital Market, any other national securities exchange or any other trading system.

We have engaged JonesTrading Institutional Services LLC (the “placement agent”) to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. Since we will deliver the securities to be issued in this offering upon our receipt of investor funds, there is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. Because there is no minimum offering amount required as a condition to closing this offering, we may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue our business goals described in this prospectus. In addition, because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill all of our contemplated objectives due to a lack of interest in this offering. Further, any proceeds from the sale of securities offered by us will be available for our immediate use, despite

uncertainty about whether we would be able to use such funds to effectively implement our business plan. See the section entitled “*Risk Factors*” for more information. We will bear all costs associated with the offering. See “*Plan of Distribution*” on page 78 of this prospectus for more information regarding these arrangements.

Investing in our securities involves risks that are described in the “*Risk Factors*” section beginning on page 10 of this prospectus.

	Per Share and Common Warrant	Per Pre-Funded Warrant and Common Warrant	Total
Public offering price	\$ 0.80	\$ 0.799	\$ 5,245,000
Placement agent fees	\$ 0.040	\$ 0.03995	\$ 262,250
Proceeds, before expenses, to us	\$ 0.76	\$ 0.75905	\$ 4,982,750

Delivery of the shares of common stock, pre-funded warrants and common warrants offered hereby is expected to be made on or about May 13, 2024, subject to the satisfaction of customary closing conditions.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.



The date of this prospectus is May 8, 2024

Organovo Holdings, Inc.

Table of Contents

Prospectus Summary	1
Special Note Regarding Forward-Looking Statements	9
Market, Industry and Other Data	10
Risk Factors	10
Use of Proceeds	32
Capitalization	33
Dilution	34
Business	36
Management's Discussion and Analysis of Financial Condition and Results of Operation	41
Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	50
Quantitative and Qualitative Disclosures About Market Risk	51
Description of Capital Stock	52
Management	58
Director Compensation	61
Executive Compensation	62
Equity Compensation Plan Information	69
Certain Relationships and Related Party Transactions	71
Principal Stockholders	71
Material U.S. Federal Income Tax Considerations for Non-U.S. Holders	73
Plan of Distribution	78
Legal Matters	80
Experts	80
Where You Can Find More Information	80
Disclosure of Commission Position on Indemnification for Securities Act Liabilities	81

About this Prospectus

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information other than the information that we have provided or incorporated by reference in this prospectus and your reliance on any unauthorized information or representation is at your own risk. This prospectus may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that the information appearing in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus, or any sale of our securities. Our business, financial condition and results of operations may have changed since those dates.

The information appearing in this prospectus and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of its respective date, regardless of the time of delivery of the respective document or of any sale of securities covered by this prospectus. You should not assume that the information contained in this prospectus, or in any free writing prospectus that we have authorized for use in connection with this offering, is accurate as of any date other than the respective dates thereof.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference filed with the U.S. Securities and Exchange Commission (the "SEC") before the date of this prospectus, on the other hand, you should rely on the information in this prospectus. If any statement in a document incorporated by reference is inconsistent with a statement in another document incorporated by reference having a later date, the statement in the document having the later date modifies or supersedes the earlier statement.

Neither we nor the placement agent have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons who come into possession of this prospectus and any free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any free writing prospectus applicable to that jurisdiction.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Industry publications and third-party research, surveys and studies often indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information and such information is inherently imprecise.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our securities. You should read this entire prospectus carefully, including the sections of this prospectus titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless otherwise indicated, all references in this prospectus to “Organovo,” the “company,” “we,” “our,” “us” or similar terms refer to Organovo Holdings, Inc. and its wholly owned subsidiaries, including Organovo, Inc. and Opal Merger Sub, Inc.

Overview

Organovo Holdings, Inc. (Nasdaq: ONVO), together with its wholly owned subsidiaries (collectively, “Organovo”, “we”, “us” and “our”), is a clinical stage biotechnology company that is focused on developing FXR314 in inflammatory bowel disease (“IBD”), including ulcerative colitis (“UC”), based on demonstration of clinical promise in three-dimensional (“3D”) human tissues as well as strong preclinical data. FXR is a mediator of gastrointestinal and liver diseases. FXR agonism has been tested in a variety of preclinical models of IBD. FXR314 is the lead compound in our established FXR program containing two clinically tested compounds (including FXR314) and over 2,000 discovery or preclinical compounds. FXR314 is a drug with safety and tolerability after daily oral dosing in Phase 1 and Phase 2 trials. Further, FXR314 has FDA clinical trial authorization for a Phase 2 trial in UC.

Our current clinical focus is in advancing FXR314 in IBD, including UC and Crohn’s disease (“CD”). We plan to start a Phase 2a clinical trial in UC in the calendar year 2024. We released Phase 2 data for FXR314 for the treatment of metabolic function-associated steatohepatitis (“MASH”) in April 2024 that are supportive of ongoing development, and we believe FXR314 has a commercial opportunity in MASH, most likely in combination therapy. We are exploring the potential for combination therapies using FXR314 and currently approved mechanisms in preclinical animal studies and our IBD disease models.

Our second focus is building high fidelity, 3D tissues that recapitulate key aspects of human disease. We use our proprietary technology 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 develop clinically effective drugs across multiple therapeutic areas.

As with the clinical development program, we are initially focusing on the intestine and have ongoing 3D tissue development efforts in human tissue models of UC and CD. We use these models to identify new molecular targets responsible for driving the disease and to explore the mechanism of action of known drugs including FXR314 and related molecules. We intend to initiate drug discovery programs around these new validated targets to identify drug candidates for partnering and/or internal clinical development.

Our current understanding of intestinal tissue models and IBD disease models leads us to believe that we can create models that provide greater insight into the biology of these diseases than are generally currently available. We are creating high fidelity disease models, leveraging our prior work including the work found in our peer-reviewed publication on bioprinted intestinal tissues (Madden et al. Bioprinted 3D Primary Human Intestinal Tissues Model Aspects of Native Physiology and ADME/Tox Functions. *iScience*. 2018 Apr 27;2:156-167. doi: 10.1016/j.isci.2018.03.015.) Our advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures.

Using these disease models, we intend to identify and validate novel therapeutic targets. After finding therapeutic drug targets, we intend to focus on developing novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these novel drug candidates towards an Investigational New Drug filing and potential future clinical trials.

We expect to broaden our work into additional therapeutic areas over time and are currently exploring specific tissues for development. In our work to identify the areas of interest, we evaluate areas that might be better served with 3D disease models than currently available models as well as the potential commercial opportunity. In line with these plans, we are building upon both our external and in house scientific expertise, which will be essential to our drug development effort.

Recent Developments

In February 2024, we formed our Mosaic Cell Sciences division (“Mosaic”) to serve as a key source of certain of the primary human cells we utilize in our research and development efforts. We believe Mosaic can help us optimize our supply chain, reduce operating expenses related to cell sourcing and procurement and ensure that the cellular raw materials we use are of the highest quality and are derived from tissues that are ethically sourced in full compliance with state and federal guidelines. We intend for Mosaic to provide us with qualified human cells for use in our clinical research and development programs. In addition to supplying us with primary human

cells, we intend for Mosaic to offer human cells for sale to life science customers, both directly and through distribution partners, which we expect to offset costs and over time become a profit center that offsets overall R&D spending by Organovo.

Financial Update (Unaudited)

As of March 31, 2024, we had cash and cash equivalents of approximately \$2.9 million.

The estimated preliminary cash and cash equivalents number presented above as of March 31, 2024 is preliminary and unaudited and may change, is based on information available to management as of the date of this prospectus, and is subject to the completion of the Company's financial closing procedures and the audit for the year ended March 31, 2024. There can be no assurance that such financial information as of March 31, 2024 will not differ from these estimates, including as a result of year-end closing and the audit and any such changes could be material. We have not yet completed our normal audit procedures as of and for the year ended March 31, 2024.

The foregoing preliminary financial data has been prepared by, and is the responsibility of, our management. This data has not been audited, is subject to change upon completion of our ongoing audit and could change as a result of further review. Complete annual results will be included in our Annual Report on Form 10-K for the year ended March 31, 2024.

Corporate Information

We were incorporated in Delaware under the name Organovo Holdings, Inc. in January 2012. We are operating the business of our subsidiaries, including Organovo, Inc., our wholly-owned subsidiary, which we acquired in February 2012. Organovo, Inc. was incorporated in Delaware in April 2007. Our common stock has traded on the Nasdaq Capital Market under the symbol "ONVO" since December 27, 2019. Prior to that time, it had traded on the Nasdaq Global Market under the symbol "ONVO" since August 8, 2016 and prior to that it traded on the NYSE MKT under the symbol "ONVO".

Our principal executive offices are located at 11555 Sorrento Valley Road, Suite 100, San Diego, CA 92121, and our telephone number is (858) 224-1000. Our website address is www.organovo.com. Any information contained on, or that can be accessed through, our website is not incorporated by reference into, nor is it in any way part of this prospectus and should not be relied upon in connection with making any decision with respect to an investment in our securities. We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. You may obtain any of the documents filed by us with the SEC at no cost from the SEC's website at <http://www.sec.gov>.

We are a "smaller reporting company" as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and have elected to take advantage of certain of the scaled disclosure available for smaller reporting companies in this prospectus as well as our filings under the Exchange Act.

The Offering

Common stock offered by us
Pre-funded warrants offered by us

1,562,500 shares of common stock.

Pre-funded warrants to purchase up to 5,000,000 shares of common stock to certain purchasers whose purchase of shares in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, in lieu of shares that would otherwise result in the purchaser's beneficial ownership exceeding 4.99% of our outstanding common stock (or, at the election of the purchaser, 9.99%). The purchase price of each pre-funded warrant will equal the price at which one share of common stock is being sold to the public in this offering, minus \$0.001, and the exercise price of each pre-funded warrant will be \$0.001 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. We are also registering the shares of common stock issuable upon the exercise of the pre-funded warrants.

Common warrants offered by us

Common warrants to purchase up to 6,562,500 shares of common stock. Each share of common stock or pre-funded warrant to purchase one share of common stock is being sold together with a common warrant to purchase one share of common stock. Each common warrant has an exercise price of \$0.80 per share, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price is subject to customary adjustments for stock splits and similar recapitalization transactions. The shares of common stock or the pre-funded warrants, as the case may be, and the accompanying common warrants can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. See "*Description of Capital Stock*" on page 52 for more information.

Common stock to be outstanding immediately after this offering

12,991,576 shares, assuming no exercise of any pre-funded warrants or common warrants.

Use of proceeds

We expect to receive net proceeds, after deducting estimated placement agent fees and estimated expenses payable by us, of approximately \$4.7 million after deducting commissions and estimated offering expenses payable by us, and assuming no exercise of any pre-funded warrants or common warrants. We intend to use the net proceeds from this offering for working capital and general corporate purposes, which could include capital expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, legal expenditures, including intellectual property protection and maintenance expenditures, acquisitions of new technologies and investments, business combinations and the repurchase of capital stock. See "*Use of Proceeds*" on page 32 for more information.

Risk factors

Investing in our securities involves a high degree of risk. As an investor, you should be able to bear a complete loss of your investment. You should carefully consider the information set forth in the “*Risk Factors*” section beginning on page 10.

Nasdaq Capital Market trading symbol

Our common stock is listed on the Nasdaq Capital Market under the symbol “ONVO.” There is no established trading market for the common warrants or the pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the common warrants or pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the common warrants and pre-funded warrants will be extremely limited.

The number of shares immediately outstanding following this offering is based on 9,838,755 shares of common stock outstanding as of December 31, 2023 and also gives effect to 1,590,321 shares of our common stock sold and issued through an “at the market offering” pursuant to a Sales Agreement that we entered into with H.C. Wainwright & Co., LLC and JonesTrading Institutional Services LLC on March 16, 2018 (the “Sales Agreement”) and excludes:

- 695,459 shares of common stock issuable upon the exercise of stock options outstanding at a weighted average exercise price of approximately \$4.35 per share;
- 123,892 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units;
- 1,000 shares of common stock available for issuance pursuant to the 2021 Inducement Equity Plan;
- 1,643,798 shares of common stock available for issuance pursuant to the 2022 Equity Incentive Plan; and
- 45,000 shares of common stock available for issuance pursuant to the 2023 Employee Stock Purchase Plan.

Unless otherwise indicated, all information in this prospectus assumes no exercise of options under our equity incentive plans and no exercise of pre-funded warrants and common warrants.

Summary Financial Data

The following tables set forth our summary statements of operations and comprehensive loss data for the years ended March 31, 2023 and 2022 and the nine months ended December 31, 2023 and 2022, and our summary balance sheet data as of December 31, 2023. The statements of operations and comprehensive loss data for the years ended March 31, 2023 and 2022 have been derived from our audited financial statements included elsewhere in this prospectus. We derived our summary statements of operations and comprehensive loss data for the nine months ended December 31, 2023 and 2022 and the summary balance sheet data as of December 31, 2023 from our unaudited condensed financial statements included elsewhere in this prospectus, which have been prepared on a basis consistent with our audited financial statements and, in the opinion of management, contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such interim financial statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future, and our interim results are not necessarily indicative of the results that may be expected for the full year or any other period. You should read the following summary financial data together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

Statement of Operations and comprehensive loss for the years ended March 31, 2023 and 2022

	Year Ended March 31, 2023	Year Ended March 31, 2022
Revenues		
Royalty revenue	\$ 370	\$ 1,500
Total Revenues	<u>370</u>	<u>1,500</u>
Research and development expenses	8,885	3,320
Selling, general, and administrative expenses	9,216	9,659
Total costs and expenses	<u>18,101</u>	<u>12,979</u>
Loss from Operations	<u>(17,731)</u>	<u>(11,479)</u>
Other Income (Expense)		
Loss on fixed asset disposals	(9)	—
Gain on investment in equity securities	29	—
Interest income	454	8
Other income	—	25
Total Other Income	<u>474</u>	<u>33</u>
Income Tax Expense	<u>(2)</u>	<u>(2)</u>
Net Loss	<u>\$ (17,259)</u>	<u>\$ (11,448)</u>
Other comprehensive income:		
Unrealized gain on available-for-sale debt securities	2	—
Comprehensive loss	<u>\$ (17,257)</u>	<u>\$ (11,448)</u>
Net loss per common share—basic and diluted	<u>\$ (1.98)</u>	<u>\$ (1.32)</u>
Weighted average shares used in computing net loss per common share—basic and diluted	8,713,032	8,703,596

Statement of Operations and comprehensive loss for the nine months ended December 31, 2023 and 2022 (unaudited)

	Nine Months Ended December 31, 2023	Nine Months Ended December 31, 2022
Revenues		
Royalty revenue	\$ 80	\$ 208
Total Revenues	<u>80</u>	<u>208</u>
Research and development expenses	4,435	3,436
Selling, general and administrative expenses	7,635	6,724
Total costs and expenses	<u>12,070</u>	<u>10,160</u>
Loss from Operations	<u>(11,990)</u>	<u>(9,952)</u>
Other Income (Expense)		
(Loss) gain on investment in equity securities	12	(123)
Interest income	354	277
Total Other Income	<u>366</u>	<u>154</u>
Income Tax Expense	<u>(2)</u>	<u>(2)</u>
Net Loss	<u>\$ (11,626)</u>	<u>\$ (9,800)</u>
Other Comprehensive Loss:		
Unrealized gain (loss) on available-for-sale debt securities	\$ (1)	\$ 3
Comprehensive Loss	<u>\$ (11,627)</u>	<u>\$ (9,797)</u>
Net loss per common share—basic and diluted	\$ (1.31)	\$ (1.13)
Weighted average shares used in computing net loss per common share—basic and diluted	8,850,881	8,712,294

Balance Sheet as of March 31, 2023 and 2022

	March 31, 2023	March 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	\$ 15,301	\$ 28,675
Accounts receivable	152	—
Investment in equity securities	706	—
Prepaid expenses and other current assets	889	858
Total current assets	17,048	29,533
Fixed assets, net	902	662
Restricted cash	143	143
Operating lease right-of-use assets	1,705	2,153
Prepaid expenses and other assets, net	515	805
Total assets	\$ 20,313	\$ 33,296
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 331	\$ 415
Accrued expenses	2,848	489
Operating lease liability, current portion	492	479
Total current liabilities	3,671	1,383
Operating lease liability, net of current portion	1,313	1,704
Total liabilities	4,984	3,087
Commitments and Contingencies		
Stockholders' Equity		
Common stock, \$0.001 par value; 200,000,000 shares authorized, 8,716,906 and 8,710,627 shares issued and outstanding at March 31, 2023 and 2022, respectively	9	9
Additional paid-in capital	340,317	337,940
Accumulated deficit	(324,998)	(307,739)
Accumulated other comprehensive income	2	—
Treasury stock, 46 shares at cost	(1)	(1)
Total stockholders' equity	15,329	30,209
Total Liabilities and Stockholders' Equity	\$ 20,313	\$ 33,296

Balance Sheet as of the nine months ended December 31, 2023 and 2022 (unaudited)

	<u>December 31, 2023</u>	<u>December 31, 2022</u>
	(Unaudited)	(Unaudited)
Assets		
Current Assets		
Cash and cash equivalents	\$ 5,295	\$ 20,196
Accounts receivable	33	76
Investment in equity securities	—	554
Prepaid expenses and other current assets	913	788
Total current assets	<u>6,241</u>	<u>21,614</u>
Fixed assets, net	739	742
Restricted cash	143	143
Operating lease right-of-use assets	1,403	1,803
Prepaid expenses and other assets, net	355	777
Total assets	<u>\$ 8,881</u>	<u>\$ 25,079</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 471	\$ 242
Accrued expenses	727	646
Operating lease liability, current portion	502	488
Total current liabilities	<u>1,700</u>	<u>1,376</u>
Operating lease liability, net of current portion	999	1,414
Total liabilities	<u>2,699</u>	<u>2,790</u>
Commitments and Contingencies (Note 7)		
Stockholders' Equity		
Common stock, \$0.001 par value; 200,000,000 shares authorized, 9,838,755 and 8,714,590 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	10	9
Additional paid-in capital	342,796	339,817
Accumulated deficit	(336,624)	(317,539)
Accumulated other comprehensive income	1	3
Treasury stock, 46 shares at cost	(1)	(1)
Total stockholders' equity	<u>6,182</u>	<u>22,289</u>
Total Liabilities and Stockholders' Equity	<u>\$ 8,881</u>	<u>\$ 25,079</u>

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and any accompanying prospectus supplement may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Exchange Act, about Organovo. These forward-looking statements are intended to be covered by the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact, and can be identified by the use of forward-looking terminology such as “believes”, “expects”, “may”, “will”, “could”, “should”, “projects”, “plans”, “goal”, “targets”, “potential”, “estimates”, “pro forma”, “seeks”, “intends” or “anticipates” or the negative thereof or comparable terminology. Forward-looking statements include discussions of strategy, financial projections, guidance and estimates (including their underlying assumptions), statements regarding plans, objectives, expectations or consequences of various transactions, and statements about the future performance, operations, products and services of Organovo. We caution our stockholders and other readers not to place undue reliance on such statements.

You should read this prospectus, any accompanying prospectus supplement and the documents incorporated by reference completely and with the understanding that our actual future results may be materially different from what we currently expect. Our business and operations are and will be subject to a variety of risks, uncertainties and other factors. Consequently, actual results and experience may materially differ from those contained in any forward-looking statements. Such risks, uncertainties and other factors that could cause actual results and experience to differ from those projected include, but are not limited to, the risk factors described in the “Risk Factors” section beginning on page 10 of this prospectus.

You should assume that the information appearing in this prospectus, any accompanying prospectus supplement and any related free writing prospectus is accurate as of its date only. Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. All written or oral forward-looking statements attributable to us or any person acting on our behalf made after the date of this prospectus are expressly qualified in their entirety by the risk factors and cautionary statements contained in and incorporated by reference into this prospectus. Unless legally required, we do not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, we have based the information concerning economic conditions, our industry and our market contained in this prospectus on a variety of sources, including information from third-party industry analysts and publications and our own estimates and research. This information involves a number of assumptions, estimates and limitations. The industry publications, surveys and forecasts and other public information generally indicate or suggest that their information has been obtained from sources believed to be reliable. None of the third-party industry publications used in this prospectus were prepared on our behalf. The industries in which we operate are subject to a high degree of uncertainty and risk due to a variety of factors, and are subject to change based on various factors, including those discussed in the “Risk Factors” section of this prospectus and in the other information contained in this prospectus. These and other factors could cause the information concerning our industry to differ materially from those expressed in this prospectus and incorporated by reference herein.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, for use in our business and therefore do not anticipate paying cash dividends in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion.

RISK FACTORS

Investment in our securities involve a substantial degree of risk and should be regarded as speculative. As a result, the purchase of our securities should be considered only by persons who can reasonably afford to lose their entire investment. Before you elect to purchase our securities, 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 prospectus occur, our business, prospects, liquidity, financial condition and results of operations could be materially and adversely affected, in which case the trading price of our common stock could decline, and you could lose all or part of your investment.

Risk factors marked with an asterisk () below include a substantive change from or an update to the risk factors included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2023, filed with the SEC on July 14, 2023.*

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our securities 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 prospectus and our other filings with the Securities and Exchange Commission before making investment decisions regarding our securities.

- *We will incur substantial additional operating losses over the next several years as our research and development activities increase.*
- *Using our platform technology to develop human tissues and disease models for drug discovery and development is new and unproven.*
- *As we pursue drug development through 3D tissues and disease models, we will require access to a constant, steady, reliable supply of human cells to support our 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.*
- *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 drug discovery and development efforts will depend on our ability to successfully establish strategic relationships.*
- *Current and future legislation may increase the difficulty and cost of commercializing our drug candidates and may affect the prices we may obtain if our 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.***
- ***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.***
- ***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 this Offering

****We need to raise capital in this offering to support our operations. If we are unable to raise capital in this offering, our financial position will be materially adversely impacted.***

We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the three months ended December 31, 2023, we had net losses of \$3.6 million. From our inception through December 31, 2023, we had an accumulated deficit of \$336.6 million. We believe that current cash on hand, prior to the receipt of any proceeds from this offering, is not sufficient to fund operations beyond June 2024. If we were to receive net proceeds of \$4.7 million from this offering, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will meet our capital needs into January 2025. If we receive the foregoing net proceeds of \$4.7 million in this offering, and if we raise an additional \$10 million in net proceeds through the sale of securities or otherwise throughout 2024, we believe that we will then meet our capital needs through the end of May 2025. In addition, the report of our independent registered public accounting firm on our financial statements for the year ended March 31, 2023 contains explanatory language that substantial doubt exists about our ability to continue as a going concern. If we do not have access to sufficient cash and liquidity to finance our business operations as currently contemplated, we would be compelled to reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. We have no additional committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations would have a material adverse effect on our business, financial condition and results of operations. If such sufficient financing is not received timely, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and/or seek bankruptcy protection.

****Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.***

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including: (i) timely delivery of shares; (ii) agreement to not enter into variable rate financings for 180 days from closing, subject to certain exceptions; (iii) agreement to not enter into any financings for 60 days from closing; and (iv) indemnification for breach of contract.

****This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.***

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth herein. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of

proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds to complete such short-term operations. Such additional fundraises may not be available or available on terms acceptable to us.

****Our management has broad discretion as to the use of the net proceeds from this offering.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled “Use of Proceeds.” Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our common stock price to decline.

****If you purchase securities in this offering, you will experience immediate and substantial dilution and may experience additional dilution in the future.***

Investors purchasing shares of our common stock and accompanying common warrants in this offering will pay a price per share that substantially exceeds the as adjusted net tangible book value per share. As a result, investors purchasing our common stock and accompanying common warrants in this offering will incur immediate dilution of \$0.23 per share, representing the difference between the public offering price of \$0.80 per share, and our as adjusted net tangible book value as of December 31, 2023. For more information on the dilution you may suffer as a result of investing in this offering, see “Dilution.”

****Because there is no minimum required for the offering to close, investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus.***

We have not specified a minimum offering amount nor have or will we establish an escrow account in connection with this offering. Because there is no escrow account and no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Further, because there is no escrow account in operation and no minimum investment amount, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan. Investor funds will not be returned under any circumstances whether during or after the offering.

****We may issue additional equity or convertible debt securities in the future, which may result in additional dilution to you.***

In order to raise additional capital, we expect to in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share and accompanying common warrant paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in this offering.

****Future sales of shares of our common stock in the public market, or the perception that such sales could occur, could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales could occur, following this offering could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock sold in this offering, as well as shares issuable upon exercise of common warrants or pre-funded warrants, upon issuance will be, freely tradable without restriction or further registration under the Securities Act. We may sell large quantities of our common stock at any time pursuant to one or more separate offerings in the future, including through “at the market offerings” pursuant to a Sales Agreement that we entered into with H.C. Wainwright & Co., LLC and JonesTrading Institutional Services LLC on March 16, 2018. We cannot predict the effect that future sales of common stock or other equity-related securities would have on the market price of our common stock.

****There is no public market for common warrants or the pre-funded warrants to purchase shares of our common stock being offered by us in this offering.***

There is no established public trading market for the common warrants or pre-funded warrants to purchase shares of our common stock that are being offered as part of this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants or pre-funded warrants on any national securities exchange or other nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the common warrants and pre-funded warrants will be limited.

****The common warrants and pre-funded warrants are speculative in nature.***

The common warrants and pre-funded warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the common warrants may exercise their right to acquire common stock and pay an exercise price of \$0.80 per share, subject to certain adjustments, prior to five years from the date on which such warrants were issued, after which date any unexercised common warrants will expire and have no further value. Holders of pre-funded warrants have identical rights, except that the pre-funded warrants have an exercise price of \$0.001 and do not expire until exercised in full. Moreover, following this offering, the market value of the common warrants and pre-funded warrants, if any, is uncertain and there can be no assurance that the market value of the common warrants or the pre-funded warrants will equal or exceed their imputed offering price.

****Holders of the common warrants and pre-funded warrants offered hereby will have no rights as common stockholders with respect to the shares our common stock underlying the common warrants and pre-funded warrants until such holders exercise their common warrants and pre-funded warrants and acquire our common stock, except as otherwise provided in the common warrants and pre-funded warrants.***

Until holders of the common warrants and pre-funded warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of the common warrants and pre-funded warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Risks Related to our Business

We are a clinical stage biotechnology company focusing on clinical drug development of the farnesoid X receptor (“FXR”) agonist FXR314, which involves a substantial degree of uncertainty, and on 3D bioprinting technology to develop human tissues and disease models for drug discovery and development, which is an unproven business strategy that may never achieve profitability.

We are a clinical stage biotechnology company focusing clinical drug development of the FXR agonist FXR314. Our secondary focus is building high fidelity, 3D tissues that recapitulate key aspects of human disease. Our success will depend upon our ability to advance the development of FXR314, our ability to determine the appropriate clinical focus for FXR314, our ability to identify additional drug candidates to pursue and the viability of our platform technology and any disease models we develop. Our success will also depend on our ability to select an appropriate development strategy for FXR314 and any other drug candidates we may identify, including internal development or partnering or licensing arrangements with pharmaceutical companies. 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 research and development activities increase.

We will 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 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 human tissues and disease models for drug discovery and development is new and unproven.

Utilizing our 3D bioprinting platform technology to develop human tissues and disease models for 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 new business model. Our future success will depend on our ability to utilize our 3D bioprinting platform to develop human tissues and disease models that will enable us to identify and develop viable drug candidates. 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 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 disease indications we may pursue, 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 discovering effective drug candidates using our 3D bioprinted tissues or disease 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 drug discovery business or entering into a strategic partnership or collaboration related to, any drug candidates we identify on favorable terms, or at all.

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

As we pursue 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 development 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 drug development efforts.

We may not be successful in establishing our Mosaic Cell Sciences division (“Mosaic”) as a profitable commercial business.

We formed Mosaic to serve as a key source of certain of the primary human cells we utilize in our research and development efforts. In addition to supplying human cells for our business requirements, we believe there is an opportunity for Mosaic to operate as a commercial business by selling human cells to other pharmaceutical, biotech and research organizations. We intend for Mosaic to

begin selling its human cell offerings to end users both directly and through distribution partners during fiscal 2025. Operating and developing Mosaic's business is subject to a number of risks and uncertainties, including:

- failing to source a sufficient supply of high-quality human organs or cells;
- failing to achieve market acceptance for its human cell offerings;
- failing to demonstrate the quality and reliability of its human cell offerings; • failing to be both cost effective and competitive with the products offered by third parties;
- failing to obtain any necessary regulatory approvals;
- failing to be able to produce its human cell offerings on a large enough scale;
- failing to establish and maintain distribution relationships with reliable third parties;
- failing to hire and retain qualified personnel; and
- infringing the proprietary rights of third parties or failing to protect our own intellectual property.

If any of these or any other risks and uncertainties occur, our efforts to establish Mosaic as a commercial business may be unsuccessful, which would harm our business and results of operations.

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 drug discovery plans. Recruiting and retaining qualified scientific and clinical personnel are 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 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 \$0.8 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 H.C. Wainwright & Co., LLC and 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 an aggregate of \$50.0 million of shares of our common stock to the public through an ATM offering. As of March 31, 2024, we have issued and sold an aggregate of 5,371,418 shares of our common stock for gross proceeds of approximately \$46.9 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 April 22, 2024, 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, or \$1,770,966. 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.

****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 U.S. Food and Drug Administration (“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; 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 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 (“GCP”) 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 (“cGMP”) conditions. Preclinical or clinical studies may not be performed or completed in accordance with Good Laboratory Practices (“GLP”) 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 drug discovery and development efforts will depend on our ability to successfully establish strategic relationships.

The near and long-term viability of our drug discovery and development 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 for a number of reasons both within and outside of our control.

Investors’ expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance (“ESG”) factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such 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 if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance

and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or 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 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.

****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. As widely reported, in the past several years, global credit and financial markets have experienced volatility and disruptions, and especially in 2020, 2021 and 2022 due to the impacts of the COVID-19 pandemic, and, more recently, the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, including, for example, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Moreover, the global impacts of the Israel-Hamas war are still unknown. 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. Absent further quantitative easing by the Federal Reserve, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our results of operations or financial condition.

Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon clinical development plans. 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.

****The impact of the Russian invasion of Ukraine and the Israel-Hamas War on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.***

The short and long-term implications of Russia's invasion of Ukraine and the Israel-Hamas war are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine and the subsequent institution of sanctions against Russia by the United States and several European and Asian countries and the Israel-Hamas war may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, prolonged conflict in Ukraine or Israel has resulted and may result, respectively, in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the war in Ukraine or Israel may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect 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 our current drug candidates or any other 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 our drug candidates and may affect the prices we may obtain if our 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 our drug candidates, restrict or regulate post-marketing activities and affect our ability to profitably sell any of our drug candidates for which we obtain regulatory approval.

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 addition, on August 16, 2022, 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 shall take 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 caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at \$2,000 a year.

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 50% discount off 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.

There have been public announcements by members of the U.S. Congress, regarding plans to repeal and replace the PPACA and Medicare. For example, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the PPACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the PPACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court’s ruling with respect to the individual mandate but remanded the case to the District Court to consider whether other parts of the law can remain in effect. While the Texas District Court Judge has stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the law and our business. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The U.S. Department of Health and Human Services has started soliciting feedback on some of these measures and, at the same time, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While any proposed measures will require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We 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 formally withdrew from the European Union on January 31, 2020, and entered into a transition period that ended on December 31, 2020. A significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union. We cannot predict what consequences the recent withdrawal of the United Kingdom from the European Union will have on the regulatory frameworks of the United Kingdom or the European Union, or on our future operations, if any, in these jurisdictions, and the United Kingdom is in the process of negotiating trade deals with other countries. Additionally, the United Kingdom's withdrawal from the European Union may increase the possibility that other countries may decide to leave the European Union again.

****Actions that we have taken to restructure our business to align our cost structure with our strategic priorities may not have the anticipated effects.***

In August 2023, we announced a plan to reduce our workforce by six employees, which represented approximately 24% of our employees as of August 18, 2023. The decision to reduce our workforce was made in order to focus spending on our clinical program for FXR314, reduce ongoing operating expenses not related to clinical expenses, and extend our cash runway. As a result of the reduction in force, we expect to incur approximately \$0.4 million of cash expenditures in connection with the reduction in force, which relate to severance pay, which are expected to be incurred through the quarter ending March 31, 2024. We may incur additional expenses not currently contemplated due to events associated with the reduction in force; for example, the reduction in force may have a future impact on other areas of our liabilities and obligations, which could result in losses in future periods. Moreover, we may not realize, in full or in part, the anticipated benefits and savings from this restructuring due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. In addition, we may need to undertake additional workforce reductions or restructuring activities in the future.

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.***

Our financial statements as of December 31, 2023 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. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, obtain government grants, reduce expenditures and generate significant revenue. Our financial statements as of December 31, 2023 do not include any adjustments that might result from the outcome of this uncertainty. The reaction of investors to the inclusion of a going concern statement by management and our auditors, and our potential inability to continue as a going concern, in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances.

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

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. Raising additional funding through debt or equity financing is likely to be difficult or unavailable altogether given the early stage of our therapeutic candidates. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. If we

incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline further and existing stockholders may not agree with our financing plans or the terms of such financings. In addition, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to our technology or potential future product candidates or otherwise agree to terms unfavorable to us.

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

We have generated operating losses each year since we began operations, including \$12.0 million and \$10.0 million for the nine months ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$336.6 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 developing and advancing FXR314 and our FXR program generally;
- successfully developing human tissues and disease models for drug discovery and development that enable us to identify drug candidates;
- successfully outsourcing certain portions of our development efforts;
- entering into collaboration or licensing arrangements with pharmaceutical companies to further develop and conduct clinical trials for any drug candidates we identify;
- obtaining any necessary regulatory approvals for any drug candidates we identify; and
- raising sufficient funds to finance our activities and long-term business plan.

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

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

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

- evaluating and implementing strategic alternatives, technology licensing opportunities, potential collaborations, and other strategic transactions;
- litigation;
- research and development expenditures, including commencement of preclinical studies and clinical trials;
- the timing of the hiring of new employees, which may require payments of signing, retention or similar bonuses; and
- changes in costs related to the general global economy.

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

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

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

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

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

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

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

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

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

Our future success will depend to a significant degree upon the continued contributions of our key personnel, especially our executive officers. We do not currently have long-term employment agreements with our executive officers or our other key personnel, and there is no guarantee that our executive officers or key personnel will remain employed with us. Moreover, we have not obtained key man life insurance that would provide us with proceeds in the event of the death, disability or incapacity of any of our executive officers or other key personnel. Further, the process of attracting and retaining suitable replacements for any executive officers and other key personnel we lose in the future would result in transition costs and would divert the attention of other members of our senior management from our existing operations. Additionally, such a loss could be negatively perceived in the capital markets. Finally, our Executive Chairman also provides services to Viscient Biosciences, Inc. (“Viscient”). Executives that provide services to us and Viscient do not dedicate all of their time to us, as disclosed in our filings, and we may therefore compete with Viscient for the time commitments of our Executive Chairman from time to time.

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

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

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

The regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation (the “GDPR”), which took effect across all member states of the European

Economic Area (the “EEA”) in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information 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.

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 information between the European Union and the United Kingdom, 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. The UK has announced plans to reform the country’s data protection legal framework in its Data Reform Bill, which may introduce significant changes from the GDPR, which may lead to additional compliance costs. 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 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. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. 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. Additionally, Delaware, Indiana, Iowa, Montana, Oregon, Tennessee and Texas have adopted

privacy laws, which take effect from July 1, 2024 through 2026. Many other states are considering similar legislation. 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 information 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 information, 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 information from our clinical trials, 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). Jeffrey N. Miner, our former Chief Scientific Officer, is a co-founder, the Chief Scientific Officer and a significant stockholder of Viscient. In addition, Adam Stern, Douglas Jay Cohen and David Gobel (through the Methuselah Foundation and the Methuselah Fund), members of our Board, 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 2024, 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, 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. 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, executives that provide services to us and Viscient may not dedicate all of their time to us and we may therefore compete with Viscient for the time commitments of our executive officers 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.

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

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

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

Our common stock is currently traded on the Nasdaq Capital Market, but there is no assurance that an active market in our common stock will continue at present levels or increase in the future. As a result, an investor may find it difficult to dispose of our common stock on the timeline and at the volumes they desire. This factor limits the liquidity of our common stock and may have a material adverse effect on the market price of our common stock and on our ability to raise additional capital.

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

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

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

The stock market is subject to significant price and volume fluctuations. 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, 2024, there were an aggregate of 12,585,625 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 2,462,899 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 45,000 shares of common stock that may be issued through our 2023 Employee Stock Purchase Plan ("ESPP").

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. 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, 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 United States Patent and Trademark Office ("PTO") 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, Clemson University and the Salk Institute for Biological Studies 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, Clemson University and the Salk Institute for Biological Studies 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 and our FXR314 agonist in gastrointestinal disease. 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, 3D tissue products and the FXR314 agonist 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.

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 Securities and Exchange Commission (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.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$4.7 million, after deducting the estimated placement agent fees and estimated offering expenses payable by us and assuming no exercise of any pre-funded warrants or common warrants. If all of the pre-funded warrants and common warrants offered hereby are exercised in full for cash, the estimated net proceeds would increase by \$5.3 million.

We intend to use the proceeds of this offering for working capital and general corporate purposes, which could include capital expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, legal expenditures, including intellectual property protection and maintenance expenditures, acquisitions of new technologies and investments, business combinations and the repurchase of capital stock. Pending these uses, we may invest the net proceeds in short- and intermediate-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States government.

However, because this is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, the placement agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We cannot currently allocate specific percentages of the net proceeds to us from this offering that we may use for the purposes specified above. Our management will have broad discretion in the application of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not result in our being profitable or increase our market value. See "*Risk Factors—Risks Related to this Offering and the Ownership of Our Common Stock—Our management has broad discretion as to the use of the net proceeds from this offering.*"

CAPITALIZATION

The following table sets forth our cash and cash equivalents and total capitalization as of December 31, 2023:

- on an actual basis;
- a pro forma basis to reflect the issuance of an aggregate of 1,590,321 shares of common stock between January 1, 2024 and April 22, 2024 pursuant to the Sales Agreement with H.C. Wainwright & Co., LLC and JonesTrading Institutional Services LLC (the “Sales Agreement”) for net proceeds to us of approximately \$2.0 million; and
- on an as adjusted basis, giving effect to the issuance and sale of 1,562,500 shares of common stock and accompanying common warrants to purchase 1,562,500 shares of common stock and pre-funded warrants to purchase 5,000,000 shares of common stock and accompanying common warrants to purchase 5,000,000 shares of common stock (assuming the exercise of the pre-funded warrants and excluding the shares of common stock issuable upon exercise of the common warrants being offered in this offering) in this offering at the combined public offering price of \$0.80 per share of common stock and accompanying common warrant and \$0.799 per pre-funded warrant to purchase one share of common stock and accompanying common warrant, and after deducting estimated placement agent fees and estimated offering expenses payable by us and assuming the exercise of the pre-funded warrants and no exercise of any common warrants.

You should read this information in conjunction with our financial statements and the related notes included elsewhere in this prospectus and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	Actual (unaudited)	December 31, 2023	
		Pro forma	Pro forma as Adjusted
	(In thousands, except share and per share data)		
Cash and cash equivalents	\$ 5,295	\$ 7,324	\$ 11,987
Stockholders' equity:			
Common stock, par value \$0.001 per share: 200,000,000 shares authorized, 9,838,755 shares issued and outstanding as of December 31, 2023, actual; 200,000,000 shares authorized, 11,429,076 shares issued and outstanding, pro forma; 200,000,000 shares authorized, 17,991,576 shares issued and outstanding, pro forma as adjusted	\$ 10	\$ 11	\$ 18
Additional paid-in capital	342,796	344,775	349,443
Accumulated deficit	(336,624)	(336,624)	(336,624)
Accumulated other comprehensive loss	1	1	1
Treasury stock, 46 shares at cost	(1)	(1)	(1)
Total stockholders' equity	6,182	8,162	12,837
Total capitalization	\$ 6,182	\$ 8,162	\$ 12,837

The number of shares immediately outstanding following this offering is based on 9,838,755 shares of common stock outstanding as of December 31, 2023 and also gives effect to 1,590,321 shares of our common stock sold and issued through an “at the market offering” pursuant to Sales Agreement and excludes:

- 695,459 shares of common stock issuable upon the exercise of stock options outstanding at a weighted average exercise price of approximately \$4.35 per share;
- 123,892 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units;
- 1,000 shares of common stock available for issuance pursuant to the 2021 Inducement Equity Plan;
- 1,643,798 shares of common stock available for issuance pursuant to the 2022 Equity Incentive Plan; and
- 45,000 shares of common stock available for issuance pursuant to the 2023 Employee Stock Purchase Plan.

DILUTION

If you purchase our common stock in this offering, your interest will be diluted to the extent of the difference between the public offering price per share of common stock and accompanying common warrant to purchase one share of common stock and the net tangible book value per share of our common stock after this offering (excluding the shares of common stock issuable upon exercise of the common warrants being offering in this offering and the payment of the exercise price therefor).

As of December 31, 2023, we had net tangible book value of approximately \$3.5 million, or \$0.35 per share. Net tangible book value per share represents the amount of total tangible assets less total liabilities divided by the number of shares of our common stock outstanding.

Our pro forma net tangible book value as of December 31, 2023, before giving effect to this offering, was approximately \$5.5 million, or \$0.48 per share of our common stock. Pro forma net tangible book value, before the issuance and sale of shares of common stock and accompanying common warrants in this offering, gives effect to the issuance of an aggregate of 1,590,321 shares of common stock between January 1, 2024 and April 22, 2024 pursuant to the Sales Agreement for net proceeds to us of approximately \$2.0 million.

After giving effect to (i) the pro forma adjustments set forth above and (ii) the issuance and sale of 1,562,500 shares of our common stock in this offering and accompanying common warrants to purchase 1,562,500 shares of our common stock and pre-funded warrants to purchase 5,000,000 shares of common stock and accompanying common warrants to purchase 5,000,000 shares of common stock (assuming the exercise of the pre-funded warrants and excluding the shares of common stock issuable upon exercise of the common warrants being offered in this offering) at the combined public offering price of \$0.80 per share of common stock and accompanying common warrant and \$0.799 per pre-funded warrant to purchase one share of common stock and accompanying common warrant, assuming the exercise of pre-funded warrants and no exercise of any common warrants and after deducting estimated placement agent fees and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2023 would have been approximately \$10.2 million, or approximately \$0.57 per share. This amount represents an immediate increase in pro forma net tangible book value of approximately \$0.08 per share to our existing stockholders and an immediate dilution in net tangible book value of approximately \$0.23 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the offering price per share paid by new investors. The pro forma as adjusted information below is based on the public offering price of \$0.80 per share of common stock and accompanying common warrant and \$0.799 per pre-funded warrant to purchase one share of common stock and accompanying common warrant, and is illustrative only.

The following table illustrates this dilution, assuming the holders of the common warrants do not exercise any of the pre-funded warrants or common warrants:

Combined public offering price per share and accompanying common warrant	\$ 0.80
Net tangible book value per share as of December 31, 2023	\$ 0.35
Increase in net tangible book value per share attributable to the issuance of 1,590,321 shares of common stock after December 31, 2023 pursuant to the Sales Agreement between January 1, 2024 and April 22, 2024	\$ 0.13
Pro forma net tangible book value per share as of December 31, 2023	\$ 0.48
Increase in pro forma net tangible book value per share attributable to this offering	\$ 0.08
Pro forma as adjusted net tangible book value per share, after giving effect to this offering	\$ 0.57
Dilution per share to investors purchasing shares in this offering	\$ 0.23

*Per share numbers may not add due to rounding.

The number of shares immediately outstanding following this offering is based on 9,838,755 shares of common stock outstanding as of December 31, 2023 and also gives effect to 1,590,321 shares of our common stock sold and issued through an “at the market offering” pursuant to Sales Agreement and excludes:

- 695,459 shares of common stock issuable upon the exercise of stock options outstanding at a weighted average exercise price of approximately \$4.35 per share;
- 123,892 shares of common stock issuable upon the vesting and settlement of outstanding restricted stock units;
- 1,000 shares of common stock available for issuance pursuant to the 2021 Inducement Equity Plan;
- 1,643,798 shares of common stock available for issuance pursuant to the 2022 Equity Incentive Plan; and

- 45,000 shares of common stock available for issuance pursuant to the 2023 Employee Stock Purchase Plan.

To the extent options, restricted units or warrants are additionally exercised or settled or other shares are issued, there may be further dilution to investors. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

BUSINESS

Overview

Organovo Holdings, Inc. (“Organovo Holdings,” “we,” “us,” “our,” the “Company” and “our Company”) is a clinical stage biotechnology company that is focused on developing FXR314 in inflammatory bowel disease (“IBD”), including ulcerative colitis (“UC”), based on demonstration of clinical promise in three-dimensional (“3D”) human tissues as well as strong preclinical data. FXR is a mediator of gastrointestinal and liver diseases. FXR agonism has been tested in a variety of preclinical models of IBD. FXR314 is the lead compound in our established FXR program containing two clinically tested compounds (including FXR314) and over 2,000 discovery or preclinical compounds. FXR314 is a drug with safety and tolerability after daily oral dosing in Phase 1 and Phase 2 trials. Further, FXR314 has FDA clinical trial authorization for a Phase 2 trial in UC.

Our current clinical focus is in advancing FXR314 in IBD, including UC and Crohn’s disease (“CD”). We plan to start a Phase 2a clinical trial in UC in the calendar year 2024. We released Phase 2 data for FXR314 for the treatment of metabolic function-associated steatohepatitis (“MASH”) in April 2024 that are supportive of ongoing development, and we believe FXR314 has a commercial opportunity in MASH, most likely in combination therapy. We are exploring the potential for combination therapies using FXR314 and currently approved mechanisms in preclinical animal studies and our IBD disease models.

Our second focus is building high fidelity, 3D tissues that recapitulate key aspects of human disease. We use our proprietary technology 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 develop clinically effective drugs across multiple therapeutic areas.

As with the clinical development program, we are initially focusing on the intestine and have ongoing 3D tissue development efforts in human tissue models of UC and CD. We use these models to identify new molecular targets responsible for driving the disease and to explore the mechanism of action of known drugs including FXR314 and related molecules. We intend to initiate drug discovery programs around these new validated targets to identify drug candidates for partnering and/or internal clinical development.

Our current understanding of intestinal tissue models and IBD disease models leads us to believe that we can create models that provide greater insight into the biology of these diseases than are generally currently available. We are creating high fidelity disease models, leveraging our prior work including the work found in our peer-reviewed publication on bioprinted intestinal tissues (Madden et al. Bioprinted 3D Primary Human Intestinal Tissues Model Aspects of Native Physiology and ADME/Tox Functions. *iScience*. 2018 Apr 27;2:156-167. doi: 10.1016/j.isci.2018.03.015.) Our advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures.

Using these disease models, we intend to identify and validate novel therapeutic targets. After finding therapeutic drug targets, we intend to focus on developing novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these novel drug candidates towards an Investigational New Drug (“IND”) filing and potential future clinical trials.

We expect to broaden our work into additional therapeutic areas over time and are currently exploring specific tissues for development. In our work to identify the areas of interest, we evaluate areas that might be better served with 3D disease models than currently available models as well as the potential commercial opportunity. In line with these plans, we are building upon both our external and in house scientific expertise, which will be essential to our drug development effort.

In February 2024, we formed our Mosaic Cell Sciences division (“Mosaic”) to serve as a key source of certain of the primary human cells we utilize in our research and development efforts. We believe Mosaic can help us optimize our supply chain, reduce operating expenses related to cell sourcing and procurement and ensure that the cellular raw materials we use are of the highest quality and are derived from tissues that are ethically sourced in full compliance with state and federal guidelines. We intend for Mosaic to provide us with qualified human cells for use in our clinical research and development programs. In addition to supplying us with primary human cells, we intend for Mosaic to offer human cells for sale to life science customers, both directly and through distribution partners, which we expect to offset costs and over time become a profit center that offsets overall R&D spending by Organovo.

Our Platform Technology

Our 3D human tissue platform is multifaceted. We approach each tissue agnostic to specific technologies, and intend to apply the best 3D technology to a given disease. We are developing novel disease models using high throughput systems, bioprinted and flow/stretch capable 3D systems as appropriate. Our proprietary NovoGen Bioprinters® and related technologies for preparing bio-inks and bioprinting multicellular tissues with complex architecture are grounded in over a decade of peer-reviewed scientific publications, deriving originally from research led by Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of

Biological Physics at the University of Missouri-Columbia (“MU”). We have a broad portfolio of intellectual property rights covering the principles, enabling instrumentation, applications, tissue constructs and methods of cell-based printing, including exclusive licenses to certain patented and patent pending technologies from MU and Clemson University. We own or exclusively license more than 100 patents and pending applications worldwide covering specific tissue designs, uses, and methods of manufacture.

The NovoGen Bioprinter® Platform

Our NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. A custom graphic user interface (“GUI”) facilitates the 3D design and execution of scripts that direct precision movement of multiple dispensing heads to deposit defined cellular building blocks called bio-ink. Bio-ink can be formulated as a 100% cellular composition or as a mixture of cells and other matter (hydrogels, particles). Our NovoGen Bioprinters® can also dispense pure hydrogel formulations, provided the physical properties of the hydrogel are compatible with the dispensing parameters. Most typically, hydrogels are deployed to create void spaces within specific locations in a 3D tissue or to aid in the deposition of specific cell types. We are able to employ a wide variety of proprietary cell- and hydrogel-based bio-inks in the fabrication of tissues. Our NovoGen Bioprinters® also serve as important components of our tissue prototyping and manufacturing platform, as they are able to rapidly and precisely fabricate intricate small-scale tissue models for *in vitro* use as well as larger-scale tissues suitable for *in vivo* use.

Generation of bio-ink comprising human cells is the first step in our standard bioprinting. A wide variety of cells and cell-laden hydrogels can be formulated into bio-ink and bioprinted tissues, including cell lines, primary cells, and stem/progenitor cells. The majority of tissue designs employ two or more distinct varieties of bio-ink, usually comprised of cells that represent distinct compartments within a target tissue. For example, a 3D liver tissue might consist of two to three distinct bio-inks that are each made from a single cell type, a combination of cell types, and/or a combination of primary cells and one or more bio-inert hydrogels that serve as physical supports for the bioprinted tissue during its maturation period, or to transiently occupy negative spaces in a tissue design.

Research Collaborations

We continue to collaborate with several academic institutions by providing them with access to our NovoGen Bioprinters® for research purposes, including: Yale School of Medicine, Knight Cancer Institute at Oregon Health & Science University, and the University of Virginia. We believe that the use of our bioprinting platform by major research institutions may help to advance the capabilities of the platform and generate new applications for bioprinted tissues. In prior instances, an academic institution or other third party provided funding to support the academic collaborator’s access to our technology platform. This funding was typically reflected as collaboration revenues in our financial statements. Our academic research collaborations typically involve both parties contributing resources directly to projects. We are not currently generating any revenues from these collaborations.

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 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 45 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 17 pending U.S. patent applications and more than 5 pending international applications in foreign jurisdictions including Australia, Canada and China. 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 connection with the recent acquisition of the FXR program from Metacrine, we acquired the related patent portfolio by way of assignment. This includes filings on the lead candidate, FXR314, and selected filings on the prior candidate (no longer in development), FXR125. With respect to this FXR portfolio, we solely own 7 issued patents and 15 international patents in jurisdictions, including Australia, China, Eurasia, India, Israel, Mexico, Japan and South Africa. We solely own 8 pending U.S. patent applications and more than 50 pending international applications in foreign jurisdictions, including Argentina, Australia, Brazil, Chile,

Canada, Eurasia, Europe, Israel, India, Japan, South Korea, Mexico, Philippines, Singapore, South Africa, Hong Kong and Taiwan. These patent families relate to FXR125 and FXR314, including generic coverage, species coverage, methods of use, formulations and polymorph crystals.

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 7 issued U.S. patents and 2 pending U.S. applications. 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.

In 2011, we obtained an exclusive license to a U.S. patent (U.S. Patent No. 7,051,654) owned by the Clemson University Research Foundation that provides us with intellectual property rights relating to methods of using ink-jet printer technology to dispense cells and relating to the creation of matrices of bioprinted cells on gel materials.

In connection with the acquisition of the FXR program from Metacrine in 2023, we were assigned and assumed a license agreement with the Salk Institute for Biological Studies requiring milestone and royalty payments based on the development and commercialization of FXR314.

The patent rights we obtained through these exclusive licenses are not only foundational within the field of 3D bioprinting and FXR agonist therapies 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 5. Collaborative Research, Development, and License Agreements” in the Notes to the Consolidated Financial Statements included elsewhere in this prospectus.

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 13 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, and 2014296246; Canada Patent No. 2,812,766; 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. These issued patents and pending patent applications carry remaining patent terms ranging from over 20 years to over 7 years. We have additional U.S. continuation applications pending in these families as well foreign counterpart applications in multiple countries.

Our ExVive[™] 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; and Canada Patent No. 2,903,844. Our ExVive[™] Human Kidney Tissue is protected by U.S. Patent Nos. 9,481,868, 10,094,821 and 10,962,526; Australian Patent No. 2015328173, Canadian Patent No. 2,962,778, European Patent No. 3204488 and Japan Patent No. 7021177. These issued patents and pending patent applications carry remaining patent terms ranging from over 11 years to over 9 years. We have additional U.S. patent applications pending in these families, as well as foreign counterpart applications. We currently have pending numerous 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 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 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 Organovo’s foundational patent portfolio in 3D bioprinting.

With respect to our FXR agonist program covering FXR314 and FXR125, we have 6 issued U.S. patents and 14 issued foreign patents directed to composition of matter protection (generic and specific) for FXR314 and FXR125, as well claims directed to methods of treatment of GI diseases, formulations of FXR314 and polymorphs of the FXR314 molecule including United States Patent Nos. 11,214,538, 10,703,712, 10,927,082, 10,961,198, 11,236,071 and 11,084,817, granted Australian Patent Nos. 2016323992 and 2018236275, Chinese Patent Nos. 201680066917 and 269065, Eurasian Patent Nos. 040003 and 040704, Israeli Patent Nos. 258011, 296068 and 296065, Indian Patent No. 380510, Japanese Patent Nos. 6905530 and 717709, Mexican Patent Nos. 386,752 and 397265 and South African Patent No. 2018/01750. In addition, we have 8 pending U.S. patent applications and over 50 pending foreign patent applications, including U.S. Patent Application Nos. 18/156,069, 18/174,393, 17/349,757, 17/906,580, 17/906,582 and 17/906,585 and over 50 pending international patent applications in a number of countries including, Australia, Brazil, Canada, Chile, China, the Eurasian Patent Office, the European Patent Office, Israel, India, Japan, South Korea, Mexico, Singapore, Philippines and Hong Kong. These issued patents and pending patent applications carry remaining patent terms ranging from over 18 years to just over 15 years.

Employees and Human Capital

As of March 31, 2024, we had 20 employees, of which 12 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 selected 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. Organovo, Inc. was incorporated in Delaware in April 2007. Our common stock has traded on The Nasdaq Stock Market LLC under the symbol "ONVO" since August 8, 2016 and our common stock currently trades on the Nasdaq Capital Market. Prior to that time, it traded on the NYSE MKT under the symbol "ONVO" and prior to that was quoted on the OTC Market.

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 <http://www.organovo.com>. The content of our website is not intended to be incorporated by reference into this prospectus or in any other report or document that we file.

Available Information

Our investor relations website is located at <http://ir.organovo.com>. 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 available free of charge, through our website. The content of our website is not intended to be incorporated by reference into this prospectus or in any other report or document that we file. We 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 are also available on the SEC's website (<http://www.sec.gov>).

Legal Proceedings

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.

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

The Company regularly reviews contingencies to determine the adequacy of its accruals and related disclosures. During the period presented, the Company has not recorded any accrual for loss contingencies associated with any claims or legal proceedings;

determined that an unfavorable outcome is probable or reasonably possible; or determined that the amount or range of any possible loss is reasonably estimable. However, the outcome of legal proceedings and claims brought against the Company is subject to significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, 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.

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 of office space in the same building. In December 2021, we took occupancy of our permanent lab and office space, located at 11555 Sorrento Valley Road, San Diego, CA 92121. See "Note 7. Leases" of the Notes to the Consolidated Financial Statements contained elsewhere in this prospectus for a further discussion of properties.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following management's discussion and analysis of financial condition and results of operations should be read in conjunction with our historical consolidated financial statements and the related notes thereto for the fiscal year ended March 31, 2023 included elsewhere in this prospectus. This management's discussion and analysis contains forward-looking statements, such as statements related to our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions such as "will," "may," "could," "should," or similar expressions, identify certain of these forward-looking statements. These forward-looking statements speak only as of the date of this prospectus and are subject to risks and uncertainties, including those described discussed in the section titled "Risk Factors" in this prospectus, that could cause our actual results or events to differ materially from those expressed or implied by such forward-looking statements. Unless the context otherwise requires, the terms "Organovo," the "Company", "we", "us" and "our" in this prospectus refer to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc. and Opal Merger Sub, Inc.

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

Basis of Presentation

The unaudited condensed consolidated financial statements included in this prospectus have been prepared in accordance with the Securities and Exchange Commission (the "SEC") instructions to Quarterly Reports on Form 10-Q. Accordingly, the unaudited condensed consolidated financial statements as of and for the nine months ended December 31, 2023 presented elsewhere in this prospectus and discussed below are unaudited and do not contain all the information required by U.S. generally accepted accounting principles ("GAAP") to be included in a full set of financial statements. The audited financial statements for the year ended March 31, 2023 included elsewhere in this prospectus, include a summary of our significant accounting policies and should be read in conjunction with the unaudited condensed consolidated financial statements as of and for the nine months ended December 31, 2023. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this prospectus. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

Overview

We are a clinical stage biotechnology company that is focusing on clinical drug development of the farnesoid X receptor ("FXR") agonist FXR314. FXR is a mediator of gastrointestinal and liver diseases. FXR agonism has been tested in a variety of preclinical models of inflammatory bowel disease ("IBD"). FXR314 is the lead compound in our established FXR program containing two clinically tested compounds (including FXR314) and over 2,000 discovery or preclinical compounds. FXR314 is a drug with safety and tolerability after daily oral dosing in Phase 1 and Phase 2 trials. Further, FXR314 has FDA clinical trial authorization for a Phase 2 trial in ulcerative colitis ("UC").

Our current clinical focus is in advancing FXR314 in IBD, including UC and Crohn's disease ("CD"). We plan to start a Phase 2a clinical trial in UC in the calendar year 2024.

Our second focus is building high fidelity, 3D tissues that recapitulate key aspects of human disease. We use our proprietary technology 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 develop clinically effective drugs across multiple therapeutic areas.

As with the clinical development program, we are initially focusing on the intestine and have ongoing 3D tissue development efforts in human tissue models of UC and CD. We use these models to identify new molecular targets responsible for driving the disease and to explore the mechanism of action of known drugs including FXR314 and related molecules. We intend to initiate drug discovery programs around these new validated targets to identify drug candidates for partnering and/or internal clinical development.

Our current understanding of intestinal tissue models and IBD disease models leads us to believe that we can create models that provide greater insight into the biology of these diseases than are generally currently available. We are creating high fidelity disease models, leveraging our prior work including the work found in our peer-reviewed publication on bioprinted intestinal tissues (Madden et al. Bioprinted 3D Primary Human Intestinal Tissues Model Aspects of Native Physiology and ADME/Tox Functions. iScience. 2018 Apr 27;2:156-167. doi: 10.1016/j.isci.2018.03.015.) Our advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures.

Using these disease models, we intend to identify and validate novel therapeutic targets. After finding therapeutic drug targets, we intend to focus on developing novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these novel drug candidates towards an Investigational New Drug (“IND”) filing and potential future clinical trials.

We expect to broaden our work into additional therapeutic areas over time and are currently exploring specific tissues for development. In our work to identify the areas of interest, we evaluate areas that might be better served with 3D disease models than currently available models as well as the potential commercial opportunity. In line with these plans, we are building upon both our external and in house scientific expertise, which will be essential to our drug development effort.

Critical Accounting Policies, Estimates, and Judgments

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

There have been no significant changes to our critical accounting policies since March 31, 2023. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our condensed consolidated financial statements, refer to Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Note 1. Description of Business and Summary of Significant Accounting Policies” in the Notes to Consolidated Financial Statements contained elsewhere in this prospectus.

Results of Operations

Comparison of the three months ended December 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended December 31, 2023 and 2022 (in thousands, except %):

	Three Months Ended December 31,		Increase (decrease)	
	2023	2022	\$	%
Revenues	\$ 5	\$ 131	\$ (126)	(96)%
Research and development	\$ 1,434	\$ 1,185	\$ 249	21%
Selling, general and administrative	\$ 2,251	\$ 2,305	\$ (54)	(2)%
Other income	\$ 76	\$ 95	\$ (19)	(20)%

Revenues

For the three months ended December 31, 2023 and 2022, total revenue was less than \$0.1 million and \$0.1 million, respectively. The revenue is related to sales-based royalties from licensing intellectual property. The decrease in royalty revenue year over year relates to a decrease in sales of royalty bearing products by the licensee. Given the trend of reduced sales during the fiscal year, we expect a decrease in sales of royalty bearing products by the licensee going forward.

Costs and Expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended December 31, 2023 and 2022 (in thousands, except %):

	Three Months Ended December 31, 2023		Three Months Ended December 31, 2022		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Research and development	\$ 1,336	93 %	\$ 1,023	86 %	\$ 313	31 %
Non-cash stock-based compensation	40	3 %	117	10 %	(77)	(66 %)
Depreciation and amortization	58	4 %	45	4 %	13	29 %
Total research and development expenses	\$ 1,434	100 %	\$ 1,185	100 %	\$ 249	21 %

For the three months ended December 31, 2023, total research and development expenses were \$1.4 million, an increase of \$0.2 million, or approximately 21%, from the prior year period. The increase year over year directly relates to the shift in strategic focus to advance the clinical drug development of FXR314 and start a Phase 2a clinical trial in the calendar year 2024. Our average full-time research and development staff decreased from an average of fifteen full-time employees for the three months ended December 31, 2022 to an average of fourteen full-time employees for the three months ended December 31, 2023. Our fiscal 2024 operations resulted in a \$0.1 million increase in consulting expenses, and a \$0.1 million increase in lab expenses. Going forward, we intend to continue to advance the clinical drug development of FXR314 and expect an associated increase in expenses.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the three months ended December 31, 2023 and 2022 (in thousands, except %):

	Three Months Ended December 31, 2023		Three Months Ended December 31, 2022		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Selling, general and administrative	\$ 2,120	94 %	\$ 1,793	77 %	\$ 327	18 %
Non-cash stock-based compensation	117	5 %	427	19 %	(310)	(73 %)
Depreciation and amortization	14	1 %	85	4 %	(71)	(84 %)
Total selling, general and administrative expenses	\$ 2,251	100 %	\$ 2,305	100 %	\$ (54)	(2 %)

For the three months ended December 31, 2023, total selling, general and administrative expenses were approximately \$2.3 million, a decrease of less than \$0.1 million, or approximately 2%, compared to the prior year period. The decrease year over year relates to a decrease in personnel. Our average full-time general and administrative staff decreased from an average of five full-time employees for the three months ended December 31, 2022 to an average of four full-time employees for the three months ended December 31, 2023. Our fiscal 2024 operations resulted in a \$0.4 million decrease in personnel related costs, including stock based compensation, related to severance for the reduction in force in the second quarter of fiscal 2024. There was also a \$0.1 million decrease in other corporate expenses and a decrease of less than \$0.1 million in depreciation and amortization expense in fiscal 2024. This was offset by a \$0.2 million increase in legal expenses and a \$0.3 million increase in investor relations expenses compared to the prior year period.

Other Income

Other income was \$0.1 million for the three months ended December 31, 2023, which was related to interest income. Other income was \$0.1 million for the three months ended December 31, 2022, which was related to interest income of approximately \$0.1 million offset by a loss on investment in equity securities of less than \$0.1 million.

Comparison of the nine months ended December 31, 2023 and 2022

The following table summarizes our results of operations for the nine months ended December 31, 2023 and 2022 (in thousands, except %):

	Nine Months Ended December 31,		Increase (decrease)	
	2023	2022	\$	%
Revenues	\$ 80	\$ 208	\$ (128)	(62 %)
Research and development	\$ 4,435	\$ 3,436	\$ 999	29 %
Selling, general and administrative	\$ 7,635	\$ 6,724	\$ 911	14 %
Other income	\$ 366	\$ 154	\$ 212	138 %

Revenues

For the nine months ended December 31, 2023 and 2022, total revenue was less than \$0.1 million and \$0.2 million, respectively. The revenue is related to sales-based royalties from licensing intellectual property. The decrease in royalty revenue year over year relates to a decrease in sales of royalty bearing products by the licensee. Given the trend of reduced sales during the fiscal year, we expect a decrease in sales of royalty bearing products by the licensee going forward.

Costs and Expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended December 31, 2023 and 2022 (in thousands, except %):

	Nine Months Ended December 31, 2023		Nine Months Ended December 31, 2022		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Research and development	\$ 4,179	94 %	\$ 2,953	86 %	\$ 1,226	42 %
Non-cash stock-based compensation	87	2 %	363	11 %	(276)	(76 %)
Depreciation and amortization	169	4 %	120	3 %	49	41 %
Total research and development expenses	\$ 4,435	100 %	\$ 3,436	100 %	\$ 999	29 %

For the nine months ended December 31, 2023, total research and development expenses were \$4.4 million, an increase of \$1.0 million, or 29%, from the prior year period. Our average full-time research and development staff increased from an average of fourteen full-time employees for the nine months ended December 31, 2022 to an average of sixteen full-time employees for the nine months ended December 31, 2023. Our fiscal 2024 research and development activities resulted in a \$0.3 million increase in personnel related costs, a \$0.3 million increase in lab expenses, a \$0.2 million increase in consulting expenses, a \$0.1 million increase in depreciation and amortization expense, and a \$0.1 million increase in facility costs. Going forward, we intend to continue to advance the clinical drug development of FXR314 with an associated increase in expenses.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the nine months ended December 31, 2023 and 2022 (in thousands, except %):

	Nine Months Ended December 31, 2023		Nine Months Ended December 31, 2022		Increase (decrease)	
	\$	% of total	\$	% of total	\$	%
Selling, general and administrative	\$ 6,374	83 %	\$ 5,096	75 %	\$ 1,278	25 %
Non-cash stock-based compensation	1,220	16 %	1,514	23 %	(294)	(19 %)
Depreciation and amortization	41	1 %	114	2 %	(73)	(64 %)
Total selling, general and administrative expenses	<u>\$ 7,635</u>	<u>100 %</u>	<u>\$ 6,724</u>	<u>100 %</u>	<u>\$ 911</u>	<u>14 %</u>

For the nine months ended December 31, 2023, total selling, general and administrative expenses were approximately \$7.6 million, an increase of approximately \$0.9 million, or approximately 14%, compared to the prior year period. The increase year over year relates to increases in legal and other corporate expenses. Our average full-time general and administrative staff remained consistent at an average of five full-time employees for both the nine months ended December 31, 2022 and December 31, 2023. However, there was a reduction in force event in the second quarter of fiscal 2024 that resulted in a decrease from five to four total employees for the quarter ended December 31, 2023. Our fiscal 2024 operations resulted in a \$0.1 million decrease in personnel related costs, including stock based compensation, related to severance for the reduction in force event, a \$0.1 million decrease in depreciation and amortization expense, offset by a \$0.1 million increase in consulting costs, a \$0.6 million increase in legal expenses, a \$0.3 million increase in investor relations expenses, and a \$0.1 million increase in other corporate expenses.

Other Income

Other income was \$0.4 million for the nine months ended December 31, 2023, related to interest income. Other income was \$0.2 million for the nine months ended December 31, 2022, which was related to interest income of approximately \$0.3 million offset by a loss on investment in equity securities of approximately \$0.1 million.

Financial Condition, Liquidity and Capital Resources

Going forward, we intend to focus on clinical drug development of FXR314, the lead compound in our established FXR program. Our current clinical focus is in advancing FXR314 in IBD, including UC and CD. We plan to start a Phase 2a clinical trial in UC in the calendar year 2024. Additionally, we plan to leverage our proprietary technology platform to develop therapeutic drugs, focusing on IBD, including CD and UC, with a goal of broadening our work into additional therapeutic areas over time.

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. At December 31, 2023, we had cash and cash equivalents of approximately \$5.3 million, restricted cash of approximately \$0.1 million and an accumulated deficit of approximately \$336.6 million. The restricted cash was pledged as collateral for a letter of credit that the Company is required to maintain as a security deposit under the terms of the lease agreement for its facilities. We had negative cash flow from operations of approximately \$12.0 million during the nine months ended December 31, 2023. At March 31, 2023, we had cash and cash equivalents of approximately \$15.3 million, restricted cash of approximately \$0.1 million and an accumulated deficit of approximately \$325.0 million.

At December 31, 2023, we had total current assets of approximately \$6.2 million and current liabilities of approximately \$1.7 million, resulting in working capital of \$4.5 million. At March 31, 2023, we had total current assets of approximately \$17.0 million and current liabilities of approximately \$3.7 million, resulting in working capital of \$13.3 million.

The following table summarizes the primary sources and uses of cash for the nine months ended December 31, 2023 and 2022 (in thousands):

	Nine Months Ended December 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	\$ (11,982)	\$ (7,675)
Investing activities	803	(804)
Financing activities	1,173	—
Net decrease in cash, cash equivalents, and restricted cash	\$ (10,006)	\$ (8,479)

Operating activities

Net cash used in operating activities for the nine months ended December 31, 2023 was approximately \$12.0 million as compared to \$7.7 million used in operating activities for the nine months ended December 31, 2022. This \$4.3 million increase in operating cash usage can be attributed primarily to the increase in research and development activities. Operating cash usage includes \$2.0 million of cash outflows for acquired in-process research and development of Metacrine's FXR drug compound, related research data, and IP.

Investing activities

Net cash provided by investing activities was \$0.8 million for the nine months ended December 31, 2023. Investing activities consisted of purchases of investments of \$9.9 million, maturities of investments of \$10.0 million, liquidation of equity securities of \$0.7 million, and fixed asset purchases of less than \$0.1 million. Net cash used in investing activities was \$0.8 million for the nine months ended December 31, 2022, which consisted of purchases of equity securities of \$1.1 million, purchases of investments of \$9.9 million, maturities of investments of \$10.0 million, sales of equity securities of \$0.4 million, and fixed asset purchases of \$0.2 million.

Financing activities

Net cash provided by financing activities was \$1.2 million for the nine months ended December 31, 2023. Financing activities consisted of the sale of common stock through “at the market offerings” (“ATM offerings”). There were no financing activities in the nine months ended December 31, 2022.

Operations funding requirements

Through December 31, 2023, we have financed our operations primarily through the sale of common stock through public and ATM offerings, the private placement of equity securities, from revenue derived from the licensing of intellectual property, products and research-based services, grants, and collaborative research agreements, and from the sale of convertible notes.

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, 2024 to be between \$13.0 million and \$15.0 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.

We previously had an effective shelf registration statement on Form S-3 (File No. 333-222929) (the “2018 Shelf”) that registered \$100.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing and expired on February 22, 2021. On January 19, 2021, we filed a shelf registration statement on Form S-3 (File No. 333-252224) to register \$150.0 million of common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the “2021 Shelf”). The 2021 Shelf registration statement was declared effective by the SEC on January 29, 2021 and replaced the 2018 Shelf at that time. On January 26, 2024, we filed a new shelf registration statement on Form S-3 (File No. 333-276722) to register \$150.0 million of the Company’s common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the “2024 Shelf”). The 2024 Shelf was declared effective by the SEC on February 8, 2024.

On March 16, 2018, we entered into a Sales Agreement (“Sales Agreement”) with H.C. Wainwright & Co., LLC and JonesTrading Institutional Services LLC (each an “Agent” and together, the “Agents”). On January 29, 2021, we filed a prospectus supplement to the 2021 Shelf (the “2021 ATM Prospectus Supplement”), pursuant to which we could offer and sell, from time to time, through the

Agents, shares of our common stock in ATM sales transactions having an aggregate offering price of up to \$50.0 million. Any shares offered and sold will be issued pursuant to our 2021 Shelf until it is replaced by the 2024 Shelf.

During the nine months ended December 31, 2023, we sold 934,621 shares of common stock in ATM offerings pursuant to the 2021 ATM Prospectus Supplement. As of December 31, 2023, we have sold an aggregate of 2,515,483 shares of common stock in ATM offerings under the 2021 ATM Prospectus Supplement, for gross proceeds of approximately \$22.9 million. As of December 31, 2023, there was approximately \$100.0 million available in future offerings under the 2021 Shelf (excluding amounts available but not yet issued under the ATM Prospectus Supplement), and approximately \$27.1 million available for future offerings through our ATM program under the 2021 ATM Prospectus Supplement.

On January 26, 2024, we also filed a prospectus to the 2024 Shelf (the "2024 ATM Prospectus"), pursuant to which we may offer and sell, from time to time, through the Agents, shares of its common stock in ATM sales transactions having an aggregate offering price of up to \$2,605,728. Any shares offered and sold in these ATM sales transactions will be issued pursuant to the 2024 Shelf.

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 eventually adversely affect our ability to operate as a going concern. 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, financial condition and ability to continue as a going concern.

On October 12, 2022, our stockholders and the Board of Directors ("Board") approved the 2022 Equity Incentive Plan ("2022 Plan"), and it became effective on that date. The 2022 Plan replaced the 2012 Equity Incentive Plan ("2012 Plan") on the effective date. Upon the effective date, we 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 1,363,000 shares of our common stock was initially reserved for issuance under the 2022 Plan. We 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, we issued 126,262 shares of common stock under the 2012 Plan. As a result, the number of shares initially reserved for future issuance under the 2022 Plan was 1,236,738 shares of common stock as of October 12, 2022. We also committed to reducing the aggregate number of shares of common stock issuable pursuant to the 2021 Inducement Equity Incentive Plan ("Inducement Plan") from 750,000 shares to 51,000 shares (which includes 50,000 shares of its common stock issuable pursuant to an outstanding option to purchase common stock with an exercise price of \$2.75 per share, leaving only 1,000 shares available for future issuance under the Inducement Plan) and the share reserve was reduced effective October 12, 2022.

As of December 31, 2023, we had 9,838,755 total issued and outstanding shares of common stock. Under the 2022 Plan, 1,643,798 shares remain available for issuance as of December 31, 2023, to executive officers, directors, advisory board members, employees and consultants. Additionally, 45,000 shares of common stock have been reserved for issuance under the 2023 Employee Stock Purchase Plan ("ESPP"), of which 45,000 shares remain available for future issuance as of December 31, 2023. Finally, 51,000 shares of common stock have been reserved for issuances under our Inducement Plan, of which 1,000 remain available for future issuance as of December 31, 2023. In aggregate, issued and outstanding common stock and shares issuable under outstanding equity awards or reserved for future issuance under the 2022 Plan, the 2012 Plan, the Inducement Plan, and the ESPP total 12,347,904 shares of common stock as of December 31, 2023.

Off-Balance Sheet Arrangements

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

Comparison of the Years Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the years ended March 31, 2023 and 2022 (in thousands, except percentages):

	Year Ended March 31,		Increase (decrease)	
	2023	2022	\$	%
Revenues	\$ 370	\$ 1,500	\$ (1,130)	(75 %)
Research and development	\$ 8,885	\$ 3,320	\$ 5,565	168 %
Selling, general and administrative	\$ 9,216	\$ 9,659	\$ (443)	(5 %)
Other income	\$ 474	\$ 33	\$ 441	1,336 %

Revenues

We had \$0.4 million of royalty revenue for the year ended March 31, 2023, compared to \$1.5 million revenue for the year ended March 31, 2022. The \$1.5 million of royalty revenue for the year ended March 31, 2022 was an upfront payment related to the licensing of certain intellectual property ("IP"). The \$0.4 million of royalty revenue for the year ended March 31, 2023, was related to the sales-based royalty revenue earned from the aforementioned licensing of IP.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended March 31, 2023 and 2022 (in thousands, except percentages):

	Year Ended March 31,		Increase (decrease)	
	2023	2022	\$	%
Research and development	\$ 8,247	\$ 2,787	\$ 5,460	196 %
Non-cash stock-based compensation	473	419	54	13 %
Depreciation and amortization	165	114	51	45 %
Total research and development expenses	\$ 8,885	\$ 3,320	\$ 5,565	168 %

Research and development expenses increased by \$5.6 million, or 168%, from approximately \$3.3 million for the year ended March 31, 2022 to approximately \$8.9 million for the year ended March 31, 2023, as we significantly increased research and development activities. Our full-time research and development staff increased from an average of nine employees for the year ended March 31, 2022 to an average of fifteen employees for the year ended March 31, 2023. Research and development activities consisted of \$2.4 million in personnel related costs, \$5.2 million in lab and research expenses, \$1.0 million in facility costs, and \$0.3 million in consulting fees, depreciation, and other miscellaneous expenses. Of the \$5.2 million in lab and research expenses, \$4.0 million relates to acquired in-process research and development ("IPR&D") of Metacrine's FXR program, related research data, and IP.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the years ended March 31, 2023 and 2022 (in thousands, except percentages):

	Year Ended March 31,		Increase (decrease)	
	2023	2022	\$	%
Selling, general and administrative	\$ 7,184	\$ 7,794	\$ (610)	(8 %)
Non-cash stock-based compensation	1,904	1,837	67	4 %
Depreciation and amortization	128	28	100	357 %
Total selling, general and administrative expenses	\$ 9,216	\$ 9,659	\$ (443)	(5 %)

Selling, general and administrative expenses decreased approximately \$0.4 million, or 5%, from \$9.7 million for the year ended March 31, 2022 to approximately \$9.2 million for the year ended March 31, 2023. Overall, the decrease year over year is due to a significant decrease in general corporate costs, most notably legal costs, as we were involved in litigation in fiscal 2022 which was resolved by the end of fiscal 2022. For the year ended March 31, 2022, we had an average of four full-time employees, which increased to an average of five full-time employees for the year ended March 31, 2023. Year over year, we had an increase in personnel related costs of approximately \$0.4 million, an increase in consulting costs of approximately \$0.3 million, an increase in depreciation and amortization of approximately \$0.1 million. These increases were offset by a \$1.2 million decrease in general

corporate costs, mostly attributable to a decrease in legal costs related to litigation regarding patent enforcement that occurred and ended in fiscal 2022.

Other Income (Expense)

Other income was \$0.5 million and less than \$0.1 million for the years ended March 31, 2023 and March 31, 2022, respectively. For the year ended March 31, 2023, interest income was approximately \$0.5 million, due to higher interest rates compared to prior years. For the year ended March 31, 2022, other income consisted of a sale of a bioprinter asset to an academic research institution as well as interest income.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On July 18, 2023, Mayer Hoffman McCann P.C. (“MHM”) informed the Company and the Audit Committee (the “Audit Committee”) of the Company’s Board of Directors that it would not stand for re-election as the Company’s independent registered public accounting firm for the audit of the Company’s financial statements for the fiscal year ending March 31, 2024. MHM ceased to serve as the Company’s independent registered public accounting firm on August 10, 2023, the date of the filing of the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023.

The audit reports of MHM on the Company’s financial statements for the fiscal years ended March 31, 2023 and 2022 did not contain an adverse opinion or a disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope or accounting principles, except for an explanatory paragraph regarding the existence of substantial doubt about the Company’s ability to continue as a going concern in the report for the fiscal year ended March 31, 2023.

During the Company’s two most recent fiscal years ended March 31, 2023 and 2022 and the subsequent interim period through July 18, 2023, there were no (a) disagreements, within the meaning of Item 304(a)(1)(iv) of Regulation S-K promulgated under the Securities Exchange Act of 1934, as amended (“Regulation S-K”), and the related instructions thereto, with MHM on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of MHM, would have caused it to make reference to the subject matter of the disagreements in connection with its reports, or (b) reportable events within the meaning of Item 304(a)(1)(v) of Regulation S-K and the related instructions thereto.

On August 31, 2023, the Audit Committee approved the appointment of Rosenberg Rich Baker Berman P.A. (“RRBB P.A.”) as the Company’s new independent registered public accounting firm, effective as of August 31, 2023. During the fiscal years ended March 31, 2023 and 2022 and the subsequent interim period through August 31, 2023, neither the Company, nor anyone on its behalf, consulted RRBB P.A. regarding either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the financial statements of the Company, and no written report or oral advice was provided to the Company by RRBB P.A. that RRBB P.A. concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a “disagreement” (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a “reportable event” (as that term is defined in Item 304(a)(1)(v) of Regulation S-K).

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our excess cash in short term, high quality interest bearing securities including US government and US 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.

DESCRIPTION OF CAPITAL STOCK

We are offering 1,562,500 shares of our common stock and pre-funded warrants to purchase up to 5,000,000 shares of our common stock together with common warrants to purchase up to 6,562,500 shares of common stock. Each share of common stock or pre-funded warrant is being sold together with a common warrant to purchase one share of common stock. The shares of common stock or pre-funded warrants and accompanying common warrants will be issued separately and will be immediately separable upon issuance but must be purchased together in this offering. We are also registering the shares of common stock issuable from time to time upon exercise of the common warrants and pre-funded warrants offered hereby.

General Matters

The following description summarizes the most important terms of our capital stock. Because it is only a summary of the provisions of our certificate of incorporation, as amended (the “Certificate of Incorporation”), and our amended and restated bylaws (the “Bylaws”), it does not contain all of the information that may be important to you. For a complete description of the matters set forth in this “Description of Capital Stock,” you should refer to our Certificate of Incorporation and Bylaws, each of which are included as exhibits to the registration statement of which this prospectus is a part, and to the applicable provisions of Delaware law.

Our authorized capital stock consists of 200,000,000 shares of common stock, \$0.001 par value per share, and 25,000,000 shares of preferred stock, \$0.001 par value per share. Our Board of Directors (the “Board”) may establish the rights and preferences of the preferred stock from time to time. As of April 30, 2024, there were 11,430,326 shares of our common stock issued and outstanding and no shares of preferred stock issued and outstanding.

Common Stock

Dividend Rights. Subject to limitations under Delaware law and preferences that may apply to any then-outstanding shares of preferred stock, holders of common stock are entitled to share ratably in dividends, if any, as may be declared from time to time by our Board in its discretion from funds legally available therefor. Dividends, if any, will be contingent upon our revenues and earnings, if any, and capital requirements and financial conditions. The payment of dividends, if any, will be within the discretion of our Board. We presently intend to retain all earnings, if any, and accordingly our Board does not anticipate declaring any dividends prior to a business combination.

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. Our Certificate of Incorporation does not provide for cumulative voting for the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes cast by all shares of common stock that are present in person or represented by proxy. The Certificate of Incorporation establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms. The Certificate of Incorporation and the Bylaws also provide that the directors may be removed only for cause. In addition, Organovo has reserved the right to amend, alter, change or repeal any provision in the Certificate of Incorporation, subject to any approval of our stockholders as may be required under the DGCL, and our Board is authorized to adopt, amend or repeal the Bylaws.

No Preemptive or Similar Rights. Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions. In the event of a liquidation, dissolution or winding up, the holders of common stock are entitled to share pro rata all assets remaining after payment in full of all liabilities and after providing for each class of stock, if any, having preference over the common stock, subject to the liquidation preference of any then outstanding shares of preferred stock.

Fully Paid and Non-Assessable. All of the outstanding shares of our common stock are duly authorized, validly issued, fully paid and non-assessable.

Common Warrants

The following summary of certain terms and provisions of the common warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of common warrant for a complete description of the terms and conditions of the common warrants.

We are offering common warrants to purchase up to an aggregate of 6,562,500 shares of our common stock.

Each common warrant issued in this offering represents the right to purchase one share of common stock at an initial exercise price of \$0.80 per share. Each common warrant may be exercised, in cash or by a cashless exercise at the election of the holder immediately upon issuance and from time to time thereafter through and including the fifth anniversary of the initial exercise date.

The common warrants will be exercisable in whole or in part by delivering to the Company a completed instruction form for exercise and complying with the requirements for exercise set forth in the common warrant. Payment of the exercise price may be made in cash or pursuant to a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the common warrants.

No Fractional Shares

No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the common warrants. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, the number of shares of common stock to be issued shall be rounded up to the nearest whole number.

Exercise Limitation

In general, a holder will not have the right to exercise any portion of a common warrant if the holder (together with its Attribution Parties (as defined in the common warrant)) would beneficially own in excess of 4.99% or 9.99%, at the election of the holder, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrant. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Cashless Exercise

If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act, is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

Adjustment for Stock Splits

The exercise price and the number of shares of common stock purchasable upon the exercise of the common warrants are subject to adjustment upon the occurrence of specific events, including sales of additional shares of common stock, stock dividends, stock splits, and combinations of our common stock.

Dividends or Distributions

If we declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of our common stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property, options, evidence of indebtedness or any other assets by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) at any time after the issuance of the common warrants, then, in each such case, the holders of the common warrants shall be entitled to participate in such distribution to the same extent that the holders would have participated therein if the holders had held the number of shares of common stock acquirable upon complete exercise of the common warrants.

Purchase Rights

If we grant, issue or sell any shares of our common stock or securities exercisable for, exchangeable for or convertible into our common stock, or rights to purchase stock, common warrants, securities or other property pro rata to the record holders of any class of shares of our common stock, referred to as Purchase Rights, then each holder of the common warrants will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon complete exercise of the common warrants immediately before the record date, or, if no such record is taken, the date as of which the record holders of shares of common stock are to be determined, for the grant, issue or sale of such Purchase Rights.

Fundamental Transactions

In the event of a fundamental transaction, as described in the common warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the consummation of a business combination with another person or group of persons whereby such other person or group acquires greater than 67% of the voting power of the outstanding common stock and preferred stock, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction.

Transferability

Subject to applicable laws, the common warrants may be offered for sale, sold, transferred or assigned. There is currently no trading market for the common warrants and a trading market is not expected to develop.

Rights as a Stockholder

Except as otherwise provided in the common warrants or by virtue of a holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, unless and until they exercise their common warrants.

Amendments

The common warrants may be amended with the written consent of the holder of such common warrant and us.

Listing

There is no established public trading market for the common warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the common warrants on any national securities exchange.

Pre-Funded Warrants

The following summary of certain terms and provisions of the pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price

Each pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.001. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability

Each pre-funded warrant may be exercised, in cash or by a cashless exercise at the election of the holder at any time following the date of issuance and from time to time thereafter until the pre-funded warrants are exercised in full. The pre-funded warrants will be exercisable in whole or in part by delivering to the Company a completed instruction form for exercise and complying with the requirements for exercise set forth in the pre-funded warrant. Payment of the exercise price may be made in cash or pursuant to a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the pre-funded warrant.

Cashless Exercise

At the time a holder exercises its pre-funded warrants, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Exercise Limitation

In general, a holder will not have the right to exercise any portion of a pre-funded warrant if the holder (together with its Attribution Parties (as defined in the pre-funded warrant)) would beneficially own in excess of 4.99% or 9.99%, at the election of the holder, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrant. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us, provided, that any increase in this limitation will not be effective until 61 days after such notice from the holder to us and such increase or decrease will apply only to the holder providing such notice.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the pre-funded warrants. Rather, the number of shares of common stock to be issued will, at our election, either be rounded up to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Trading Market

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Preferred Stock

As of the date of this prospectus, no shares of preferred stock are issued and outstanding. Our Board is authorized, subject to limitations prescribed by Delaware law, to issue up to 25,000,000 shares of preferred stock in one or more series, to determine and fix from time to time the number of shares to be included in such series, and to fix the designations, powers, preferences and rights, qualifications, limitations and restrictions thereof, including, without limitation, dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions), redemption price or prices and liquidation preferences of such series, in each case without further vote or action by the stockholders. Our Board can also increase or decrease the number of shares of any such series, but not above the total number of authorized shares and not below the number of shares of such series then outstanding, without any further vote or action by the stockholders.

Our Board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation, Bylaws and the General Corporation Law of the State of Delaware

Certain provisions of Delaware law, along with the Certificate of Incorporation and the Bylaws, may have the effect of delaying, deferring or discouraging another person from acquiring control of us. These provisions are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to first negotiate with our Board. However, these provisions could have the effect of delaying, discouraging or preventing attempts to acquire us, which could deprive the stockholders of opportunities to sell their shares of our common stock at prices higher than prevailing market prices.

Delaware Law

We are subject to Section 203 of the General Corporation Law of the State of Delaware (“DGCL”), which prohibits persons deemed to be “interested stockholders” from engaging in a “business combination” with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by our Board.

Choice of Forum

The Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state or federal court located in the State of Delaware) will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty by any of our directors, officers or stockholders to us or our stockholders; (3) any action arising pursuant to any provision of the DGCL or the Certificate of Incorporation or the Bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. The provision will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the choice of forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. However, the Certificate of Incorporation does not relieve us of our duties to comply with federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. The Bylaws also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision.

This choice of forum provision in the Bylaws may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees or agents. In addition, stockholders who do bring a claim in the Court of Chancery in the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. Furthermore, the enforceability of similar choice of forum provisions in other companies’ governing documents has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Board of Directors Vacancies. Any vacancy or newly created directorship in our Board, however occurring, shall be filled only by the vote of a majority of the directors then in office, although less than a quorum, and shall not be filled by the stockholders, unless our Board determines by resolution that any such vacancy or newly created directorship shall be filled by the stockholders. In addition, the number of directors constituting our Board shall be determined from time to time by a resolution adopted by our Board. These provisions may prevent a stockholder from increasing the size of our Board and then gaining control of our Board by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our Board and promotes continuity of management.

Classified Board. Our Board is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by the stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Stockholder Meetings. The Bylaws provide that a special meeting of stockholders may be called only by the chairperson of our Board, chief executive officer or president (in the absence of a chief executive officer) or a majority of the authorized number of directors, thus prohibiting a stockholder (in the capacity as a stockholder) from calling a special meeting. These provisions might delay the ability of the stockholders to force consideration of a proposal or for stockholders controlling a majority of the capital stock to take any action, including the removal of directors.

Elimination of Stockholder Action by Written Consent. The Certificate of Incorporation and the Bylaws eliminate the right of stockholders to act by written consent without a meeting unless the action to be effected by written consent and the taking of such action by written consent is approved in advance by resolution of our Board. As a result, a holder controlling a majority of the capital stock would not be able to amend the Bylaws or remove directors without holding a meeting of the stockholders called in accordance with the Bylaws.

Advance Notice Requirements for Stockholder Proposals and Director Nominations. The Bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors. The Bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude the stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

No Cumulative Voting. The Certificate of Incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of Preferred Stock may be entitled to elect.

Directors Removed Only for Cause. The Certificate of Incorporation and the Bylaws provide that no member of our Board may be removed from office by the stockholders except for cause.

Issuance of Undesignated Preferred Stock. The ability of our Board, without action by the stockholders, to issue up to 25,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our Board could impede the success of any attempt to change control of our company. This may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Amendment of Charter Provisions. Organovo has reserved the right to amend, alter, change or repeal any provision in the Certificate of Incorporation, subject to any approval of our stockholders as may be required under the DGCL, and our Board is authorized to adopt, amend or repeal the Bylaws. The provisions of the DGCL, the Certificate of Incorporation and the Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our Board. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock is Continental Stock Transfer & Trust Company, One State Street, 30th Floor, New York, NY 10004.

Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol "ONVO". There is no established public trading market for the pre-funded warrants or common warrants to be sold in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the common warrants or pre-funded warrants on any national securities exchange.

MANAGEMENT

Board of Directors

Our Board of Directors is comprised of six directors. Our Board is divided into three classes, with one class standing for election each year for a three-year term. There are currently two Class I directors, two Class II directors, and two Class III directors.

In addition to the information set forth below regarding our directors and the skills that led our Board to conclude that these individuals should serve as directors, we also believe that all of our directors have a reputation for integrity, honesty and adherence to the highest ethical standards. We believe they each have demonstrated business acumen and an ability to exercise sound judgment, as well as a commitment of service to our Company and to their Board duties.

Information About Our Directors

The following sets forth information regarding the business experience of our current directors:

Name	Age ⁽¹⁾	Position(s)	Director Class
Keith Murphy	52	Director and Executive Chairman	Class III
Adam Stern	60	Director	Class III
Douglas Jay Cohen	53	Lead Independent Director	Class II
David Gobel	71	Director	Class II
Alison Tjosvold Milhous	45	Director	Class I
Vaidehi Joshi	38	Director and Director of Discovery Biology	Class I

(1) As of April 29, 2024.

Class I Directors Continuing in Office until the 2024 Annual Meeting of Stockholders

Alison Tjosvold Milhous, Director, has served on our Board since September 2020. She has 20 years of audit and technical accounting experience and is a certified public accountant. She is currently the Vice President of Accounting at Erasca, Inc., a clinical-stage precision oncology company. Prior to joining Erasca, she was an independent consultant assisting public and private companies with accounting and reporting needs primarily within the life sciences and technology industries. Ms. Milhous was previously an audit partner at Grant Thornton LLP from August 2015 through September 2019 and held various positions with increasing responsibility at Grant Thornton from June 2002 as an audit associate through July 2015 as an audit senior manager. She began her career in June 2000 at Arthur Andersen LLP. Ms. Milhous served on the membership committee of Athena San Diego, a professional women's leadership organization with a STEM focus, from August 2012 through September 2019 and was on the Pinnacle steering committee from September 2013 through April 2015. Ms. Milhous received a Bachelor of Science degree in Business Administration with a dual concentration in Accounting and Finance from California State Polytechnic University, San Luis Obispo.

We believe Ms. Milhous' extensive financial and accounting experience and her experience providing audit and consulting services to life sciences companies qualify her to serve as a member of our Board.

Vaidehi Joshi, Director, has served on our Board since March 2022 and as our Director of Discovery Biology since April 2022. Ms. Joshi has over a decade of experience in early-stage biotech companies developing unique therapeutic solutions, cutting-edge research products, and cell-based therapies. Since November 2020, Ms. Joshi has served as Director of Discovery Biology at Viscient Biosciences, Inc., where she leads the MASH small molecule drug discovery program as well as 3D model development for other tissue programs. Prior to joining Viscient, Ms. Joshi worked her way up at Organovo, Inc., where she led the pre-clinical research program for the design, development, and manufacture of 3D bioprinted therapeutic human liver tissues targeted towards the treatment of inborn errors of metabolism and genetic diseases. She received her Bachelor of Engineering in Biotechnology at the Rashtriya Vidyalyaya College of Engineering (RVCE) in Bangalore, India and received a Master of Science in Biomedical Engineering from University of California, Los Angeles (UCLA), with a specialization in Tissue Engineering and Biomaterials. While at UCLA, her

focus was on primary intestinal epithelial stem cell isolations and 3D cultures for intestinal tissue regeneration for short gut syndrome. Ms. Joshi is an experienced speaker, panelist, and presenter at several biomedical conferences both in the U.S and internationally. Ms. Joshi has co-authored several published peer reviewed articles, and is an inventor on multiple Organovo patents and patent applications. We believe Ms. Joshi's extensive scientific background, previous experience in the biotechnology field, and her educational experience qualify her to serve as a member of our Board.

We believe Ms. Joshi's extensive scientific background, previous experience in the biotechnology field, and her educational experience qualify her to serve as a member of our Board.

Class II Directors Continuing in Office Until the 2025 Annual Meeting of Stockholders

Douglas Jay Cohen, Lead Independent Director, has served on our Board since September 2020 and has served as our Lead Independent Director since September 2022. He has served as president and Chief Executive Officer of IR Medtek LLC since January 2019, a medical device company developing a non-invasive probe for cancer detection by primary care physicians using a technology licensed from the Ohio State University. Prior to IR Medtek, Mr. Cohen served as President and Chief Executive Officer of Beacon Street Innovations, an advanced technology printing company from September 2016 to present. From January 1994 to September 2016, Mr. Cohen served as Vice President of Operations and Engineering at Screen Machine Industries, an industrial and construction heavy equipment manufacturer. As an active investor in startup companies, Mr. Cohen has invested in more than 20 biotech startups in the past 10 years, including investing in Organovo in 2013 and maintaining a position in the company ever since. Mr. Cohen received a B.S. from the Massachusetts Institute of Technology.

We believe Mr. Cohen's experience in the life sciences industry, his experience in managing emerging growth companies and his experience in developing business strategies qualifies him to serve as a member of our Board.

David Gobel, Director, has served on our Board since September 2020. He has served as Chief Executive Officer of Methuselah Fund LLC since December 2016 and as Chief Executive Officer of Methuselah Foundation since September 2001, promoting increasing the healthy human lifespan by various means including: performance prizes, targeted grant making, education, and the creation/funding of biotech startups. Mr. Gobel became Chief Venture Strategist at Transportation Security Administration from January 2009 until March 2013, where he was responsible for strategic planning, innovation management and creation of a novel Venture Capital capability for TSA and then Department of Homeland Security by partnering with In-Q-Tel. Mr. Gobel was a member of the board of Volumetric Biotechnologies, a company that focuses on the development of bioholographic human tissue printing, from April 2018 to January 2020. Since July 2018, Mr. Gobel served as member of the board for Turn Bio, and since May 2020 as chairman of the board of Turn Bio. Mr. Gobel served as a board member of Leucadia Therapeutics from October 2015 to August 2022, and as an independent founding board member of Oisin Therapeutics since December 2014.

We believe Mr. Gobel's previous services as chief executive officer for other biotechnology companies, his experience and expertise with human tissue printing companies and his extensive board experience qualify him to serve as a member of our Board.

Class III Directors Continuing in Office Until the 2026 Annual Meeting of Stockholders

Keith Murphy, Director and Executive Chairman, re-joined our Board in July 2020 and has served as our Executive Chairman since September 2020. Mr. Murphy is the Chief Executive Officer and Chairman of Viscient Biosciences, Inc. ("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). Mr. Murphy previously served as the President and Chief Executive Officer of Organovo from February 2012 through April 2017, and as Chairman from February 2012 through August 2017. Mr. Murphy also previously served as President, Chief Executive Officer, and Chairman of Organovo, Inc., Organovo's primary operating company prior to its going-public transaction, from August 2007 to February 2012. Prior to founding Organovo, Mr. Murphy served in various roles at Amgen, Inc. from August 1997 to July 2007 including as Global Operations Leader for the osteoporosis/bone cancer drug Prolia/Xgeva (denosumab). Prior to joining Amgen, Mr. Murphy served at Alkermes, Inc., a biotechnology company, from July 1993 to July 1997, where he played a role on the development team for their first approved product, Nutropin (hGH) Depot. Mr. Murphy served as a member of the board of directors of Kintara Therapeutics, Inc. from August 2020 to February 2022, and served on its compensation committee and nominating and corporate governance committee. He holds a B.S. in Chemical Engineering from MIT and is an alumnus of the UCLA Anderson School of Management.

We believe Mr. Murphy's previous experience in the biotechnology field, especially in developing novel products, his experience and expertise with our 3D bioprinting technology and product development opportunities and strategy, and his educational experience qualify him to be a member of our Board of Directors.

Adam Stern, Director, re-joined our Board in July 2020. Mr. Stern is currently the Chief Executive Officer of SternAegis Ventures, the private equity group at Aegis Capital Corp. responsible for venture capital and private equity financing, and has been the Head of Private Equity Banking at Aegis Capital Corp., a full-service investment banking firm, since December 2012. Prior to SternAegis, Mr. Stern served as Senior Managing Director at Spencer Trask Ventures, Inc., a private equity and venture firm, from 1997 to 2012, where he managed the structured finance group focusing primarily on technology and life sciences companies. From 1989 to 1997, Mr. Stern was at Josephthal & Co., Inc., Members of the New York Stock Exchange, where he served as Head of Private Equity and Managing Director. He has been a FINRA licensed securities broker since 1987 and a Registered General Securities Principal since 1991. Mr. Stern previously served as a director of Organovo from February 2012 to June 2013. Mr. Stern is a current director at DarioHealth Corp. (Nasdaq: DRIO), privately held Amplifica Holdings, Group, Inc., and Aerami Therapeutics Holdings Inc. Mr. Stern is a former director of Adgero Biopharmaceuticals Holdings, Matinas BioPharma Holdings, Inc. (NYSE: MTNB), Hydrofarm Holdings Group Inc. (Nasdaq: HYFM), InVivo Therapeutics, Inc. (Nasdaq: NVIV) and PROLOR Biotech prior to its sale in 2013 to Opko Health, Inc. (Nasdaq: OPK). Mr. Stern graduated with a Bachelor of Arts degree from the University of South Florida in 1987.

We believe Mr. Stern’s extensive experience in corporate finance, his expertise in the life sciences industries and his previous experience as a member of our Board qualify him to be a member of our Board of Directors.

No Family Relationships

There are no family relationships between any of our officers and directors.

Board Independence

Our shares of common stock are listed for trading on the Nasdaq Capital Market. As a result, our Board utilizes the definition of “independence” as that term is defined by the listing standards of the Nasdaq Capital Market and the rules and regulations of the SEC, including the additional independence requirements for members of our Audit Committee and the Compensation Committee. Our Board considers a director “independent” when the director is not an officer or employee of the Company or its subsidiaries, does not have any relationship which would, or could reasonably appear to, materially interfere with the independent judgment of such director, and the director otherwise meets the independence requirements under the listing standards of the Nasdaq Capital Market and the rules and regulations of the SEC. Our Board has reviewed the materiality of any relationship that each of our directors has with the Company, either directly or indirectly. Based on this review, our Board has affirmatively determined that the following four of our six current directors qualify as “independent” directors: Douglas Jay Cohen, David Gobel, Alison Tjosvold Milhous and Adam Stern. Keith Murphy and Vaidehi Joshi do not qualify as an independent director. Mr. Murphy currently serves as our Executive Chairman and as Chief Executive Officer of Viscient, which has made payments to the Company in sufficient amounts to qualify as related party transactions leading to director non-independence. Please see the section “Certain Relationships and Related Transactions” for an additional information. Ms. Joshi is currently our Director of Discovery Biology.

Executive Officers

The following persons are our executive officers as of the date of this prospectus and hold the positions set forth opposite their names as of April 29, 2024:

Name	Age	Position
Keith Murphy	52	Executive Chairman
Thomas Hess	60	President and Chief Financial Officer

See the section entitled “Board of Directors Information”, above, for a description of the business experience and educational background of Mr. Murphy.

Thomas Hess, President and Chief Financial Officer, joined us in October 2021. Mr. Hess is currently employed by Danforth Advisors, LLC (“Danforth”), a professional financial consulting services firm. He has over twenty years of experience and has been with Danforth since September 2021. Mr. Hess recently served as Chief Financial Officer and Senior Vice President of Finance of Genomind, Inc., until his retirement in May 2021. From September 2011 until its sale in April 2014, Mr. Hess served as Chief Financial Officer and Executive Vice President of Finance of The Keane Organization. Mr. Hess also previously served in various other capacities including, but not limited to, Chief Financial Officer and Senior Vice President of Yaupon Therapeutics, Inc.; Chief Financial Officer and Vice President, Finance of Adolor Corporation; Corporate Controller of Vicuron Pharmaceuticals, Inc.; and Senior Manager, Accounting and Audit of KPMG. Mr. Hess received his B.S. in accounting from The Pennsylvania State University and his MBA from Katz Graduate School of Business, University of Pittsburgh and is a Certified Public Accountant in the State of Pennsylvania. He currently serves on the Alumni Council of Penn State.

Director Compensation

Our directors play a critical role in guiding our strategic direction and overseeing the management of our Company. Ongoing developments in corporate governance and financial reporting have resulted in an increased demand for such highly qualified and productive public company directors. The many responsibilities and risks and the substantial time commitment of being a director of a public company require that we provide adequate incentives for our directors' continued performance by paying compensation commensurate with our directors' workload. Our directors are compensated based upon their respective levels of Board participation and responsibilities, including service on Board committees.

Our director compensation is overseen by the Compensation Committee, which makes recommendations to our Board on the appropriate structure for our director compensation program and the appropriate amount of compensation. Our Board is responsible for final approval of our director compensation program and the compensation paid to our directors.

In connection with establishing our director compensation for the fiscal year ended March 31, 2024 ("Fiscal 2024"), the Compensation Committee retained Anderson Pay Advisors ("Anderson") as its independent compensation consultant. With the assistance of Anderson, the Board and Compensation Committee conducted a formal review of our director compensation and incentive programs relative to the same peer group used in benchmarking the compensation for our executive officers.

Fiscal 2024 Director Compensation Framework

For Fiscal 2024, our Director Compensation Framework provided to both non-employee and employee directors annual cash retainers for Board service and for service as the chair or member of one of the standing Board committees. Our directors are not entitled to any Board meeting fees or Board committee meeting fees.

Annual Cash Retainers. For Fiscal 2024, each of our directors was eligible to receive an annual cash retainer of \$66,300 for Board membership.

In addition, each of our directors are eligible to receive the applicable annual retainers set forth below for serving as committee chairs and for service as a member of a Board committee, with total cash compensation for each director not to exceed \$105,000 per fiscal year:

Position	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee	Science and Technology Committee
Committee Chair	\$ 25,500	\$ 25,500	\$ 25,500	\$ 25,500
Committee Member (excluding Chair)	\$ 15,300	\$ 15,300	\$ 15,300	\$ 15,300

No additional meeting fees were paid to our directors for Fiscal 2024.

Equity Awards. In addition, in November 2023, each director received a restricted stock unit award with respect to 19,607 shares of common stock (a value of approximately \$27,200), which will vest in full on the earlier of (i) November 17, 2024 or (ii) the date of our next annual meeting of the stockholders, subject to acceleration in the event of a change of control.

Reimbursement. Our directors are entitled to reimbursement for their reasonable travel and lodging expenses for attending Board and Board committee meetings.

Director Compensation Table

The following table sets forth the compensation earned and paid to each member of our Board for service as a director during Fiscal 2024:

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)(1)	Option Awards (\$)	All Other Compensation (\$)	Total (\$)
Douglas Jay Cohen	\$ 105,000	\$ 27,254	\$ —	\$ —	\$ 132,254
David Gobel	105,000	27,254	—	—	132,254
Alison Tjosvold Milhous	105,000	27,254	—	—	132,254
Adam Stern	96,900	27,254	—	—	121,154
Keith Murphy	81,600	27,254	—	—	108,854 ⁽²⁾
Vaidehi Joshi	91,800	27,254	—	—	119,054

- (1) These amounts represent the grant date fair value of time-based restricted stock unit awards granted by the Board, determined in accordance with FASB ASC Topic 718. All awards are amortized over the vesting life of the award. For the assumptions used in our valuations, see “Note 5 – Stockholders’ Equity” of our notes to consolidated financial statements included elsewhere in this prospectus.
- (2) Comprised solely of the compensation received by Mr. Murphy for his service as a member of the Board. Mr. Murphy’s additional compensation for Fiscal 2024 is included in the section entitled “Summary Compensation Table” on page 68 of this prospectus.

Executive Compensation

The following discussion is designed to provide our stockholders with an understanding of our compensation philosophy and objectives as well as an overview of the analysis that our Compensation Committee performed in setting the compensation of our executive officers for Fiscal 2024 (i.e., the period from April 1, 2023 to March 31, 2024).

This discussion summarizes the Compensation Committee’s determination of how and why, in addition to what, compensation actions were taken for our named executive officers, as follows:

- Keith Murphy, our Executive Chairman and Principal Executive Officer;
- Thomas Hess, our Chief Financial Officer;
- Thomas Jurgensen, our former General Counsel and Corporate Secretary⁽¹⁾; and
- Jeffrey Miner, our former Chief Scientific Officer⁽²⁾.

- (1) Mr. Jurgensen’s employment with the Company was terminated as of August 25, 2023 in connection with Company’s reduction in force announced on August 18, 2023.
- (2) Dr. Miner’s employment with the Company was terminated as of August 25, 2023 in connection with Company’s reduction in force announced on August 18, 2023.

Other than Mr. Murphy, Mr. Hess was the only executive officer serving at the end of Fiscal 2024. These four individuals are collectively referred to in this prospectus as our “named executive officers”.

Recent “Say-on-Pay” Votes

Our recent stockholder advisory votes, commonly referred to as a “Say-on-Pay” vote, to approve the compensation of our named executive officers for Fiscal 2023 (i.e., the period from April 1, 2022 to March 31, 2023) was approved by our stockholders, with approximately 85% of stockholder votes cast in favor of the proposal.

During Fiscal 2024, our Executive Chairman, former General Counsel, and Chief Financial Officer maintained significant stockholder engagement efforts to monitor how our investors vote, obtain their views on key corporate governance and disclosure matters and determine how best to respond to feedback each year going forward. Specifically, we reached out to our stockholders representing over 95% of our institutional stock holdings multiple times. None of the stockholders indicated a need or desire to engage with the Company to discuss or express any concerns.

Going forward, we plan to continue to:

- at least annually, reach out to institutional stockholders representing a majority of the shares held by our institutional stockholders; and

- invite them to engage and participate in calls to discuss our executive compensation programs, their feedback and questions and how we may best address them.

One or more members of executive management are expected to be active participants on all such calls, as will one or more members of our Compensation Committee. All such feedback will be shared with our Board.

In evaluating potential changes to our executive compensation programs' structure and disclosure, the Compensation Committee will closely examine, and aim to understand further, our stockholders' feedback, including any common themes from our stockholders' feedback. The Compensation Committee will also seek the advice of independent compensation consultants with respect to the design of our executive compensation program.

Compensation Philosophy and Objectives

Our executive compensation program focuses on creating alignment between our stockholders and executive officers by including both performance- and incentive-based compensation elements. Our compensation package also combines both short- and long-term components (cash and equity, respectively) at the levels the Compensation Committee determined to be appropriate to motivate, reward, and retain our executive officers. Our executive compensation program is designed to achieve the following key objectives:

- Attract, retain, and reward talented executives and motivate them to contribute to the Company's success and to build long-term stockholder value;
- Establish financial incentives for executives to achieve our key financial, operational, and strategic goals;
- Enhance the relationship between executive pay and stockholder value by utilizing long-term equity incentives; and
- Recognize and reward executives for superior performance.

Use of Market Data and Benchmarking

The Compensation Committee endeavors to set compensation at competitive levels. In order to do this, the Compensation Committee compares our compensation packages with the packages offered by other peer companies that are similarly situated, and with which we compete for talent. Selection criteria includes:

- Industry, specifically biotechnology and medical research,
- Company focus, with an emphasis on technology platforms,
- Stage of leading drug candidate, with an emphasis on Phase II/III,
- Market capitalization, targeting less than \$100 million,
- Number of employees, targeting less than 50 employees, and
- Location, specifically nationwide.

For Fiscal 2024, the Compensation Committee engaged Anderson, an independent compensation consultant, as the Compensation Committee's advisor reporting directly to the chair of the Compensation Committee. The Compensation Committee determined that no conflict of interest exists that would preclude Anderson from serving as an independent consultant to the Compensation Committee.

The Compensation Committee requested Anderson conduct a review and analysis of our executive compensation programs as compared against competitive benchmarks. This included a benchmarking analysis against prevailing market practices of a peer group of comparable companies approved by the Compensation Committee and broader industry trends and benchmarks. The analysis included a review of the "Total Direct Compensation" (which includes salary, cash incentives, and equity awards) of our executive officers, and was based on an assessment of market trends covering available public information as well as proprietary information provided by Anderson.

For Fiscal 2024, based on recommendations from Anderson, our Compensation Committee determined that our peer group should be modified to better reflect our current market valuation as well as the growing importance of our therapeutics program to our overall business model. With input from Anderson, our Compensation Committee added a group of companies focused on technology platforms, with comparable size, revenues, market valuations, and stage of leading drug candidate. Our Compensation Committee also replaced some of the companies previously included in our peer group because their market valuations had grown too high for direct comparison to our Company, and/or their business focus had become less relevant for direct comparison to our Company. Our

Compensation Committee then used the compensation data from this revised peer group in setting executive compensation for Fiscal 2024.

The peer group for Fiscal 2024 included:

Aceragen*	Cohbar Inc.*	Onconova Therapeutics, Inc.
Aligos Therapeutics, Inc.*	Fresh Tracks Therapeutics Inc.*	OncoSec Medical Incorporated
Aprea Therapeutics, Inc.	Galectin Therapeutics Inc.*	Pulmatrix, Inc.
aTyr Pharma, Inc.	Galmed Pharmaceuticals Ltd.*	Regulus Therapeutics Inc.
Ayala Pharmaceuticals*	Hepion Pharmaceuticals, Inc.*	Seelos Therapeutics, Inc.
Bellicum Pharmaceuticals, Inc.	Imunon, Inc.*	Soligenix, Inc.
Capricor Therapeutics, Inc.	LadRx Corp*	Theriva Biologics, Inc.*

* Indicates addition to peer group from Fiscal 2023.

Determination of Executive Compensation

In addition to peer group data, the Compensation Committee considered relevant publicly available market data and surveys and the compensation reports it received from Anderson. The Compensation Committee also reviewed and considered the compensation recommendations of our Executive Chairman, the Company's overall performance during Fiscal 2024, the Company's financial status and operating runway, each executive officer's responsibilities and contribution to the Company's achievement of the Fiscal 2024 corporate goals, and each executive officer's individual performance during Fiscal 2024. With respect to new hires, our Compensation Committee considered the executive officer's background and historical compensation in lieu of prior year performance in addition to benchmark data for the newly hired executive's position.

Commitment to Good Compensation Governance Practices

In designing our executive compensation program, our Compensation Committee intends to create alignment between our stockholders and executive officers and to implement good compensation governance by:

- ***Annual Advisory Vote on the Compensation of our Named Executive Officers*** – We provide our stockholders with the ability to vote annually on the compensation of our named executive officers.
- ***Independent Compensation Consultant*** – The Compensation Committee engaged Anderson during Fiscal 2023 to serve as its independent compensation consultant. Anderson did not provide any other services to the Company during the periods it served as a consultant to the Compensation Committee.
- ***Performance and Incentive Based*** – Previously, approximately 40% of the Total Direct Compensation our executive officers could earn was performance and incentive based, thereby aligning the interests of our executive officers with our stockholders' interests. As our current executive officers are retained through consulting firms, neither are eligible for performance based compensation.
- ***Compensation Risk Assessment*** – The Compensation Committee oversees and evaluates an annual risk assessment of the Company's compensation program. The Compensation Committee believes that the performance goals established for incentives do not encourage excessive risk-taking or have the potential to encourage behavior that may have a material adverse effect on the Company.
- ***Prohibitions on Hedging, Pledging and Margin Activities*** – Our insider trading policy prohibits hedging transactions by Company employees. Under the policy, all short-term, speculative or hedging transactions in Organovo securities are prohibited by all employees. In addition, the policy specifically prohibits the use of Organovo securities for pledging and margin activities.
- ***No Single Trigger Change in Control Vesting*** – We do not provide for the acceleration of vesting solely upon the occurrence of a change in control in our equity awards for our directors and executive officers.
- ***No Excise Tax Gross Ups*** – We do not include excise tax gross ups for any change in control payments.
- ***Director and Executive Officer Stock Ownership Guidelines*** – We have adopted stock ownership guidelines that require each director and executive officer to accumulate and hold a specified value of our stock within five years of most recently starting employment with us or becoming a director.

The Compensation Committee believes that the program and policies described above demonstrate the Company’s commitment to, and consistent execution of, an effective performance-oriented executive compensation program.

Components of Executive Compensation

The framework established by the Compensation Committee, based on the data provided by Anderson, for our executive compensation program consists of a base salary, performance-based cash incentives and long-term equity-based incentives. The Compensation Committee endeavors to combine these compensation elements to develop a compensation package that provides competitive pay, rewards our executive officers for achieving our commercial, operational and strategic objectives and aligns the interests of our executive officers with those of our stockholders.

Salary. The Compensation Committee has provided, and will continue to provide, our executive officers with a base salary to compensate them for services provided during the fiscal year. In addition to benchmark data from our peer group, our Compensation Committee considers the Company’s overall performance during the prior fiscal year, cash burn, the Company’s financial status and operating profile, each executive officer’s responsibilities and contribution to the achievement of the prior year’s corporate goals, and each executive officer’s individual performance during the prior fiscal year. The evaluations and recommendations proposed by our Executive Chairman are also considered (other than with respect to determining his own compensation). With respect to new hires, the Compensation Committee considers an executive’s background and historical compensation in lieu of prior year performance as well as benchmark data for the new hire’s position. Our Compensation Committee evaluates and sets the base salaries for our executives following annual performance evaluations, as well as upon a promotion or other change in responsibility. Our Compensation Committee expects to continue to utilize these policies going forward.

For Fiscal 2024, the Compensation Committee determined that it was in the best interests of the Company and its stockholders to freeze Mr. Jurgensen’s and Dr. Miner’s salaries for Fiscal 2024 at Fiscal 2023 levels, or \$381,600 for Mr. Jurgensen and \$238,500 for Dr. Miner.

Pursuant to the terms of our consulting agreement with Multi Dimensional Bio Insight LLC (“MDBI”), a biotechnology consulting firm through which we retain Mr. Murphy, MDBI has the right, on an annual basis, to increase hourly consultant rates by up to 4%. From January 1, 2021 to May 1, 2022, the hourly rate for Mr. Murphy’s services was \$375, which was increased to \$413 effective May 1, 2022 and remained the same throughout the remainder of Fiscal 2023 and Fiscal 2024. The cash amount paid to MDBI increased from \$543,781 for Fiscal 2023 to \$657,984 for Fiscal 2024, with approximately a 21% increase in Mr. Murphy’s hours for Fiscal 2024 as compared to Fiscal 2023.

Pursuant to the terms of our consulting agreement with Danforth Advisors, LLC (“Danforth”), a financial consulting firm through which we retain Mr. Hess, Danforth has the right, on an annual basis, to increase hourly consultant rates by up to 4%. From April 1, 2022 to March 31, 2023, the hourly rate for Mr. Hess’ services was \$433, which was increased to \$450 effective January 1, 2024 and remained the same throughout the remainder of Fiscal 2024. The cash amount paid to Danforth decreased from \$269,402 for Fiscal 2023 to \$199,322 for Fiscal 2024, with approximately a 29% decrease in Mr. Hess’ hours for Fiscal 2024 as compared to Fiscal 2023.

The base salaries of our named executive officers for Fiscal 2024 as compared to Fiscal 2023 are set forth in the following table:

Name and Title	Fiscal 2024 Base Salary	Fiscal 2023 Base Salary
Keith Murphy, <i>Executive Chairman</i> ⁽¹⁾	\$ 657,984	\$ 543,781
Thomas Hess, <i>Chief Financial Officer</i> ⁽²⁾	199,322	269,402
Thomas Jurgensen, <i>Former General Counsel and Corporate Secretary</i> ⁽³⁾	381,262	381,262
Jeffrey Miner, <i>Former Chief Scientific Officer</i> ⁽⁴⁾	238,292	238,292

- (1) Mr. Murphy was appointed our Executive Chairman on September 15, 2020. The Company retains Mr. Murphy through MDBI, a biotechnology consulting firm, pursuant to the terms of a consulting agreement, pursuant to which Company has agreed to pay MDBI \$375-390 per hour of services provided by Mr. Murphy, with an annual increase in rates by up to 4%. The amounts reported under “Fiscal 2024 Base Salary” and “Fiscal 2023 Base Salary” are comprised of the actual amounts paid to MDBI for its consulting services. Mr. Murphy did not directly receive a base salary from the Company in Fiscal 2024 or Fiscal 2023. Mr. Murphy’s increase in base salary was primarily due to additional time commitment of Mr. Murphy in his consulting role as Executive Chairman of the Company.
- (2) Mr. Hess was appointed our Chief Financial Officer on October 6, 2022. The Company retains Mr. Hess through Danforth, a financial consulting firm, pursuant to the terms of a consulting agreement, pursuant to which Company has agreed to pay Danforth \$400 per hour of services provided by Mr. Hess, with an annual increase in rates by up to 4%. The amounts reported under “Fiscal 2024 Base Salary” and “Fiscal 2023 Base Salary” are comprised of the actual amounts paid to Danforth for its consulting services. Mr. Hess did not directly receive a base salary from the Company in Fiscal 2024 or Fiscal 2023. Mr. Hess’s decrease in base salary was primarily due to reduced time commitment of Mr. Hess in his consulting role as Chief Financial Officer of the Company.
- (3) Mr. Jurgensen’s employment with the Company was terminated as of August 25, 2023 in connection with Company’s reduction in force announced on August 18, 2023.

(4) Dr. Miner's employment with the Company was terminated as of August 25, 2023 in connection with Company's reduction in force announced on August 18, 2023

Performance-Based Cash Incentive Awards. Our executive compensation program includes an annual performance-based cash incentive award, which provides our executive officers with an annual cash incentive opportunity as a percentage of their base salaries based upon the achievement of corporate and individual performance goals evaluated and approved by the Compensation Committee. For Fiscal 2024, the Compensation Committee determined that the annual target bonus opportunity expressed as a percentage of base salary for each of Mr. Jurgensen and Dr. Miner should be 40% of each of their respective base salaries. The Company continues to use an objectives and key results goal-setting framework ("OKRs") used by individuals, teams, and the Company to define measurable goals and track their outcomes, originally developed and implemented by Andrew Grove at Intel. See: <http://www.whatmatters.com>. Each executive officer was eligible to receive an increase in his target bonus amount based on the achievement of individual and corporate OKRs. For Fiscal 2024, the Compensation Committee did not award bonuses to Mr. Jurgensen or Dr. Miner.

Mr. Murphy is retained through MDBI, a biotechnology consulting firm, pursuant to the terms of a consulting agreement. As such, Mr. Murphy is not eligible to receive a bonus for services provided during the fiscal year.

Mr. Hess is retained through Danforth, a financial consulting firm, pursuant to the terms of a consulting agreement. As such, Mr. Hess is not eligible to receive a bonus for services provided during the fiscal year.

Equity-Based Incentive Awards. In addition to base salaries and annual performance-based cash incentives, the Compensation Committee has provided long-term, equity-based incentive awards to our executive officers. In determining the size and terms of the awards, the Compensation Committee considered benchmark data from our peer group, publicly available market and survey data and the individual performance of the named executive officers. The Compensation Committee did not grant any awards for Fiscal 2024.

Other Benefits

In order to attract and retain qualified individuals and pay market levels of compensation, we have historically provided, and will continue to provide, our executives with the following benefits:

- **Health Insurance** – We provide each of our executives and their spouses and children the same health, dental, and vision insurance coverage we make available to our other eligible employees.
- **Life and Disability Insurance** – We provide each of our executives with the same life and disability insurance as we make available to our other eligible employees.
- **Pension Benefits** – We do not provide pension arrangements or post-retirement health coverage for our executives or employees. We implemented a 401(k) Plan effective January 1, 2014. We provide a company matching contribution up to 3.5% of compensation for all participants in the 401(k) plan, including our executive officers, to help attract and retain top talent.
- **Nonqualified Deferred Compensation** – We do not provide any nonqualified defined contribution or other deferred compensation plans to any of our employees.
- **Perquisites** – We limit the perquisites that we make available to our executive officers. In certain cases, we have reimbursed our executive officers for their relocation expenses on their initial hire.

Severance Arrangements

As of November 10, 2020, the Company implemented a change in control arrangement, which provides that, in the event an executive is terminated in connection with a Change in Control: the executive will receive (a) in the case of our Executive Chairman, 18 months of base salary or consulting fees, as applicable, and (b) in the case of our other executives, 12 months of base salary.

On September 7, 2023, in connection with Mr. Jurgensen's termination, the Company entered into a Separation Agreement and General Release (the "Jurgensen Separation Agreement") with Mr. Jurgensen, to be effective as of September 15, 2023. Pursuant to the Jurgensen Separation Agreement, Mr. Jurgensen released any claims against the Company and the Company paid Mr. Jurgensen an aggregate of \$345,000 (less applicable federal, state, and local withholdings), in three separate installment payments of \$115,000 on or before September 28, 2023, October 16, 2023 and January 5, 2024.

On September 19, 2023, in connection with Dr. Miner's termination, the Company entered into a Separation Agreement and General Release (the "Miner Separation Agreement") with Dr. Miner, to be effective as of September 27, 2023. Pursuant to the Miner

Separation Agreement, Dr. Miner released any claims against the Company and the Company (i) provided Dr. Miner a consulting contract for a period of six months, pursuant to which the Company paid Dr. Miner an aggregate of \$169,250 for his consulting services, and (ii) granted Dr. Miner a stock option to purchase 40,000 shares of common stock of the Company (the “Option”). The Option will vest as follows: 13,000 shares vested immediately upon issuance, 13,500 shares will vest on the one year anniversary of the Miner Separation Agreement and 13,500 shares will vest on the two year anniversary of the Miner Separation Agreement. The exercise price is equal to the closing price of a share of common stock on the date the Option was approved by the Company’s Board of Directors.

Potential Payments upon Termination or Change in Control

The following table sets forth the amounts payable to each of our named executive officers based on an assumed termination as of March 31, 2024 based upon certain designated events.

Name	Cash Severance (\$)	Health and Other Insurance Benefits (\$)	Stock Options (Unvested and Accelerated) (\$)	Restricted Stock Units (Unvested and Accelerated) (\$)	Fiscal Year 2024 Total (\$)
Keith Murphy					
Termination in connection with a Change in Control	\$ 1,288,560	\$ —	\$ —	\$ —	1,288,560
Thomas Hess					
Termination in connection with a Change in Control	\$ 936,000	\$ —	\$ —	\$ —	936,000
Thomas Jurgensen					
Termination in connection with a Change in Control ⁽¹⁾	\$ 345,000	\$ —	\$ —	\$ —	345,000
Jeffrey Miner					
Termination in connection with a Change in Control ⁽²⁾	\$ 169,250	\$ —	\$ —	\$ —	169,250

(1) Mr. Jurgensen’s employment was terminated as of August 25, 2023. Pursuant to the Jurgensen Separation Agreement, the Company paid Mr. Jurgensen an aggregate of \$345,000.

(2) Dr. Miner’s employment was terminated as of August 25, 2023. Pursuant to the Miner Separation Agreement, for his consulting services, the Company paid Dr. Miner an aggregate of \$169,250, and granted Dr. Miner a stock option to purchase 40,000 shares of common stock of the Company (the “Option”). The Option vests as follows: 13,000 shares vested immediately upon issuance, 13,500 shares will vest on the one year anniversary of the Miner Separation Agreement and 13,500 shares will vest on the two year anniversary of the Miner Separation Agreement.

Death or Disability Benefits

The outstanding equity awards held by our executive officers provide such executive officers with accelerated vesting if the executive officer terminates services with the Company as a result of death or disability. In order for an equity award to be eligible for accelerated vesting, the executive officer’s death or disability must occur more than 90 days after the date the equity award was granted. With respect to performance-based equity awards, an executive officer will vest at target levels upon the executive officer’s death or disability.

Summary Compensation Table

The following table summarizes the total compensation paid to or earned by each named executive officer for Fiscal 2024 and Fiscal 2023.

Name and Principal Position	Year or Period	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$) ⁽¹⁾	Non-Equity Incentive Plan Compensation (\$) ⁽²⁾	All Other Compensation (\$)	Total (\$)
Keith Murphy ⁽³⁾ Executive Chairman	2024	657,984	—	—	—	—	23,152 ⁽⁴⁾	681,136
	2023	543,781	—	—	73,921	—	3,746 ⁽⁴⁾	621,448
Thomas Hess ⁽⁵⁾ Chief Financial Officer	2024	199,322	—	—	—	—	—	199,322
Thomas Jurgensen Former General Counsel and Corporate Secretary	2024	161,446	—	—	—	—	348,454 ⁽⁶⁾	509,900
	2023	381,263	—	—	73,921	—	10,790 ⁽⁷⁾	465,974
Jeffrey Miner Former Chief Scientific Officer	2024	100,904	—	—	46,337 ⁽⁸⁾	—	172,790 ⁽⁹⁾	320,031
	2023	238,292	—	—	73,921	—	3,540 ⁽⁷⁾	315,753

- (1) These amounts represent the grant date fair value of time-based stock option awards granted by the Company during the periods presented, determined in accordance with FASB ASC Topic 718. All awards are amortized over the vesting life of the award. For the assumptions used in our valuations, see “Note 5 – Stockholders’ Equity” of the Notes to Consolidated Financial Statements included elsewhere in this prospectus.
- (2) Includes amounts paid under the Company’s Performance-Based Cash Incentive Award program based on the achievement of corporate and individual performance goals established and measured by the Compensation Committee.
- (3) Mr. Murphy was appointed our Executive Chairman on September 15, 2020. The amounts reported under “Salary” are comprised of the amounts paid to MDBI for its consulting services. Mr. Murphy did not receive a base salary from the Company in Fiscal 2024 or Fiscal 2023. Mr. Murphy also received compensation for services as a member of the Board of Directors, which is included in the section entitled “Director Compensation Table” on page 62 of this prospectus.
- (4) This amount includes \$14,777 for expense reimbursements, \$1,775 for administrative services and \$6,600 for office rent in Fiscal 2024 and \$1,996 for expense reimbursements, \$1,200 for administrative services and \$550 for office rent in Fiscal 2023.
- (5) Mr. Hess was appointed our Chief Financial Officer on October 6, 2022. The amounts reported under “Salary” are comprised of the amounts paid to Danforth for its consulting services. Mr. Hess did not receive a base salary from the Company in Fiscal 2024. Mr. Hess’ compensation for Fiscal 2023 has been omitted from this table as Mr. Hess was not a named executive officer for Fiscal 2023.
- (6) Pursuant to the Separation Agreement and General Release entered into on September 7, 2023 with Mr. Jurgensen, the Company agreed to pay Mr. Jurgensen an aggregate of \$345,000. In addition, this amount includes \$3,454 in matching contributions to the 401(k) Plan for Fiscal 2024. The formula for determining the matching contributions is the same for named executive officers as it is for all salaried employees (and are subject to the same statutory maximum). Excludes payments made for the reimbursement of medical insurance premiums and life insurance available for all salaried employees. For more information regarding these benefits, see above under “Other Benefits.”
- (7) Consists of matching contributions to the 401(k) Plan. The formula for determining the matching contributions is the same for named executive officers as it is for all salaried employees (and are subject to the same statutory maximum). Excludes payments made for the reimbursement of medical insurance premiums and life insurance available for all salaried employees.
- (8) Pursuant to the Separation Agreement entered into on September 10, 2023 with Dr. Miner, the Company granted Dr. Miner a stock option to purchase 40,000 shares of common stock, which will vest as follows: 13,000 shares will be vested immediately upon issuance, 13,500 shares will vest on the one year anniversary of the Separation Agreement and 13,500 shares will vest on the two year anniversary of the Separation Agreement.
- (9) Pursuant to the Separation Agreement entered into on September 10, 2023 with Dr. Miner, the Company agreed to pay Dr. Miner an aggregate of \$169,250 for his consulting services. In addition, this amount includes \$3,540 in matching contributions to the 401(k) Plan for Fiscal 2024. The formula for determining the matching contributions is the same for named executive officers as it is for all salaried employees (and are subject to the same statutory maximum). Excludes payments made for the reimbursement of medical insurance premiums and life insurance available for all salaried employees. For more information regarding these benefits, see above under “Other Benefits.”

Outstanding Equity Awards at Fiscal Year End

The following table shows certain information regarding outstanding equity awards as of March 31, 2024 for our named executive officers:

Name	Option Awards				Stock Awards	
	No. of Securities Underlying Unexercised Options (#) Exercisable	No. of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	No. of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)
Keith Murphy	15,000 ⁽¹⁾	25,000	\$ 2.36	8/30/2032	5,000 ⁽²⁾	\$ 5,150
Jeffrey Miner	13,000 ⁽³⁾	27,000	7.64	11/13/2033		

- (1) The option shares vest in 16 equal quarterly installments beginning August 31, 2022.
- (2) 25% of the shares subject to the restricted stock unit vested on March 8, 2022 and the remaining shares vest in 12 equal quarterly installments thereafter.
- (3) Pursuant to the Separation Agreement entered into on September 10, 2023 with Dr. Miner, the Company granted Dr. Miner a stock option to purchase 40,000 shares of common stock, which will vest as follows: 13,000 shares will be vested immediately upon issuance beginning November 13, 2023, 13,500 shares will vest on the one year anniversary of the Separation Agreement and 13,500 shares will vest on the two year anniversary of the Separation Agreement.

As of March 31, 2024, neither Mr. Hess nor Mr. Jurgensen held any outstanding equity awards.

Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee has at any time been our employee. None of our executive officers serves, or has served during the last fiscal year, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving as a member of our Board or our Compensation Committee.

Equity Compensation Plan Information

The following tables set forth certain information regarding the beneficial ownership of our common stock as of March 31, 2024 by (i) each of our directors and named executive officers (as disclosed in this prospectus); and (ii) all of our current executive officers and directors as a group. To our knowledge, based solely on our review of Schedules 13D and 13G filed with the SEC, no person beneficially owned more than 5% of our common stock as of March 31, 2024. Unless otherwise indicated in the table or the footnotes to the following table, each person named in the table has sole voting and investment power and such person's address is c/o Organovo Holdings, Inc., 11555 Sorrento Valley Rd., Suite 100, San Diego, CA 92121.

We determined the number of shares of common stock beneficially owned by each person under rules promulgated by the SEC, based on information obtained from Company records and filings with the SEC on or before March 31, 2024. In cases of holders who are not directors or named executive officers, Schedules 13G or 13D filed with the SEC, as applicable (and, consequently, ownership reflected here), often reflect holdings as of a date prior to March 31, 2024. The information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power and also any shares which the individual or entity had the right to acquire within 60 days of March 31, 2024. These shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other person or entity.

Applicable percentages are based on 10,077,726 shares of common stock outstanding as of March 31, 2024, as adjusted as required by the rules promulgated by the SEC. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of March 31, 2024, or issuable pursuant to restricted stock units that are subject to vesting conditions expected to occur within 60 days of March 31, 2024, to be outstanding and to be beneficially owned by the person holding the stock option or restricted stock units for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person or entity.

Name of Beneficial Owner	Beneficial Ownership ⁽¹⁾	
	Number of Common Shares	Percent of Common Shares
Directors and Named Executive Officers		
Keith Murphy	115,927 (2)	1.1%
Douglas Jay Cohen	84,107 (3)	*
Alison Tjosvold Milhous	72,107 (4)	*
Adam Stern	72,107 (4)	*
David Gobel	52,500 (5)	*
Vaidehi Joshi	42,941 (6)	*
Jeffrey Miner	13,000 (5)	*
All current executive officers and directors as a group (7 persons)	439,689 (7)	4.3%

* Less than one percent.

- (1) Beneficial ownership of shares and percentage ownership are determined in accordance with the rules of the SEC. Unless otherwise indicated and subject to community property laws where applicable, the individuals named in the table above have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.
- (2) Represents 100,927 shares of common stock held by Mr. Murphy and 15,000 shares subject to options that are immediately exercisable or exercisable within 60 days of March 31, 2024.
- (3) Represents 29,607 shares of common stock held by Mr. Cohen, 2,000 shares held by Mr. Cohen's children and 52,500 shares subject to options that are immediately exercisable or exercisable within 60 days of March 31, 2024.
- (4) Represents 19,607 shares of common stock held and 52,500 shares subject to options that are immediately exercisable or exercisable within 60 days of March 31, 2024.
- (5) Represents shares subject to options that are immediately exercisable or exercisable within 60 days of March 31, 2024.
- (6) Represents 19,607 shares of common stock held and 23,334 shares subject to options that are immediately exercisable or exercisable within 60 days of March 31, 2024.
- (7) Comprised of shares included under "Directors and Named Executive Officers" other than Dr. Miner and Mr. Jurgensen, as neither is currently an executive officer.

Securities Authorized for Issuance Under Equity Compensation Plans.

The following table summarizes information about the Company's equity compensation plans by type as of March 31, 2023:

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)	1,528,934 (2)	\$ 6.62	1,129,897 (3)
Equity compensation plans not approved by security holders (4)	50,000 (5)	\$ 2.75	1,000 (6)

(1) Includes the 2008 Equity Incentive Plan, the Amended and Restated 2012 Equity Incentive Plan, the 2022 Equity Incentive Plan, and the Employee Stock Purchase Plan (the "ESPP") of the Company.

(2) Includes stock options to purchase 1,401,217 shares of common stock with a per share weighted-average exercise price of \$6.62. Also includes 127,717 restricted stock units with no exercise price.

(3) Includes 58,426 shares of common stock available for purchase under the ESPP as of March 31, 2023.

(4) Includes certain Inducement Award Stock Option Agreements and Inducement Award Performance-Based Restricted Stock Unit Agreements and the 2021 Inducement Equity Incentive Plan of the Company (the "Inducement Plan").

(5) Includes 50,000 stock options with a per share exercise price of \$2.75 granted pursuant to the Inducement Plan.

(6) Includes 1,000 shares of common stock reserved for issuance pursuant to the Inducement Plan.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Since April 1, 2021, there have not been any transactions or series of similar transactions to which we were or are a party in which the amount involved exceeded or exceeds the lesser of \$120,000 or one percent of the average of our total assets at fiscal year-end for the last two completed fiscal years, and in which any of our directors or executive officers, any holder of more than 5% of any class of our voting securities or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than (i) the transactions described below and (ii) the compensation arrangements with our executive officers and non-employee directors described in “Executive Compensation” and “Director Compensation,” respectively.

Intercompany Agreement with Viscient

Viscient is an entity for which Keith Murphy, our Executive Chairman and member of our Board, serves as the Chief Executive Officer and President. Dr. Jeffrey Miner, the Company’s former Chief Scientific Officer, is also the Chief Scientific Officer of Viscient, and Thomas Jurgensen, the Company’s former General Counsel, previously served as outside legal counsel to Viscient through his law firm, Optima Law Group, APC. In addition, Messrs. Stern, Cohen and Gobel (through the Methuselah Foundation and the Methuselah Fund) have invested funds through a convertible promissory note in Viscient, but do not serve as an employee, officer or director of Viscient.

On December 28, 2020, the Company entered into an intercompany agreement (the “Intercompany Agreement”) with Viscient and Organovo, Inc., the Company’s wholly-owned subsidiary, which included an asset purchase agreement for certain lab equipment. Pursuant to the Intercompany Agreement, the Company agreed to provide Viscient certain services related to 3D bioprinting technology which includes, but is not limited to, histology services, cell isolation, and proliferation of cells and Viscient agreed to provide the Company certain services related to 3D bioprinting technology, including bioprinter training, bioprinting services, and qPCR assays, in each case on payment terms specified in the Intercompany Agreement and as may be further determined by the parties. In addition, the Company and Viscient each agreed to share certain facilities and equipment, and, subject to further agreement, to each make certain employees available for specified projects for the other party at prices to be determined in good faith by the parties. 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 Financial Accounting Standards Board Topic 606 (“Revenue from Contracts with Customers”) as the Intercompany Agreement is not a contract with a customer. For the years ended March 31, 2024, 2023 and 2022, the Company provided approximately \$14,000, \$59,000 and \$48,000 of histology services to Viscient, respectively. Additionally, for the year ended March 31, 2022, the Company incurred approximately \$47,000 in consulting expenses from Viscient. No consulting services from Viscient were incurred for the years ended March 31, 2024 or 2023.

Related Party Transaction Policy and Procedures

Pursuant to our written Related Party Transaction Policy and Procedures, our executive officers, directors, and principal stockholders, including their immediate family members and affiliates, are prohibited from entering into a related party transaction with us without the prior consent of our Audit Committee or a committee of our independent directors. Any request for us to enter into a transaction with an executive officer, director, principal stockholder, or any of such persons’ immediate family members or affiliates, in which the amount involved exceeds \$120,000, must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting the proposed agreement, our Audit Committee will consider the relevant facts and circumstances available and deemed relevant, including, but not limited to, the terms of the transaction, the nature of the related party’s interest in the transaction, the significance of the transaction to us and the related party, the nature of the related party’s relationship with us and whether the transaction would be likely to impair (or create an appearance of impairing) the judgement of a director or executive officer to act in our best interest. Our Audit Committee shall approve only those agreements that, in light of known circumstances, are in, or are not inconsistent with, our best interests, as our Audit Committee determines in the good faith exercise of its discretion.

PRINCIPAL STOCKHOLDERS

The following tables set forth certain information regarding the beneficial ownership of our common stock as of April 22, 2024 by (i) each of our directors and named executive officers (as disclosed in this prospectus); and (ii) all of our current executive officers and directors as a group. To our knowledge, based solely on our review of Schedules 13D and 13G filed with the SEC, no person beneficially owned more than 5% of our common stock as of April 22, 2024. Unless otherwise indicated in the table or the footnotes

to the following table, each person named in the table has sole voting and investment power and such person's address is c/o Organovo Holdings, Inc., 11555 Sorrento Valley Rd., Suite 100, San Diego, CA 92121.

We determined the number of shares of common stock beneficially owned by each person under rules promulgated by the SEC, based on information obtained from Company records and filings with the SEC on or before April 22, 2024. In cases of holders who are not directors or named executive officers, Schedules 13G or 13D filed with the SEC, as applicable (and, consequently, ownership reflected here), often reflect holdings as of a date prior to April 22, 2024. The information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power and also any shares which the individual or entity had the right to acquire within 60 days of April 22, 2024. These shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other person or entity.

Applicable percentages are based on 11,430,326 shares of common stock outstanding as of April 22, 2024, as adjusted as required by the rules promulgated by the SEC. We have deemed shares of our common stock subject to stock options that are currently exercisable or exercisable within 60 days of April 22, 2024, or issuable pursuant to restricted stock units that are subject to vesting conditions expected to occur within 60 days of April 22, 2024, to be outstanding and to be beneficially owned by the person holding the stock option or restricted stock units for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person or entity.

Name of Beneficial Owner	Beneficial Ownership(1)	
	Number of Common Shares	Percent of Common Shares
Directors and Named Executive Officers		
Keith Murphy	119,677 (2)	1.0%
Douglas Jay Cohen	84,107 (3)	*
Alison Tjosvold Milhous	72,107 (4)	*
Adam Stern	72,107 (4)	*
David Gobel	52,500 (5)	*
Vaidehi Joshi	45,857 (6)	*
Jeffrey Miner (7)	13,000 (5)	*
Thomas Jurgensen (8)	-	-
Thomas Hess	-	-
All current executive officers and directors as a group (7 persons)	446,355 (9)	3.8%

* Less than one percent.

- (1) Beneficial ownership of shares and percentage ownership are determined in accordance with the rules of the SEC. Unless otherwise indicated and subject to community property laws where applicable, the individuals named in the table above have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.
- (2) Represents 102,177 shares of common stock held by Mr. Murphy and 17,500 shares subject to options that are immediately exercisable or exercisable within 60 days of April 22, 2024.
- (3) Represents 29,607 shares of common stock held by Mr. Cohen, 2,000 shares held by Mr. Cohen's children and 52,500 shares subject to options that are immediately exercisable or exercisable within 60 days of April 22, 2024.
- (4) Represents 19,607 shares of common stock held and 52,500 shares subject to options that are immediately exercisable or exercisable within 60 days of April 22, 2024.
- (5) Represents shares subject to options that are immediately exercisable or exercisable within 60 days of April 22, 2024.
- (6) Represents 19,607 shares of common stock held and 26,250 shares subject to options that are immediately exercisable or exercisable within 60 days of April 22, 2024.
- (7) Dr. Miner's employment with the Company was terminated as of August 25, 2023 in connection with Company's reduction in force announced on August 18, 2023.
- (8) Mr. Jurgensen's employment with the Company was terminated as of August 25, 2023 in connection with Company's reduction in force announced on August 18, 2023.
- (9) Comprised of shares included under "Directors and Named Executive Officers" other than Dr. Miner and Mr. Jurgensen, as neither was an executive officer as of April 22, 2024.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors, and greater than 10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. Based solely upon a review of the copies of such forms and amendments thereto, we believe that, during Fiscal 2023, none of our officers, directors, and greater than 10% beneficial owners failed to file on a timely basis the reports required by Section 16(a).

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following is a summary of the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock, common warrants and pre-funded warrants, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. Throughout this summary, all references to our common stock are meant to include our pre-funded warrants. This summary is based upon the provisions of the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed or subject to differing interpretations, possibly with retroactive effect, with the resulting U.S. federal income tax consequences being different from those set forth below. We have not sought and will not seek any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any U.S. state or local or any non-U.S. jurisdiction, estate or gift tax, the 3.8% Medicare tax on net investment income or any alternative minimum tax consequences. In addition, this discussion does not address tax considerations applicable to a holder's particular circumstances or to a holder that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- tax-exempt or government organizations;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5.0% of our capital stock;
- certain U.S. expatriates, citizens or former long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction," synthetic security, other integrated investment, or other risk reduction transaction;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, for investment purposes);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- pension plans;
- partnerships, or other entities or arrangements treated as partnerships for U.S. federal income tax purposes, or investors in any such entities;
- persons for whom our stock constitutes "qualified small business stock" within the meaning of Section 1202 of the Code;
- integral parts or controlled entities of foreign sovereigns;
- passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax; or
- persons that acquire our common stock or common warrants as compensation for services.

In addition, if a partnership, including any entity or arrangement classified as a partnership for U.S. federal income tax purposes, holds our common stock or common warrants, the tax treatment of a partner generally will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships that hold our common stock or common warrants, and partners in such partnerships, should consult their tax advisors regarding the U.S. federal income tax consequences to them of the purchase, ownership, and disposition of our common stock or common warrants.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock or common warrants arising under the U.S. federal estate or gift tax rules or under the laws of any U.S. state or local or any non-U.S. or other taxing jurisdiction or under any applicable tax treaty.

Definition of a U.S. Holder

For purposes of this summary, a “U.S. Holder” is any beneficial owner of our common stock or common warrants that is a “U.S. person,” and is not a partnership, or an entity treated as a partnership or disregarded from its owner, each for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a U.S. person for U.S. federal income tax purposes.

For purposes of this summary, a “Non-U.S. Holder” is any beneficial owner of our common stock or common warrants that is not a U.S. Holder or a partnership, or other entity treated as a partnership or disregarded from its owner, each for U.S. federal income tax purposes.

Tax Consequences to U.S. Holders

Distributions on Common Stock

As discussed above under “Dividend Policy,” we do not currently expect to make distributions on our common stock. In the event that we do make distributions of cash or other property, distributions paid on common stock, other than certain pro rata distributions of common stock, will be treated as a dividend to the extent paid out of our current or accumulated earnings and profits, if any, and will be includible in income by the U.S. Holder and taxable as ordinary income when received. If a distribution exceeds our current and accumulated earnings and profits, the excess will be first treated as a tax-free return of the U.S. Holder’s investment, up to the U.S. Holder’s tax basis in the common stock. Any remaining excess will be treated as a capital gain. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be eligible for taxation as “qualified dividend income” and therefore may be taxable at rates applicable to long-term capital gains. U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. Dividends received by a corporate U.S. Holder will be eligible for the dividends-received deduction if the U.S. Holder meets certain holding period and other applicable requirements.

Sale or Other Disposition of Common Stock

For U.S. federal income tax purposes, gain or loss realized on the sale or other disposition of common stock will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common stock for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder’s tax basis in the common stock disposed of and the amount realized on the disposition. Long-term capital gains recognized by non-corporate U.S. Holders will be subject to reduced tax rates. The deductibility of capital losses is subject to limitations.

Sale or Other Disposition, Exercise or Expiration of Common Warrants

A U.S. Holder will recognize gain or loss on the sale or other taxable disposition of common warrants in an amount equal to the difference, if any, between the amount of cash plus the fair market value of any property received and such U.S. Holder’s tax basis in common warrants sold or otherwise disposed of, in each case as determined in U.S. dollars. Gain or loss recognized on such sale or other taxable disposition generally will be a capital gain or loss, which will be long-term capital gain or loss if the common warrant is held for more than one year. The gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. Deductions for capital losses are subject to complex limitations under the Code.

A U.S. Holder should not recognize gain or loss on the exercise of common warrants and related receipt of common stock. A U.S. Holder’s initial tax basis in the common stock received on the exercise of a common warrant should be equal to the sum of (i) such U.S. Holder’s initial tax basis in such common warrant plus (ii) the exercise price paid by such U.S. Holder on the exercise of such common warrant.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of the common warrants into shares of common stock. The U.S. federal income tax treatment of a cashless exercise of common warrants into shares of common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a common warrant

described in the preceding paragraph. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of common warrants.

Upon the lapse or expiration of a warrant, a U.S. Holder will recognize a loss in an amount equal to such U.S. Holder's tax basis in the warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the warrants are held for more than one year. Deductions for capital losses are subject to complex limitations under the Code.

Certain Adjustments to the Common Warrants and Pre-funded Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of the common warrants or pre-funded warrants, or an adjustment to the exercise price of the common warrants or pre-funded warrants, may be treated as a constructive distribution to a U.S. Holder of the common warrants or pre-funded warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our earnings and profits or our assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or property to the shareholders). Adjustments to the exercise price of the common warrants or pre-funded warrants made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders of the common warrants or pre-funded warrants should generally not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property (see more detailed discussion of the rules applicable to distributions we make at "Distributions on Common Stock" above).

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, we believe a pre-funded warrant should be treated as common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of our common stock, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the common stock received. Similarly, the tax basis of the pre-funded warrant should carry over to the common stock received upon exercise, increased by the exercise price of \$0.01 per share. However, our characterization of a pre-funded warrant is not binding on the IRS, and the IRS may treat our pre-funded warrants as warrants to acquire our common stock. If so, the amount and character of your gain with respect to an investment in our pre-funded warrants could change. Accordingly, each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of pre-funded warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that our characterization described above is respected for U.S. federal income tax purposes.

Tax Consequences to Non-U.S. Holders

Distributions

As discussed in the section entitled "Dividend Policy," we do not anticipate paying any dividends on our common stock in the foreseeable future. If we make distributions on our common stock, those payments will constitute dividends for U.S. federal income tax purposes to the extent we have current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce a Non-U.S. Holder's basis in our common stock, as applicable, but not below zero. Any excess will be treated as capital gain and will be treated as described below under the "—Gain on Sale or Other Disposition of Common Stock" section. Any such distributions would be subject to the discussions below regarding back-up withholding and the Foreign Account Tax Compliance Act, or FATCA.

Subject to the discussion below on effectively connected income, any dividend paid to a Non-U.S. Holder generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. To receive a reduced treaty rate, a Non-U.S. Holder must provide us or our agent with an IRS Form W-8BEN (generally including a U.S. taxpayer identification number), IRS Form W-8 BEN-E or another appropriate version of IRS Form W-8 (or a successor form), which must be updated periodically, and which, in each case, must certify qualification for the reduced treaty rate. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States and that are not eligible for relief from U.S. (net basis) income tax under an applicable income tax treaty, generally are exempt from the (gross basis) withholding tax described above. To obtain this exemption from withholding tax, the Non-U.S. Holder must provide the applicable withholding agent with an IRS Form W-8ECI or successor form or other applicable IRS Form W-8 certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United

States. Such effectively connected dividends, if not eligible for relief under a tax treaty, would not be subject to a withholding tax, but would be taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits and if, in addition, the Non-U.S. Holder is a corporation, may also be subject to a branch profits tax at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

If you are eligible for a reduced rate of withholding tax pursuant to a tax treaty, you may be able to obtain a refund of any excess amounts withheld if you timely file an appropriate claim for refund with the IRS.

Gain on Sale or Other Disposition of Common Stock and Common Warrants

Subject to the discussion below regarding backup withholding and FATCA, a Non-U.S. Holder generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock or common warrants unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States and not eligible for relief under an applicable income tax treaty, in which case the Non-U.S. Holder will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and for a Non-U.S. Holder that is a corporation, such Non-U.S. Holder may be subject to the branch profits tax at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items;
- the Non-U.S. Holder is an individual who is present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met, in which case the Non-U.S. Holder will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by U.S. source capital losses (even though the Non-U.S. Holder is not considered a resident of the United States) (subject to applicable income tax or other treaties); or
- we are a "U.S. real property holding corporation" for U.S. federal income tax purposes, or a USRPHC, at any time within the shorter of the five-year period preceding the disposition or the Non-U.S. Holder's holding period for our common stock. We believe we are not currently and do not anticipate becoming a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to United States federal income tax if (a) shares of our common stock are "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, such as Nasdaq, and (b) the Non-U.S. Holder owns or owned, actually and constructively, 5% or less of the shares of our common stock throughout the five-year period ending on the date of the sale or exchange. If the foregoing exception does not apply, such Non-U.S. Holder's proceeds received on the disposition of shares will generally be subject to withholding at a rate of 15% and such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Information Reporting and Backup Withholding

Information returns may be filed with the IRS in connection with distributions on common stock, and the proceeds of a sale or other disposition of common stock or common warrants. A non-exempt U.S. Holder may be subject to U.S. backup withholding on these payments if it fails to provide its taxpayer identification number to the withholding agent and comply with certification procedures or otherwise establish an exemption from backup withholding.

A Non-U.S. Holder may be subject to U.S. information reporting and backup withholding on these payments unless the Non-U.S. Holder complies with certification procedures to establish that it is not a U.S. person (within the meaning of the Code). The certification requirements generally will be satisfied if the Non-U.S. Holder provides the applicable withholding agent with a statement on the applicable IRS Form (or a suitable substitute or successor form), together with all appropriate attachments, signed under penalties of perjury, stating, among other things, that such Non-U.S. Holder is not a U.S. Person. Applicable Treasury Regulations provide alternative methods for satisfying this requirement. In addition, the amount of distributions on common stock paid to a Non-U.S. Holder, and the amount of any U.S. federal tax withheld therefrom, must be reported annually to the IRS and the holder. This information may be made available by the IRS under the provisions of an applicable tax treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides.

Payment of the proceeds of the sale or other disposition of common stock or common warrants to or through a non-U.S. office of a U.S. broker or of a non-U.S. broker with certain specified U.S. connections generally will be subject to information reporting requirements, but not backup withholding, unless the Non-U.S. Holder certifies under penalties of perjury that it is not a U.S. person or an exemption otherwise applies. Payments of the proceeds of a sale or other disposition of common stock or common warrants to or

through a U.S. office of a broker generally will be subject to information reporting and backup withholding, unless the Non-U.S. Holder certifies under penalties of perjury that it is not a U.S. person or otherwise establishes an exemption.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment generally will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle the holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

The Code generally imposes a U.S. federal withholding tax of 30% on dividends and, subject to the discussion below regarding proposed regulations recently issued by the U.S. Treasury Department, the gross proceeds of a disposition of our securities paid to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise qualifies for an exemption from these rules. A U.S. federal withholding tax of 30% also applies to dividends and, subject to the discussion below regarding proposed regulations recently issued by the U.S. Treasury Department, will apply to the gross proceeds of a disposition of our securities paid to a non-financial foreign entity (as defined in the Code), unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect. "United States owners" (as defined in the Code), provides information regarding each substantial United States owners of the entity, or otherwise qualifies for an exemption from these rules.

Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph.

The U.S. Treasury Department released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock or common warrants. In its preamble to such proposed regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Prospective investors should consult their own tax advisors regarding the possible impact of these rules on their investment in our common stock or common warrants, and the possible impact of these rules and the proposed regulations on the entities through which they hold our common stock or common warrants, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR SECURITIES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS. IN ADDITION, SIGNIFICANT CHANGES IN U.S. FEDERAL TAX LAWS WERE RECENTLY ENACTED. PROSPECTIVE INVESTORS SHOULD ALSO CONSULT WITH THEIR TAX ADVISORS WITH RESPECT TO SUCH CHANGES IN U.S. TAX LAW AS WELL AS POTENTIAL CONFORMING CHANGES IN STATE TAX LAWS.

PLAN OF DISTRIBUTION

We have engaged JonesTrading Institutional Services LLC, or the placement agent, to act as our exclusive placement agent to solicit offers to purchase the shares of our common stock, pre-funded warrants and common warrants offered by this prospectus. The placement agent is not purchasing or selling any such securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of such securities, other than to use its “reasonable best efforts” to arrange for the sale of such securities by us. Therefore, we may not sell all of the shares of common stock, pre-funded warrants and common warrants being offered. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investors. The placement agent will have no authority to bind us by virtue of the placement agency agreement. This is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering. The placement agent may retain sub-agents and selected dealers in connection with this offering. Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers which enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract is material to larger purchasers in this offering as a means to enforce the following covenants uniquely available to them under the securities purchase agreement: (i) a covenant to not enter into variable rate financings for a period of 180 days following the closing of the offering, subject to certain exceptions; and (ii) a covenant to not enter into any equity financings for 60 days from closing of the offering, subject to certain exceptions.

The nature of the representations, warranties and covenants in the securities purchase agreements shall include:

- standard issuer representations and warranties on matters such as organization, qualification, authorization, no conflict, no governmental filings required, current in SEC filings, no litigation, labor or other compliance issues, environmental, intellectual property and title matters and compliance with various laws such as the Foreign Corrupt Practices Act; and
- covenants regarding matters such as registration of warrant shares, no integration with other offerings, filing of a Current Report on 8-K to disclose entering into these securities purchase agreements, no shareholder rights plans, no material nonpublic information, use of proceeds, indemnification of purchasers, reservation and listing of common stock, and no subsequent equity sales for 60 days.

Delivery of the common shares, pre-funded warrants and common warrants offered hereby is expected to occur on or about May 13, 2024, subject to satisfaction of certain customary closing conditions.

We have agreed to pay the placement agent an aggregate fee equal to 5% of the gross proceeds received in the offering. In addition, we have agreed to reimburse the placement agent for its legal fees and expenses and other out-of-pocket expenses in an amount up to \$75,000 if a transaction is consummated or \$40,000 if a transaction is not consummated.

Subject to certain conditions, we have granted the placement agent for a period of nine months after the date of the closing of this offering, a right of participation to act as lead or co-lead agent of a sale of equity or debt securities through an at the market offering or participate in any public or private offering of equity, equity-linked debt securities or other capital markets financing.

We estimate the total expenses of this offering paid or payable by us, exclusive of the placement agent’s cash fee of 5% of the gross proceeds and expenses, will be approximately \$320,000. After deducting the fees due to the placement agent and our estimated expenses in connection with this offering, we expect the net proceeds from this offering will be approximately \$4.7 million.

The following table shows the per share and total cash fees we will pay to the placement agent in connection with the sale of the common stock and shares of common stock underlying the pre-funded warrants and common warrants pursuant to this prospectus.

	Per Share and Common Warrant	Per Pre-Funded Warrant and Common Warrant	Total
Public offering price	\$ 0.80	\$ 0.799	\$ 5,245,000
Placement agent fees	\$ 0.04	\$ 0.03995	\$ 262,250
Proceeds, before expenses, to us	\$ 0.76	\$ 0.75905	\$ 4,982,750

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in our placement agency agreement with the placement agent. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

Lock-up Agreements

Each of our executive officers and directors have agreed with the placement agent to be subject to a lock-up period of 45 days following the date of closing of the offering pursuant to this prospectus and we have agreed with the placement agent to be subject to a lock-up period of 60 days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, we and such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any of our shares of common stock or any securities convertible into, or exercisable or exchangeable for, shares of common stock, subject to customary exceptions. The placement agent may waive the terms of these lock-up agreements in its sole discretion and without notice. In addition, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our common stock or upon a specified or contingent event in the future or enter into any agreement to issue securities at a future determined price for a period of one hundred and eighty (180) days following the closing date of this offering, subject to certain exceptions.

Other Relationships

From time to time, the placement agent may provide in the future various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except with respect to a sales agreement that we entered into with H.C. Wainwright & Co., LLC and JonesTrading Institutional Services LLC, or the agents, on March 16, 2018, pursuant to which we may offer and sell through the agents shares of our common stock in at-the-market sales transactions, and as otherwise disclosed in this prospectus, we have no present arrangements with the placement agent for any further services.

Regulation M Compliance

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the sale of our securities offered hereby by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Trading Market

Our common stock is listed on the Nasdaq Capital Market under the symbol "ONVO." There is no established public trading market for the pre-funded warrants and common warrants to be sold in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the pre-funded warrants or common warrants on any national securities exchange.

LEGAL MATTERS

The validity of the securities being offered by this prospectus will be passed upon for us by Paul Hastings LLP, Palo Alto, California. Certain legal matters will be passed upon for the placement agent by Duane Morris LLP, New York, New York.

EXPERTS

The consolidated financial statements of Organovo Holdings, Inc. (“Company”) as of and for the years ended March 31, 2023 and 2022, appearing in this prospectus, have been audited by Mayer Hoffman McCann P.C., independent registered public accounting firm, as set forth in their report (which report includes an explanatory paragraph regarding the existence of substantial doubt about the Company’s ability to continue as a going concern), appearing elsewhere herein, and have been included in reliance upon such report given on the authority of such firm as experts in accounting and auditing, in giving said reports.

WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities being offered under this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities being offered under this prospectus, we refer you to the registration statement of which this prospectus is a part and the exhibits filed as a part of the registration statement. Statements contained in this prospectus as to the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Organovo Holdings, Inc. The SEC’s Internet site can be found at <http://www.sec.gov>. You may also request a copy of these filings, at no cost, by writing us at 11555 Sorrento Valley Road, Suite 100, San Diego, CA 92121 or telephoning us at (858) 224-1400.

We are subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available at the website of the SEC referred to above. We also maintain a website at www.organovo.com. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or connected to our website is not a part of, and is not incorporated into, this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and persons controlling us pursuant to the provisions described in Item 14 of the registration statement of which this prospectus is a part or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than our payment of expenses incurred or paid by our directors, officers, or controlling persons in the successful defense of any action, suit, or proceeding) is asserted by our directors, officers, or controlling persons in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of the issue.

Organovo Holdings, Inc.
Index to Consolidated Financial Statements

	<u>Page Number</u>
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of March 31, 2023 and 2022	F-3
Consolidated Statements of Operations and Other Comprehensive Loss for the years ended March 31, 2023 and 2022	F-4
Consolidated Statements of Stockholders' Equity for the years ended March 31, 2023 and 2022	F-5
Consolidated Statements of Cash Flows for the years ended March 31, 2023 and 2022	F-6
Notes to Consolidated Financial Statements	F-7

Index to Unaudited Condensed Consolidated Financial Statements

	<u>Page Number</u>
Unaudited Condensed Consolidated Balance Sheets as of December 31, 2023 and 2022	F-22
Unaudited Condensed Consolidated Statements of Operations and Other Comprehensive Loss for the Nine Months Ended December 31, 2023 and 2022	F-23
Unaudited Condensed Consolidated Statements of Stockholders' Equity for the Nine Months Ended December 31, 2023 and 2022	F-24
Unaudited Condensed Consolidated Statements of Cash Flows for the Nine Months Ended December 31, 2023 and 2022	F-25
Notes to Unaudited Condensed Consolidated Financial Statements	F-26

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of:
Organovo Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of **Organovo Holdings, Inc.** ("Company") as of March 31, 2023 and 2022, and the related consolidated statements of operations and other comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended March 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the 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 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

Critical audit matters 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. We determined that there were no critical audit matters.

/s/ Mayer Hoffman McCann P.C.

We served as the Company's auditor from 2011 to 2023.

San Diego, California
July 13, 2023

ORGANOVO HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands except for share and per share data)

	March 31, 2023	March 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	\$ 15,301	\$ 28,675
Accounts receivable	152	—
Investment in equity securities	706	—
Prepaid expenses and other current assets	889	858
Total current assets	17,048	29,533
Fixed assets, net	902	662
Restricted cash	143	143
Operating lease right-of-use assets	1,705	2,153
Prepaid expenses and other assets, net	515	805
Total assets	\$ 20,313	\$ 33,296
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 331	\$ 415
Accrued expenses	2,848	489
Operating lease liability, current portion	492	479
Total current liabilities	3,671	1,383
Operating lease liability, net of current portion	1,313	1,704
Total liabilities	4,984	3,087
Commitments and Contingencies		
Stockholders' Equity		
Common stock, \$0.001 par value; 200,000,000 shares authorized, 8,716,906 and 8,710,627 shares issued and outstanding at March 31, 2023 and 2022, respectively	9	9
Additional paid-in capital	340,317	337,940
Accumulated deficit	(324,998)	(307,739)
Accumulated other comprehensive income	2	—
Treasury stock, 46 shares at cost	(1)	(1)
Total stockholders' equity	15,329	30,209
Total Liabilities and Stockholders' Equity	\$ 20,313	\$ 33,296

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

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS

(in thousands except for share and per share data)

	Year Ended March 31, 2023	Year Ended March 31, 2022
Revenues		
Royalty revenue	\$ 370	\$ 1,500
Total Revenues	<u>370</u>	<u>1,500</u>
Research and development expenses	8,885	3,320
Selling, general, and administrative expenses	9,216	9,659
Total costs and expenses	<u>18,101</u>	<u>12,979</u>
Loss from Operations	<u>(17,731)</u>	<u>(11,479)</u>
Other Income (Expense)		
Loss on fixed asset disposals	(9)	—
Gain on investment in equity securities	29	—
Interest income	454	8
Other income	—	25
Total Other Income	<u>474</u>	<u>33</u>
Income Tax Expense	<u>(2)</u>	<u>(2)</u>
Net Loss	<u>\$ (17,259)</u>	<u>\$ (11,448)</u>
Other comprehensive income:		
Unrealized gain on available-for-sale debt securities	2	—
Comprehensive loss	<u>\$ (17,257)</u>	<u>\$ (11,448)</u>
Net loss per common share—basic and diluted	<u>\$ (1.98)</u>	<u>\$ (1.32)</u>
Weighted average shares used in computing net loss per common share—basic and diluted	8,713,032	8,703,596

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

ORGANOVO HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock			Treasury Stock			Accumulated Other Comprehensive Income	Total
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulated Deficit		
Balance at March 31, 2021	8,671	\$ 9	\$ 335,479	—	\$ (1)	\$ (296,291)	—	\$ 39,196
Issuance of common stock under employee and director stock option, RSU and purchase plans	13	—	(46)	—	—	—	—	(46)
Stock-based compensation expense	—	—	2,256	—	—	—	—	2,256
Issuance of common stock from public offering, net	27	—	251	—	—	—	—	251
Net loss	—	—	—	—	—	(11,448)	—	(11,448)
Balance at March 31, 2022	8,711	\$ 9	\$ 337,940	—	\$ (1)	\$ (307,739)	—	\$ 30,209
Issuance of common stock under employee and director stock option, RSU and purchase plans	6	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	2,377	—	—	—	—	2,377
Net loss	—	—	—	—	—	(17,259)	—	(17,259)
Unrealized gain on available-for-sale debt securities	—	—	—	—	—	—	2	2
Balance at March 31, 2023	8,717	\$ 9	\$ 340,317	—	\$ (1)	\$ (324,998)	\$ 2	\$ 15,329

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

ORGANOVO HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended March 31, 2023	Year Ended March 31, 2022
Cash Flows From Operating Activities		
Net loss	\$ (17,259)	\$ (11,448)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on investment in equity securities	(29)	—
Loss on disposal of fixed assets	9	—
Accretion on investments	(105)	—
Depreciation and amortization	293	142
Stock-based compensation	2,377	2,256
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(152)	—
Prepaid expenses and other assets	177	384
Accounts payable	(148)	134
Accrued expenses	2,359	49
Operating right-of-use asset and lease liability, net	70	30
Net cash used in operating activities	(12,408)	(8,453)
Cash Flows From Investing Activities		
Purchases of fixed assets	(396)	(409)
Purchases of investments	(9,893)	—
Maturities of investments	10,000	—
Purchases of equity securities	(1,061)	—
Proceeds from sales of equity securities	384	—
Net cash used in investing activities	(966)	(409)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock, net	—	251
Employee taxes paid related to net share settlement of equity awards	—	(46)
Net cash provided by financing activities	—	205
Net Decrease in Cash, Cash Equivalents, and Restricted Cash	(13,374)	(8,657)
Cash, cash equivalents, and restricted cash at beginning of period	28,818	37,475
Cash, cash equivalents, and restricted cash at end of period	\$ 15,444	\$ 28,818
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	\$ 15,301	\$ 28,675
Restricted cash	143	143
Total cash, cash equivalents and restricted cash	\$ 15,444	\$ 28,818
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	\$ 2	\$ 2
Operating lease liabilities arising from obtaining right-of-use assets	\$ —	\$ 2,301
Purchases of fixed assets in accounts payable	\$ 64	\$ —

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

Organovo Holdings, Inc.

Notes to Consolidated Financial Statements

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

Nature of operations and basis of presentation

Organovo Holdings, Inc. (“Organovo Holdings,” “Organovo,” and the “Company”) is a biotechnology company that focuses on building high fidelity, 3D tissues that recapitulate key aspects of human disease. The Company uses these models to identify gene targets responsible for driving the disease and intends to initiate drug discovery programs around these validated targets. The Company is initially focusing on the intestine and has ongoing 3D tissue development efforts in ulcerative colitis (“UC”) and Crohn’s disease (“CD”). The Company intends to add additional tissues/diseases/targets to its portfolio over time. In line with these plans, the Company is building upon both its external and in house scientific expertise, which will be essential to its drug development effort.

The Company uses its proprietary technology to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. Organovo’s advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures. Management believes these attributes can enable critical complex, multicellular disease models that can be used to develop clinically effective drugs across multiple therapeutic areas.

The Company’s NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. The Company believes that the use of its bioprinting platform as well as complementary 3D technologies will allow it to develop an understanding of disease biology that leads to validated novel drug targets and therapeutics to those targets to treat disease.

The majority of the Company’s current focus is in inflammatory bowel disease (“IBD”), including CD and UC. The Company is creating high fidelity disease models, leveraging its prior work including the work found in its peer-reviewed publication on bioprinted intestinal tissues (Madden et al. Bioprinted 3D Primary Human Intestinal Tissues Model Aspects of Native Physiology and ADME/Tox Functions. *iScience*. 2018 Apr 27;2:156-167. doi: 10.1016/j.isci.2018.03.015.) The Company’s current understanding of intestinal tissue models and IBD disease models leads it to believe that it can create models that provide greater insight into the biology of these diseases than are generally currently available. Using these disease models, the Company intends to identify and validate novel therapeutic targets. After finding therapeutic drug targets, the Company intends to focus on developing novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these novel drug candidates towards an Investigational New Drug (“IND”) filing and potential future clinical trials.

In March of 2023, the Company entered into and closed an asset purchase agreement with Metacrine, Inc to acquire their farnesoid X receptor (“FXR”) program. FXR is a mediator of gastrointestinal (“GI”) and liver diseases. FXR agonism has been tested in a variety of preclinical models of IBD. The acquired program contains two clinically tested compounds and over 2,000 discovery or preclinical compounds.

The Company expects to broaden its work into additional therapeutic areas over time and is currently exploring specific tissues for development. In the Company’s work to identify the areas of interest, it evaluates areas that might be better served with 3D disease models than currently available models as well as the potential commercial opportunity.

Except where specifically noted or the context otherwise requires, references to “Organovo Holdings”, “the Company”, and “Organovo” in these notes to the consolidated financial statements refers to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc., and Opal Merger Sub, Inc.

Liquidity and Going Concern

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, 2023, the Company had cash and cash equivalents of approximately \$15.3 million, restricted cash of approximately \$0.1 million and an accumulated deficit of approximately \$325.0 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 \$12.4 million during the year ended March 31, 2023.

Through March 31, 2023, the Company has financed its operations primarily through the sale of common stock through public and at-the-market (“ATM”) offerings, the private placement of equity securities, from revenue derived from the licensing of intellectual

property, products and research-based services, grants, and collaborative research agreements, and from the sale of convertible notes. During the year ended March 31, 2023, the Company issued zero shares of its common stock through its ATM facility.

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. As the Company continues its operations and is focusing its efforts on drug discovery and development, the Company will need to raise additional capital to implement this business plan. The Company cannot predict with certainty the exact amount or timing for any future capital raises. The Company will seek to raise additional capital through debt or equity financings, or through some other financing arrangement. However, the Company cannot be sure that additional financing will be available if and when needed, or that, if available, it can obtain financing on terms favorable to its stockholders. Any failure to obtain financing when required will have a material adverse effect on the Company's business, operating results, and financial condition.

Use of estimates

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

Investments

Investments consist of investments in debt securities and investments in equity securities.

Investments in debt securities consist of investments in U.S. Treasury bills. As of March 31, 2023, all investments that have original maturities of three months or less are classified as cash equivalents on the Consolidated Balance Sheets. Prior to March 31, 2023, the Company classified certain investments as held-to-maturity. All investments previously classified as held-to-maturity matured prior to March 31, 2023. As of March 31, 2023, all investments are 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.

Investments in equity securities consist of investments in the common stock of entities traded in active markets. The Company does not have the ability to exercise significant influence over any entities. Therefore, initial investments are recorded at cost, and are remeasured at fair value as of the balance sheet date. Any gains or losses resulting from the change in fair value are recorded in net income. The investments in equity securities are classified as current assets.

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.

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.

Restricted cash

As of March 31, 2023 and 2022, the Company had approximately \$0.1 million of restricted cash, respectively, 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.

Fixed assets and depreciation

Fixed assets are carried at cost. 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 year 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, 2023 and 2022.

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

The Company has acquired drug candidates in development. The costs to acquire a drug candidate are immediately expensed as acquired in-process research and development, provided that the drug candidate has no alternative future use. Acquired in-process research and development expenses are included in total research and development expenses on the Consolidated Statements of Operations and Other Comprehensive Loss.

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. For the year ended March 31, 2023, the Company paid a \$2.0 million upfront payment, and the remaining \$2.0 million will be paid in the next fiscal year (see detail in "Note 4. Accrued Expenses") upon final transfer of the drug compounds, related data, and IP.

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 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

The Company has generated revenues from payments received from licensing intellectual property.

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 vs. agent, whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company 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 5: Collaborative Research, Development, and License Agreements” for further information.

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’s requisite service period (generally the vesting period of the equity grant).

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 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 excludes any assumed exercise of stock options and warrants, shares reserved for purchase under the Company’s 2016 Employee Stock Purchase Plan (“ESPP”), the assumed release of restriction of restricted stock units (“RSUs”), and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the years ended March 31, 2023 and 2022 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 were approximately 1.6 million shares and 1.2 million shares for the years ended March 31, 2023 and 2022, respectively.

Note 2. Investments and fair value measurement

Investments in debt securities

As of March 31, 2023, the Company held \$4.9 million of investments in debt securities (which are included in the \$15.3 million of cash and cash equivalents). For the year ended March 31, 2023, there was \$0.3 million of interest income related to the investments in debt securities. There were less than \$0.1 million of unrealized gains recorded on investments in debt securities for the year ended March 31, 2023. 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 following table summarizes the Company’s investments in debt securities that are measured at fair value as of March 31, 2023 (in thousands):

	<u>Amortized costs basis</u>	<u>Gross unrealized gains</u>	<u>Gross unrealized losses</u>	<u>Fair value</u>
As of March 31, 2023				
Investment in debt securities	\$ 4,943	\$ 2	\$ —	\$ 4,945

Investments in equity securities

For the year ended March 31, 2023, there was \$1.1 million of equity securities purchased, and \$0.4 million of equity securities sold. As of March 31, 2023, the fair value of investment in equity securities was \$0.7 million, resulting in less than a \$0.1 million unrealized gain on investment in equity securities. As the investments in equity securities consist of common stock from active markets, the fair value is measured using level 1 inputs.

The following table presents the activity for investments in equity securities measured at fair value for the year ended March 31, 2023 (in thousands):

	Investment in Equity Securities (in thousands)	
Balance at March 31, 2022	\$	—
Purchases at cost		1,061
Sales		(384)
Gain on investment in equity securities		29
Balance at March 31, 2023	\$	706

Note 3. Fixed Assets

Fixed assets consisted of the following (in thousands):

	March 31, 2023	March 31, 2022
Laboratory equipment	\$ 1,575	\$ 1,171
Furniture and fixtures	66	38
Computer software and equipment	537	524
Fixed Assets, gross	2,178	1,733
Less accumulated depreciation	(1,276)	(1,071)
Fixed Assets, net	\$ 902	\$ 662

As of March 31, 2023 and 2022, all of the Company's fixed assets were active and in use. Depreciation expense for the years ended March 31, 2023 and 2022 was approximately \$211,000 and \$128,000, respectively.

Note 4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2023	March 31, 2022
Accrued compensation	\$ 609	\$ 434
Accrued legal and professional fees	193	27
Acquired in-process research and development	2,000	—
Other accrued expenses	46	28
	\$ 2,848	\$ 489

Note 5. Collaborative Research, Development, and License Agreements

License Agreements

From June 2021 to February 2022, certain patents owned or sublicensed by the Company became the subject of IPR proceedings filed by Cellink AB and its subsidiaries (collectively, "BICO Group AB"). The Company and BICO Group AB were also engaged in litigation regarding patent infringement during the same time period. On February 22, 2022, the Company and BICO Group AB signed a settlement and patent license agreement ("License Agreement") to close all matters noted above. In addition to closing all legal matters and patent disputes noted above, as part of the agreement, 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. The Company concluded that the nature of the license granted represents functional intellectual property.

As part of the License Agreement, BICO Group AB agreed to pay the Company a one time, nonrefundable upfront fee of \$1,500,000. Based on Topic 606, the Company concluded that the performance obligation related to this upfront fee consisted of the Company filing stipulations of dismissal of all legal matters noted above, as well as the Company granting the non-exclusive license of the aforementioned patents within five days of receiving the upfront payment. The conditions of the performance obligation were satisfied, and therefore the Company recognized revenue of \$1,500,000 on February 22, 2022, the executed date of the License Agreement.

Additionally, as part of the License Agreement, BICO Group AB agreed to pay the Company ongoing sales-based royalties (based on percentages of BICO Group AB's net sales) for the use of the granted license. The sales-based royalties became effective beginning on February 22, 2022, the effective date of the License Agreement, and continue 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. Sales-based royalties that occurred prior to fiscal 2023 were recognized as revenue on a one quarter lag due to constraints on the estimates of variable consideration. During fiscal 2023, the Company began to estimate sales-based royalties earned each quarter. For the year ended March 31, 2023, the Company recorded \$370,000 of royalty revenue based on sales-based royalties from the License Agreement. This recognized revenue is related to sales-based royalties earned from February 22, 2022 through March 31, 2023.

Also as part of the License Agreement, certain patents involved in the agreement are sublicensed by the Company from the University of Missouri and 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. The Company paid the minimum annual royalty of \$25,000 in January 2022 for its respective calendar year, which is credited against royalties due during the subsequent twelve months. No payments have been made in excess of the minimum annual royalties in the years ended March 31, 2023 and 2022.

The license agreement with the University of Missouri also includes an additional sales royalty of 3% of all revenue received from a sublicensee, when such sublicense is entered pursuant to settlement of litigation. Such revenue shall include, but not be limited to, all option fees, license issue fees (upfront payments), license maintenance fees, equity, and all royalty payments. Such revenue shall not include research funding provided to licensee by sublicensee. However, per the agreement, in the event that the Company defends the technology by litigation, it can offset any royalties due by legal expenses incurred. As of March 31, 2023, the Company's legal expenses exceeded royalties owed from the upfront payment and sales-based royalties related to the License Agreement. Therefore, no royalty expense to the University of Missouri was recorded for the year ended March 31, 2023. No royalty expense related to sales-based royalties has been recorded to date.

On December 5, 2022, the Company amended the license agreement with the University of Missouri, whereas 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, 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 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 is 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 terminates upon expiration of the patents licensed, which are expected to expire in May 2024, and is subject to certain conditions as defined in the license agreement. Minimum annual royalty payments of \$20,000 were due for each of the two years beginning with

calendar 2014, and \$40,000 per year beginning with calendar 2016. Royalty payments of \$40,000 were made in each of the years ended March 31, 2023 and 2022. The annual minimum royalty is creditable against royalties owed during the same calendar year.

In addition to the annual royalties noted above, the University is 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 defends the technology by litigation, it can offset any royalties due by legal expenses incurred. As of March 31, 2023, the Company's legal expenses exceeded royalties owed from the upfront payment and sales-based royalties related to the License Agreement. Therefore, no royalty expense to Clemson University was recorded for the year ended March 31, 2023. No royalty expense related to sales-based royalties has been recorded to date.

Capitalized License Fees

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

	March 31, 2023	March 31, 2022
License fees	\$ 114	\$ 218
Less accumulated amortization	(101)	(124)
License fees, net	<u>\$ 13</u>	<u>\$ 94</u>

The above license fees, net of accumulated amortization, are included in 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 \$82,000 and \$14,000 for the years ended March 31, 2023 and 2022, respectively. At March 31, 2023, the weighted average remaining amortization period for all licenses was approximately 2 years. The annual amortization expense of licenses for the next five years is estimated to be approximately \$3,000 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 have been 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 provides certain payments to Salk upon the successful development and commercialization of the lead compound, FXR314. The Company is required to pay Salk royalties ranging from 1% to 1.125% of net sales of therapeutics based on FXR314. In addition, the Company is 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 are also reduced milestone payments application to a second or third licensed product, if any. Should the company sublicense the a licensed product to a third party, then it must pay a 3.5% of sublicensing revenue attributable to such a sublicense.

Note 6. 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 Board approved the 2012 Plan. The 2012 Plan authorized the issuance of up to 327,699 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. The Board and stockholders of the Company approved an amendment to the 2012 Plan in August 2013 to increase the number of shares of common stock that may be issued under the 2012 Plan by 250,000 shares. In August 2015, the Board and stockholders of the Company approved an amendment to the 2012 Plan to further increase the number of shares of common stock that may be issued under the 2012 Plan by 300,000 shares. In July 2018, the Board and stockholders of the Company approved an amendment to the 2012 Plan to further increase the number of shares of common stock that may be issued under the 2012 Plan by 550,000 shares. In October 2021, the Board and stockholders of the Company approved an amendment to the 2012 Plan to further increase the number of shares of common stock that may be issued under the 2012 Plan by 900,000, bringing the

aggregate shares issuable under the 2012 Plan to 2,327,699. The 2012 Plan as amended and restated became effective on July 26, 2018 and terminates ten years after such date.

In March 2021, the Board approved the Inducement Plan. The Inducement Plan authorized the issuance of up to 750,000 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, 50,000 incentive stock options were issued under the Inducement Plan.

On October 12, 2022, the Company's stockholders and the Board approved the 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 1,363,000 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 126,262 shares of its common stock under the 2012 Plan. As a result, the number of shares reserved for future issuance under the 2022 Plan is 1,236,738 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 750,000 shares to 51,000 shares (which includes 50,000 shares of its common stock issuable pursuant to an outstanding option to purchase common stock with an exercise price of \$2.75 per share, leaving only 1,000 shares available for future issuance under the Inducement Plan) and the share reserve was reduced effective October 12, 2022.

The Company previously had an effective shelf registration statement on Form S-3 (File No. 333-222929) and the related prospectus previously declared effective by the SEC on February 22, 2018 (the "2018 Shelf"), which registered \$100.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that was set to expire on February 22, 2021. On January 19, 2021, the Company filed a shelf registration statement on Form S-3 (File No. 333-252224) 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 "2021 Shelf") and a related prospectus. The 2021 Shelf was declared effective by the SEC on January 29, 2021 and replaced the 2018 Shelf at that time.

On March 16, 2018, the Company entered into a Sales Agreement ("Sales Agreement") with H.C. Wainwright & Co., LLC and Jones Trading Institutional Services LLC (each an "Agent" and together, the "Agents"). On January 29, 2021, the Company filed a prospectus supplement to the 2021 Shelf (the "ATM Prospectus Supplement"), pursuant to which the Company may offer and sell, from time to time through the Agents, shares of its common stock in ATM sales transactions having an aggregate offering price of up to \$50.0 million. Any shares offered and sold will be issued pursuant to the 2021 Shelf. During the year ended March 31, 2023, the Company issued zero shares of common stock in ATM offerings under the ATM Prospectus Supplement. As of March 31, 2023, the Company has sold an aggregate of 1,580,862 shares of common stock in ATM offerings under the ATM Prospectus Supplement, with gross proceeds of approximately \$21.7 million. As of March 31, 2023, there was approximately \$100.0 million available for future offerings under the 2021 Shelf (excluding amounts available but not yet issued under the ATM Prospectus Supplement), and approximately \$28.3 million available for future offerings through the Company's ATM program under the ATM Prospectus Supplement.

Restricted stock units

The following table summarizes the Company's RSUs activity for the year ended March 31, 2023:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2022	15,500	\$ 10.58
Granted	117,642	\$ 1.53
Vested	(5,425)	\$ 11.02
Cancelled / forfeited	—	\$ —
Unvested at March 31, 2023	<u>127,717</u>	<u>\$ 2.22</u>

Stock options

During the year ended March 31, 2023 under both the 2022 Plan and 2012 Plan, 255,474 stock options were granted at various exercise prices, respectively.

On March 8, 2021, the Company granted 120,000 and 25,000 stock options, respectively, to its Executive Chairman and its Chief Scientific Officer under the 2012 Plan. On October 7, 2021, the Company granted an additional 120,000 and 25,000 stock options, respectively, to the aforementioned officers. These stock options have unique vesting criteria based on market conditions, more specifically the Company's stock price. As these 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. As of March 31, 2023, half of the aforementioned stock options were fully expensed over their requisite service periods. However, to date, none of the stock options have vested.

On October 7, 2021, the Company granted 60,000 and 15,000 stock options, respectively, to its Executive Chairman and its Chief Scientific Officer under the 2012 Plan. These stock options have unique vesting criteria based on specific Company performance conditions. The vesting criteria for half of these options was relating to the Company recognizing \$1.5 million of revenue per year based on three quarters of results, which was achieved on February 22, 2022 (refer to "Note 4. Collaborative Research, Development, and License Agreements" for more information). The remaining unvested options have vesting criteria relating to the Company closing a seven-figure cash up front deal with a major pharmaceutical company. As of March 31, 2023, management estimated there was a 0% probability of achievement, and therefore no expense has been recorded to date.

The following table summarizes stock option activity for the year ended March 31, 2023:

	Options Outstanding	Weighted- Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2022	1,203,671	\$ 7.36	\$ 71,650
Options granted	255,474	\$ 2.34	\$ —
Options canceled	(7,928)	\$ 5.66	\$ —
Options exercised	—	\$ —	\$ —
Outstanding at March 31, 2023	<u>1,451,217</u>	\$ 6.49	\$ 38,327
Vested and Exercisable at March 31, 2023	<u>559,685</u>	\$ 7.07	\$ 472

The weighted-average remaining contractual term of stock options exercisable and outstanding at March 31, 2023 was approximately 8.00 years.

During the years ended March 31, 2023 and 2022, the Company issued zero shares of common stock upon exercise of stock options.

Employee Stock Purchase Plan

In June 2016, the Board, and in August 2016, its stockholders subsequently approved, the ESPP. The Company reserved 75,000 shares of common stock for issuance thereunder. The ESPP permits employees after five months of service to purchase common stock through payroll deductions, limited to 15 percent of each employee's compensation up to \$25,000 per employee per year. 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 period commenced in September 2016. During the year ended March 31, 2023, 1,009 shares were issued under the ESPP. At March 31, 2023, there were 58,426 shares remaining available for the purchase under the ESPP.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at March 31, 2023:

Common stock issuable pursuant to options outstanding and reserved under the 2012 Plan	1,345,664
Common stock reserved under the 2012 Plan	—
Common stock issuable pursuant to options outstanding and reserved under the 2022 Plan	55,553
Common stock reserved under the 2022 Plan	1,071,471
Common stock reserved under the ESPP	58,426
Common stock reserved under the 2021 Inducement Equity Plan	1,000
Common stock issuable pursuant to restricted stock units outstanding under the 2012 Plan	10,075
Common stock issuable pursuant to restricted stock units outstanding under the 2022 Plan	117,642
Common stock issuable pursuant to options outstanding and reserved under the Inducement Plan	50,000
Total at March 31, 2023	<u>2,709,831</u>

Stock-based compensation expense and valuation information

Stock-based awards include stock options and RSUs under the Company's 2022 Equity Incentive Plan ("2022 Plan"), Amended and Restated 2012 Equity Incentive Plan ("2012 Plan"), inducement awards, performance-based RSUs under an Incentive Award Performance-Based Restricted Stock Unit Agreement, the 2021 Inducement Equity Incentive Plan ("Inducement Plan"), and rights to purchase stock under the ESPP. The Company calculates the grant date fair value of all stock-based awards in determining the stock-based compensation expense.

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

	Year Ended March 31, 2023	Year Ended March 31, 2022
Research and development	\$ 473	\$ 419
General and administrative	1,904	1,837
Total	\$ 2,377	\$ 2,256

The total unrecognized compensation cost related to unvested stock option grants as of March 31, 2023 was approximately \$2,492,000 and the weighted average period over which these grants are expected to vest is 2.05 years.

The total unrecognized stock-based compensation cost related to unvested RSUs (not including performance-based RSUs) as of March 31, 2023 was approximately \$210,000, which will be recognized over a weighted average period of 1.24 years.

As of March 31, 2023, there are no participants enrolled into the ESPP for the current purchase period, beginning March 1, 2023.

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 was 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 was 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 fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	Year Ended March 31, 2023	Year Ended March 31, 2022
Dividend yield	—	—
Volatility	95.53 %	95.65 %
Risk-free interest rate	3.32 %	1.30 %
Expected life of options	6.00 years	5.75 years
Weighted average grant date fair value	\$ 1.83	\$ 4.73

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

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

	Year Ended March 31, 2023	Year Ended March 31, 2022*
Dividend yield	—	—
Volatility	86.58 %	0.00 %
Risk-free interest rate	3.34 %	0.00 %
Expected term	6 months	—
Grant date fair value	\$ 0.82	\$ —

*There were no participants in the ESPP for the purchase periods March 1, 2021 – August 31, 2022 nor any participants in the ESPP for the current purchase period (beginning March 1, 2023).

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 7. Leases

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

Operating Leases

From October 2019 to July 2021, the Company rented office space in Solana Beach, California. This agreement was a month-to-month contract and could be terminated at-will by either party at any time. As such, the Company concluded that this agreement did not contain a lease and was expensed as incurred (referred to as "rent expense"). Monthly rental payments were approximately \$4,000 per month.

On November 23, 2020, the Company entered into two lease agreements, pursuant to which the Company temporarily leased approximately 3,212 square feet of lab and office space (the "Temporary Lease") in San Diego and permanently leased approximately 8,051 square feet of office space (the "Permanent Lease") in San Diego once certain tenant improvements for the Company's permanent premises 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 Temporary Lease commenced on November 27, 2020 and served as temporary premises until the Permanent Lease was ready for occupancy. 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 \$40,900 with 3% annual escalators.

The Company determined that the Temporary Lease is considered a short term lease under ASC 842 and therefore elected an accounting policy for short term leases to recognize lease payments as an expense on a straight-line basis over the lease term (referred to as "short term lease expense"). Variable lease expenses related to the short term lease, such as payments for additional monthly fees to cover the Company's share of certain facility expenses (common area maintenance, or CAM) are expensed as incurred.

The Company determined that the Permanent Lease is considered an operating lease under ASC 842, and therefore upon the lease commencement date of December 17, 2021, recognized lease liabilities and corresponding right-of-use assets of \$2.3 million. The Company aggregates all lease and non-lease components for each class of underlying assets into a single lease component. As the Permanent Lease did not have a discount rate implicit in the lease, the Company estimated its incremental borrowing rate to discount the lease payments based on information available at the lease commencement. 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, or CAM) are expensed as incurred.

The table below summarizes the Company's lease liabilities and corresponding right-of-use assets as of March 31, 2023 (in thousands):

	March 31, 2023
ASSETS	
Operating lease right-of-use assets	\$ 1,705
Total lease right-of-use assets	<u>\$ 1,705</u>
LIABILITIES	
Current	
Operating lease liability	\$ 492
Noncurrent	
Operating lease liability, net of current portion	\$ 1,313
Total lease liabilities	<u>\$ 1,805</u>
Weighted average remaining lease term:	3.83 years
Weighted average discount rate:	6%

The Company recorded rent expense of approximately zero and \$18,000 for the years ended March 31, 2023 and 2022, respectively. Variable lease expense was approximately \$146,000 and \$59,000 for the years ended March 31, 2023 and 2022, respectively. Short term lease expense was approximately zero and \$117,000 for the years ended March 31, 2023 and 2022, respectively. Lastly, operating lease expense was approximately \$499,000 and \$172,000 for the years ended March 31, 2023 and 2022, respectively.

Cash outflows associated with the Company's operating lease for the years ended March 31, 2023 and 2022 were \$430,000 and \$183,000, respectively.

Future lease payments relating to the Company's operating lease liabilities as of March 31, 2023 are as follows (in thousands):

Fiscal year ending March 31, 2024	\$ 508
Fiscal year ending March 31, 2025	523
Fiscal year ending March 31, 2026	538
Fiscal year ending March 31, 2027	460
Thereafter	—
Total future lease payments	<u>2,029</u>
Less: Imputed Interest	<u>(224)</u>
Total lease obligations	1,805
Less: Current obligations	<u>(492)</u>
Noncurrent lease obligations	<u>\$ 1,313</u>

Note 8. 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.

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

The Company regularly reviews contingencies to determine the adequacy of its accruals and related disclosures. During the period presented, the Company has not recorded any accrual for loss contingencies associated with any claims or legal proceedings; determined that an unfavorable outcome is probable or reasonably possible; or determined that the amount or range of any possible

loss is reasonably estimable. However, the outcome of legal proceedings and claims brought against the Company is subject to significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, 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 9. Income Taxes

A reconciliation of the statutory federal rate and the effective rate, for operations, is as follows for the years ended March 31, 2023 and 2022 (in thousands, except percentages):

	March 31, 2023		March 31, 2022	
Tax computed at federal statutory rate	\$ (3,624)	21%	\$ (2,404)	21%
State income tax, net of federal benefit	(44)	0.2%	(6)	0%
Stock-based compensation	167	-1%	1,857	-16.2%
Research credits	60	-0.4%	(249)	2.1%
Change in tax rate	157	-0.9%	454	-4.0%
Removal of net operating losses and research development credits	1,410	-8.2%	2,269	-19.8%
Other	1	0%	20	-0.1%
Valuation allowance	1,873	-10.7%	(1,941)	16.9%
Provision (benefit) for income taxes	\$ —	0.0%	\$ —	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, 2023 and 2022 (in thousands, except percentages):

	March 31, 2023		March 31, 2022	
Deferred tax assets:				
Amortization	\$	598	\$	—
Section 174 R&D capitalization		855		—
Accrued expenses and reserves		116		110
Operating lease liability		384		611
Stock-based compensation		755		554
Inventory		251		—
Other, net		3		3
Total deferred tax assets		2,962		1,278
Valuation allowance		(2,458)		(583)
Net deferred tax assets	\$	504	\$	695
Deferred tax liabilities:				
Operating lease right-of-use assets		(363)		(603)
Depreciation		(135)		(92)
Investment in equity securities		(6)		—
Total deferred tax liabilities	\$	(504)	\$	(695)
	\$	—	\$	—

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 ("IRC") 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, 2023. 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 \$1.6 million and \$1.5 million for the years ended March 31, 2023 and 2022, 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 increased by approximately \$1,875,000 and decreased by approximately \$1,941,000 for the years ended March 31, 2023 and 2022, respectively.

The Company had federal and state net operating loss carryforwards of approximately \$210.5 million and \$40.9 million, respectively, as of March 31, 2023. Federal net operating loss carryforwards of approximately \$66.8 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 “CARES Act”). The remaining federal net operating losses will begin to expire in 2028, unless previously utilized. The state net operating loss carryforwards (“NOLs”) will begin to expire in 2028, unless previously utilized.

The Company had federal and state research tax credit carryforwards of approximately \$4.7 million and \$4.3 million at March 31, 2023, 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, 2023.

The Company did not accrue either interest or penalties from inception through March 31, 2023.

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, 2023, 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 10. Concentrations

Credit risk and significant customers

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments. The Company maintains cash balances at various financial institutions located within the United States. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. Balances may exceed federally insured limits. The Company is also potentially subject to concentrations of credit risk in its revenues and accounts receivable. However, the Company only receives royalty revenue from one licensee and has not historically experienced any accounts receivable write-downs.

Note 11. Related Parties

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

Viscient Biosciences (“Viscient”) is an entity for which Keith Murphy, the Company’s Executive Chairman, serves as the Chief Executive Officer and President. Dr. Jeffrey Miner, the Company’s Chief Scientific Officer, is also the Chief Scientific Officer of Viscient, and Thomas Jurgensen, the Company’s General Counsel, previously served as outside legal counsel to Viscient through his law firm, Optima Law Group, APC.

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. 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 years ended March 31, 2023 and 2022, the Company incurred approximately zero and \$47,000 in consulting expenses from Viscient, respectively. Additionally, for the years ended March 31, 2023 and 2022, the Company provided approximately \$59,000 and \$48,000 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, 2023 and 2022 were approximately \$10,000 and \$25,000, respectively.

Note 13. Recent Accounting Pronouncements

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

Organovo Holdings, Inc.
Condensed Consolidated Balance Sheets
(in thousands except for share and per share data)

	December 31, 2023	March 31, 2023
	(Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	\$ 5,295	\$ 15,301
Accounts receivable	33	152
Investment in equity securities	—	706
Prepaid expenses and other current assets	913	889
Total current assets	6,241	17,048
Fixed assets, net	739	902
Restricted cash	143	143
Operating lease right-of-use assets	1,403	1,705
Prepaid expenses and other assets, net	355	515
Total assets	\$ 8,881	\$ 20,313
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 471	\$ 331
Accrued expenses	727	2,848
Operating lease liability, current portion	502	492
Total current liabilities	1,700	3,671
Operating lease liability, net of current portion	999	1,313
Total liabilities	2,699	4,984
Commitments and Contingencies (Note 7)		
Stockholders' Equity		
Common stock, \$0.001 par value; 200,000,000 shares authorized, 9,838,755 and 8,716,906 shares issued and outstanding at December 31, 2023 and March 31, 2023, respectively	10	9
Additional paid-in capital	342,796	340,317
Accumulated deficit	(336,624)	(324,998)
Accumulated other comprehensive income	1	2
Treasury stock, 46 shares at cost	(1)	(1)
Total stockholders' equity	6,182	15,329
Total Liabilities and Stockholders' Equity	\$ 8,881	\$ 20,313

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

Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Operations and Other Comprehensive Loss
(in thousands except share and per share data)

	Three Months Ended December 31, 2023	Three Months Ended December 31, 2022	Nine Months Ended December 31, 2023	Nine Months Ended December 31, 2022
Revenues				
Royalty revenue	\$ 5	\$ 131	\$ 80	\$ 208
Total Revenues	5	131	80	208
Research and development expenses	1,434	1,185	4,435	3,436
Selling, general and administrative expenses	2,251	2,305	7,635	6,724
Total costs and expenses	3,685	3,490	12,070	10,160
Loss from Operations	(3,680)	(3,359)	(11,990)	(9,952)
Other Income (Expense)				
(Loss) gain on investment in equity securities	—	(48)	12	(123)
Interest income	76	143	354	277
Total Other Income	76	95	366	154
Income Tax Expense	—	—	(2)	(2)
Net Loss	\$ (3,604)	\$ (3,264)	\$ (11,626)	\$ (9,800)
Other Comprehensive Loss:				
Unrealized gain (loss) on available-for-sale debt securities	\$ —	\$ 3	\$ (1)	\$ 3
Comprehensive Loss	\$ (3,604)	\$ (3,261)	\$ (11,627)	\$ (9,797)
Net loss per common share—basic and diluted	\$ (0.40)	\$ (0.37)	\$ (1.31)	\$ (1.13)
Weighted average shares used in computing net loss per common share—basic and diluted	9,115,455	8,713,617	8,850,881	8,712,294

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

Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Stockholders' Equity
(in thousands)

	Three and Nine Months Ended December 31, 2022							
	Common Stock			Treasury Stock			Accumulated Other Comprehensive Income	Total
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulate d Deficit		
Balance at March 31, 2022	8,711	\$ 9	\$ 337,940	—	\$ (1)	\$ (307,739)	\$ —	\$ 30,209
Issuance of common stock under employee and director stock option, RSU, and purchase plans	1	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	660	—	—	—	—	660
Net loss	—	—	—	—	—	(3,215)	—	(3,215)
Balance at June 30, 2022 (Unaudited)	8,712	\$ 9	\$ 338,600	—	\$ (1)	\$ (310,954)	\$ —	\$ 27,654
Issuance of common stock under employee and director stock option, RSU, and purchase plans	1	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	673	—	—	—	—	673
Net loss	—	—	—	—	—	(3,321)	—	(3,321)
Balance at September 30, 2022 (Unaudited)	8,713	\$ 9	\$ 339,273	—	\$ (1)	\$ (314,275)	\$ —	\$ 25,006
Issuance of common stock under employee and director stock option, RSU, and purchase plans	1	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	544	—	—	—	—	544
Net loss	—	—	—	—	—	(3,264)	—	(3,264)
Unrealized gain on available-for-sale debt securities	—	—	—	—	—	—	3	3
Balance at December 31, 2022 (Unaudited)	8,714	\$ 9	\$ 339,817	—	\$ (1)	\$ (317,539)	\$ 3	\$ 22,289

	Three and Nine Months Ended December 31, 2023							
	Common Stock			Treasury Stock			Accumulated Other Comprehensive Income	Total
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulate d Deficit		
Balance at March 31, 2023	8,717	\$ 9	\$ 340,317	—	\$ (1)	\$ (324,998)	\$ 2	\$ 15,329
Issuance of common stock under employee and director stock option, RSU, and purchase plans	1	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	475	—	—	—	—	475
Net loss	—	—	—	—	—	(4,028)	—	(4,028)
Balance at June 30, 2023 (Unaudited)	8,718	\$ 9	\$ 340,792	—	\$ (1)	\$ (329,026)	\$ 2	\$ 11,776
Issuance of common stock under employee and director stock option, RSU, and purchase plans	1	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	675	—	—	—	—	675
Net loss	—	—	—	—	—	(3,994)	—	(3,994)
Unrealized loss on available-for-sale debt securities	—	—	—	—	—	—	(1)	(1)
Balance at September 30, 2023 (Unaudited)	8,719	\$ 9	\$ 341,467	—	\$ (1)	\$ (333,020)	\$ 1	\$ 8,456
Issuance of common stock under employee and director stock option, RSU, and purchase plans	119	—	—	—	—	—	—	—
Issuance of common stock from public offering	935	1	1,172	—	—	—	—	1,173
Stock-based compensation expense	66	—	157	—	—	—	—	157
Net loss	—	—	—	—	—	(3,604)	—	(3,604)
Balance at December 31, 2023 (Unaudited)	9,839	\$ 10	\$ 342,796	—	\$ (1)	\$ (336,624)	\$ 1	\$ 6,182

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

Organovo Holdings, Inc.
Unaudited Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended December 31, 2023	Nine Months Ended December 31, 2022
Cash Flows From Operating Activities		
Net loss	\$ (11,626)	\$ (9,800)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on investment in equity securities	(12)	123
Accretion on investments	(128)	(104)
Depreciation and amortization	209	234
Stock-based compensation	1,307	1,877
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	119	(76)
Prepaid expenses and other assets	132	18
Accounts payable	140	(173)
Accrued expenses	(2,121)	157
Operating lease right-of-use assets and liabilities, net	(2)	69
Net cash used in operating activities	(11,982)	(7,675)
Cash Flows From Investing Activities		
Purchases of fixed assets	(42)	(234)
Purchases of investments	(9,873)	(9,893)
Maturities of investments	10,000	10,000
Purchases of equity securities	—	(1,061)
Sales of equity securities	—	384
Liquidation of equity securities	718	—
Net cash provided by (used in) investing activities	803	(804)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock, net	1,173	—
Net cash provided by financing activities	1,173	—
Net decrease in cash, cash equivalents, and restricted cash	(10,006)	(8,479)
Cash, cash equivalents, and restricted cash at beginning of period	15,444	28,818
Cash, cash equivalents, and restricted cash at end of period	\$ 5,438	\$ 20,339
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	\$ 5,295	\$ 20,196
Restricted cash	143	143
Total cash, cash equivalents, and restricted cash	\$ 5,438	\$ 20,339
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	\$ 2	\$ 2

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

Organovo Holdings, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. Description of Business

Nature of Operations

Organovo Holdings, Inc. (“Organovo Holdings,” “Organovo,” and the “Company”) is a clinical stage biotechnology company that focuses on clinical drug development of the farnesoid X receptor (“FXR”) agonist FXR314. FXR is a mediator of gastrointestinal and liver diseases. FXR agonism has been tested in a variety of preclinical models of inflammatory bowel disease (“IBD”). FXR314 is the lead compound in the Company’s established FXR program containing two clinically tested compounds (including FXR314) and over 2,000 discovery or preclinical compounds. FXR314 is a drug with safety and tolerability after daily oral dosing in Phase 1 and Phase 2 trials. Further, FXR314 has FDA clinical trial authorization for a Phase 2 trial in ulcerative colitis (“UC”).

The Company’s current clinical focus is in advancing FXR314 in IBD, including UC and Crohn’s disease (“CD”). The Company plans to start a Phase 2a clinical trial in UC in the calendar year 2024.

A second focus of the Company is building high fidelity, 3D tissues that recapitulate key aspects of human disease. The Company uses its proprietary technology to build functional 3D human tissues that mimic key aspects of native human tissue composition, architecture, function and disease. Management believes these attributes can enable critical complex, multicellular disease models that can be used to develop clinically effective drugs across multiple therapeutic areas.

As with the clinical development program, the Company is initially focusing on the intestine and has ongoing 3D tissue development efforts in human tissue models of UC and CD. The Company uses these models to identify new molecular targets responsible for driving these diseases and to explore the mechanism of action of known drugs including FXR314 and related molecules. The Company intends to initiate drug discovery programs around these new validated targets to identify drug candidates for partnering and/or internal clinical development.

The Company’s current understanding of intestinal tissue models and IBD disease models leads it to believe that it can create models that provide greater insight into the biology of these diseases than are generally currently available. The Company is creating high fidelity disease models, leveraging its prior work including the work found in its peer-reviewed publication on bioprinted intestinal tissues (Madden et al. Bioprinted 3D Primary Human Intestinal Tissues Model Aspects of Native Physiology and ADME/Tox Functions. *iScience*. 2018 Apr 27;2:156-167. doi: 10.1016/j.isci.2018.03.015.) Organovo’s advances include cell type-specific compartments, prevalent intercellular tight junctions, and the formation of microvascular structures.

Using these disease models, the Company intends to identify and validate novel therapeutic targets. After finding therapeutic drug targets, the Company intends to focus on developing novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these novel drug candidates towards an Investigational New Drug (“IND”) filing and potential future clinical trials.

The Company expects to broaden its work into additional therapeutic areas over time and is currently exploring specific tissues for development. In the Company’s work to identify the areas of interest, it evaluates areas that might be better served with 3D disease models than currently available models as well as the potential commercial opportunity. In line with these plans, the Company is building upon both its external and in house scientific expertise, which will be essential to its drug development effort.

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

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not necessarily include all information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at March 31, 2023 is derived from the Company’s audited consolidated balance sheet at that date.

The unaudited condensed consolidated financial statements include the accounts of Organovo and its wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the unaudited financial information for the interim periods presented reflects all adjustments, which are only normal and recurring, necessary for a fair statement of the Company's financial position, results of operations, stockholders' equity and cash flows. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended March 31, 2023, as filed with the Securities and Exchange Commission ("SEC"). Operating results for any interim period are not necessarily indicative of the operating results for any other interim period or the Company's full fiscal year ending March 31, 2024 (see "Note 1. Description of Business").

Liquidity and Going Concern

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 December 31, 2023, the Company had cash and cash equivalents of approximately \$5.3 million, restricted cash of approximately \$0.1 million and an accumulated deficit of approximately \$336.6 million. The restricted cash was pledged as collateral for a letter of credit that the Company is required to maintain as a security deposit under the terms of the lease agreement for its facilities. The Company also had negative cash flows from operations of approximately \$12.0 million during the nine months ended December 31, 2023.

Through December 31, 2023, 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 service-based services, grants, and collaborative research agreements, and from the sale of convertible notes. During the nine months ended December 31, 2023, the Company issued 934,621 shares of its common stock through its ATM facility.

Based on the Company's current operating plan and available cash resources, it will need substantial additional funding to support future operating activities. The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by it raise substantial doubt about its 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 the Company be unable to continue as a going concern. As the Company continues its operations and is focusing its efforts on drug discovery and development, the Company will need to raise additional capital to implement this business plan. The Company cannot predict with certainty the exact amount or timing for any future capital raises. The Company will seek to raise additional capital through debt or equity financings, or through some other financing arrangement. However, the Company cannot be sure that additional financing will be available if and when needed, or that, if available, it can obtain financing on terms favorable to its stockholders. Any failure to obtain financing when required will have a material adverse effect on the Company's business, operating results, and financial condition.

Use of Estimates

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

Investments

Investments consist of investments in debt securities and investments in equity securities.

Investments in debt securities consist of investments in U.S. Treasury bills. All investments that have original maturities of three months or less are classified as cash equivalents on the Condensed Consolidated Balance Sheets. Prior to December 31, 2022, the Company classified certain investments as held-to-maturity. All investments previously classified as held-to-maturity matured prior to December 31, 2022. As of December 31, 2023 and March 31, 2023, all investments are 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 have minimal risk, any declines in fair value are considered temporary.

Investments in equity securities consist of investments in the common stock of entities traded in active markets. The Company does not have the ability to exercise significant influence over any entities. Therefore, initial investments are recorded at cost, and are remeasured at fair value as of the balance sheet date. Any gains or losses resulting from the change in fair value are recorded in net income. The investments in equity securities are classified as current assets.

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.

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 excludes any assumed exercise of stock options, shares reserved for purchase under the Company's 2016 Employee Stock Purchase Plan ("2016 ESPP"), the assumed vesting of restricted stock units ("RSUs"), and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for each of the three and nine months ended December 31, 2023 and 2022 as the Company reported a net loss for each respective period and the effect would have been anti-dilutive.

Common stock equivalents excluded from computing diluted net loss per share due to their anti-dilutive effect were approximately 0.8 million at December 31, 2023 and 1.5 million at December 31, 2022.

Revenue recognition

The Company has generated revenues from payments received from licensing intellectual property.

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 vs. agent, whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company 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.

Recent Accounting Pronouncements

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

Note 3. Investments and Fair Value Measurement

Investments in debt securities

As of December 31, 2023, the Company held \$2.0 million of investments in debt securities (which are included in the \$5.3 million of cash and cash equivalents). For the three and nine months ended December 31, 2023, there was less than \$0.1 million and \$0.1 million, respectively, 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 following table summarizes the Company's investments in debt securities that are measured at fair value as of December 31, 2023 (in thousands):

	Amortized costs basis	Gross unrealized gains	Gross unrealized losses	Fair value
As of March 31, 2023				
Investment in debt securities	\$ 4,943	\$ 2	\$ —	\$ 4,945
As of December 31, 2023				
Investment in debt securities	\$ 1,995	\$ —	\$ —	\$ 1,995

Investments in equity securities

For the nine months ended December 31, 2023, there was \$0.7 million of equity securities liquidated and less than a \$0.1 million gain on the investment in equity securities. As of December 31, 2023, the fair value of investment in equity securities was zero, as a result of the liquidation of the shares by the underlying company on June 26, 2023. As the investment in equity securities consists of common stock from active markets, the fair value is measured using level 1 inputs.

The following table presents the activity for investments in equity securities measured at fair value for the nine months ended December 31, 2023 (in thousands):

	Investment in Equity Securities (in thousands)
Balance at March 31, 2023	\$ 706
Liquidation of equity securities	(718)
Gain on investment in equity securities	12
Balance at December 31, 2023	\$ —

Note 4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2023	March 31, 2023
Accrued compensation	\$ 439	\$ 609
Accrued legal and professional fees	97	193
Acquired in-process research and development	—	2,000
Other accrued expenses	191	46
	\$ 727	\$ 2,848

Note 5. Stockholders' Equity

Preferred Stock

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

Common Stock

In March 2021, the Company's Board of Directors ("Board") approved the 2021 Inducement Equity Incentive Plan ("Inducement Plan"). The Inducement Plan authorized the issuance of up to 750,000 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. The only persons eligible to receive grants under the Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq guidance. The Company also committed to reducing the aggregate number of shares of its common stock issuable pursuant to the Inducement Plan from 750,000 shares to 51,000 shares (which includes 50,000 shares of its common stock issuable pursuant to an outstanding option to purchase common stock with an exercise price of \$2.75 per share, leaving only 1,000 shares available for future issuance under the Inducement Plan) and the share reserve was reduced accordingly effective October 12, 2022. As of December 31, 2023, there were 1,000 shares available for future grant under the Inducement Plan.

On October 12, 2022, the Company's stockholders and the Board approved the 2022 Equity Incentive Plan ("2022 Plan"), and it became effective on that date. The 2022 Plan replaced the Amended and Restated 2012 Equity Incentive Plan ("2012 Plan") on the effective date. Upon the effective date, the Company ceased granting awards under the 2012 Plan and any shares remaining available for future issuance under the 2012 Plan were cancelled and are no longer available for future issuance. The 2012 Plan continues to govern awards previously granted under it. At the time the Board approved the 2022 Plan, an aggregate of 1,363,000 shares of the Company's common stock was initially reserved for issuance under the 2022 Plan. The Company committed to reducing the 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 126,262 shares of its common stock under the 2012 Plan. As a result, the number of shares initially reserved for future issuance under the 2022 Plan was 1,236,738 shares of common stock.

The Company previously had an effective shelf registration statement on Form S-3 (File No. 333-222929), declared effective by the SEC on February 22, 2018 (the "2018 Shelf"), which registered \$100.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that expired on February 22, 2021. On January 19, 2021, the Company filed a shelf registration statement on Form S-3 (File No. 333-252224) 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 "2021 Shelf"). The 2021 Shelf was declared effective by the SEC on January 29, 2021 and replaced the 2018 Shelf at that time. 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 has not yet been declared effective by the SEC.

On March 16, 2018, the Company entered into a Sales Agreement ("Sales Agreement") with H.C. Wainwright & Co., LLC and Jones Trading Institutional Services LLC (each an "Agent" and together, the "Agents"). On January 29, 2021, the Company filed a prospectus supplement to the 2021 Shelf (the "2021 ATM Prospectus Supplement"), pursuant to which the Company may offer and sell, from time to time, through the Agents, shares of its common stock in ATM sales transactions having an aggregate offering price of up to \$50.0 million. Any shares offered and sold will be issued pursuant to the 2021 Shelf until it is replaced by the 2024 Shelf. During each of the three and nine months ended December 31, 2023, the Company issued 934,621 shares of common stock in ATM offerings under the 2021 ATM Prospectus Supplement. As of December 31, 2023, the Company had sold an aggregate of 2,515,483 shares of common stock in ATM offerings, with gross proceeds of approximately \$22.9 million. As of December 31, 2023, there was approximately \$100.0 million available for future offerings under the 2021 Shelf (excluding amounts available but not yet issued under the ATM Prospectus Supplement), and approximately \$27.1 million available for future offerings through the Company's ATM program under the 2021 ATM Prospectus Supplement. On January 26, 2024, the Company filed a prospectus to the 2024 Shelf (the "2024 ATM Prospectus"), pursuant to which the Company may offer and sell, from time to time, through the Agents, shares of its common stock in ATM sales transactions having an aggregate offering price of up to \$2,605,728. Any shares offered and sold in these ATM sales transactions will be issued pursuant to the 2024 Shelf.

Restricted Stock Units

The following table summarizes the Company's RSUs activity for the nine months ended December 31, 2023:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2023	127,717	\$ 2.22
Granted	117,642	\$ 1.39
Vested	(121,467)	\$ 1.81
Cancelled / forfeited	—	\$ —
Unvested at December 31, 2023	123,892	\$ 1.84

Stock Options

During the three and nine months ended December 31, 2023, under the 2022 Plan, 40,000 and 171,257 stock options were granted at various exercise prices, respectively.

On August 28, 2023, the Company's Executive Chairman voluntarily forfeited 462,500 outstanding stock options, of which 312,918 were unvested and therefore cancelled, and 149,582 were vested and therefore expired. The forfeited stock option awards were not replaced by other awards or other compensation and there is no plan to replace the forfeited awards. Therefore, all previous unrecognized compensation expense associated with the forfeited awards, approximately \$519,000, was recognized as a selling, general, and administrative expense on the date of forfeiture.

The following table summarizes the Company's stock option activity from March 31, 2023 to December 31, 2023:

	Options Outstanding	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2023	1,451,217	\$ 6.49	\$ 38,327
Options granted	171,257	\$ 1.72	\$ —
Options cancelled / forfeited	(593,384)	\$ 7.10	\$ —
Options expired	(333,631)	\$ 7.42	\$ —
Outstanding at December 31, 2023	<u>695,459</u>	\$ 4.35	\$ —
Vested and Exercisable at December 31, 2023	<u>381,029</u>	\$ 5.83	\$ —

The weighted average remaining contractual term of stock options exercisable and outstanding at December 31, 2023 was approximately 7.36 years.

Employee Stock Purchase Plan

In June 2016, the Board adopted, and in August 2016, the Company's stockholders subsequently approved, the 2016 ESPP. The Company reserved 75,000 shares of common stock for issuance thereunder. As of October 31, 2023, the 2016 ESPP was replaced by the 2023 ESPP (as defined below).

In July 2023, the Board adopted, and on October 31, 2023, the Company's stockholders subsequently approved, the 2023 Employee Stock Purchase Plan (the "2023 ESPP"). The 2023 ESPP became effective on October 31, 2023 and replaced the 2016 ESPP on that date. The Company reserved 45,000 shares of common stock for issuance thereunder. The 2023 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 500 shares per employee per six-month purchase period. Shares under the 2023 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 2023 ESPP will commence in March 2024.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following at December 31, 2023:

Common stock issuable pursuant to options outstanding and reserved under the 2012 Plan	440,591
Common stock reserved under the 2012 Plan	—
Common stock issuable pursuant to options outstanding and reserved under the 2022 Plan	204,868
Common stock reserved under the 2022 Plan	1,643,798
Common stock reserved under the 2023 ESPP	45,000
Common stock reserved under the 2021 Inducement Equity Plan	1,000
Common stock issuable pursuant to restricted stock units outstanding under the 2012 Plan	6,250
Common stock issuable pursuant to restricted stock units outstanding under the 2022 Plan	117,642
Common stock issuable pursuant to options outstanding and reserved under the Inducement Plan	<u>50,000</u>
Total at December 31, 2023	<u>2,509,149</u>

Stock-based Compensation Expense and Valuation Information

Stock-based awards include stock options and RSUs under the 2022 Plan, 2012 Plan, Inducement Plan, and rights to purchase stock under the 2023 ESPP. The Company calculates the grant date fair value of all stock-based awards in determining the stock-based compensation expense.

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

	Three Months Ended December 31, 2023	Three Months Ended December 31, 2022	Nine Months Ended December 31, 2023	Nine Months Ended December 31, 2022
Research and development	\$ 40	\$ 117	\$ 87	\$ 363
General and administrative	117	427	1,220	1,514
Total	<u>\$ 157</u>	<u>\$ 544</u>	<u>\$ 1,307</u>	<u>\$ 1,877</u>

The total unrecognized compensation cost related to unvested stock option grants as of December 31, 2023 was approximately \$0.6 million and the weighted average period over which these grants are expected to vest is 2.30 years.

The total unrecognized compensation cost related to unvested RSUs as of December 31, 2023 was \$0.2 million, which will be recognized over a weighted average period of 0.97 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:

	Three Months Ended December 31, 2023	Three Months Ended December 31, 2022	Nine Months Ended December 31, 2023	Nine Months Ended December 31, 2022
Dividend yield	—	—	—	—
Volatility	100.31 %	95.93 %	98.93 %	95.43 %
Risk-free interest rate	4.66 %	3.97 %	4.12 %	3.21 %
Expected life of options	6.00 years	6.00 years	6.00 years	6.00 years
Weighted average grant date fair value	\$ 1.16	\$ 1.23	\$ 1.38	\$ 1.96

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 2016 ESPP and the 2023 ESPP. Stock-based compensation expense is recognized over the purchase period using the straight-line method. The fair value of ESPP shares was estimated at the purchase period commencement date using the following assumptions:

	Three Months Ended December 31, 2023*	Three Months Ended December 31, 2022*	Nine Months Ended December 31, 2023*	Nine Months Ended December 31, 2022
Dividend yield	—	—	—	—
Volatility	0.00 %	0.00 %	0.00 %	86.58 %
Risk-free interest rate	0.00 %	0.00 %	0.00 %	3.34 %
Expected term	—	—	—	6 months
Grant date fair value	\$ —	\$ —	\$ —	\$ 0.82

*There were no participants in the 2016 ESPP or the 2023 ESPP for the purchase periods beginning September 1, 2022, March 1, 2023 or September 1, 2023.

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

Note 6. Collaborative Research, Development, and License Agreements

License Agreements

From June 2021 to February 2022, certain patents owned or sublicensed by the Company became the subject of *inter partes* review proceedings filed by Cellink AB and its subsidiaries (collectively, "BICO Group AB"). The Company and BICO Group AB were also engaged in litigation regarding patent infringement during the same time period. On February 22, 2022, the Company and BICO Group AB signed a settlement and patent license agreement ("License Agreement") to close all matters noted above. In addition to closing all legal matters and patent disputes noted above, as part of the agreement, 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. The Company concluded that the nature of the license granted represents functional intellectual property.

As part of the License Agreement, BICO Group AB agreed to pay the Company ongoing sales-based royalties (based on percentages of BICO Group AB's net sales) for the use of the granted license. The sales-based royalties became effective beginning on February 22, 2022, the effective date of the License Agreement, and continue 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. The Company estimated royalty revenue of \$33,000 for the three months ended December 31, 2023. However, there was a decrease adjustment of approximately \$28,000 relating to the prior quarter. For the three and nine months ended December 31, 2023, the Company recorded \$5,000 and \$80,000 of royalty revenue based on sales-based royalties from the License Agreement, respectively.

Also as part of the License Agreement, certain patents involved in the agreement are sublicensed by the Company from the University of Missouri and 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 ("University of Missouri") to in-license certain technology and intellectual property relating to self-assembling cell aggregates and intermediate cellular units. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company 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.

The license agreement with the University of Missouri also includes an additional sales royalty of 3% of all revenue received from a sublicensee, when such sublicense is entered pursuant to settlement of litigation. Such revenue shall include, but not be limited to, all option fees, license issue fees (up-front payments), license maintenance fees, equity, and all royalty payments. Such revenue shall not include research funding provided to licensee by sublicensee. However, per the agreement, in the event that the Company defends the technology by litigation, it can offset any royalties due by legal expenses incurred. No royalty expense related to sales-based royalties has been recorded to date.

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

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 is required to pay CURF 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 terminates upon expiration of the patents licensed, which are expected to expire in May 2024, and is subject to certain conditions as defined in the license agreement. Minimum annual royalty payments of \$20,000 were due for two years beginning in calendar 2014, and \$40,000 per year beginning in calendar 2016. Royalty payments of \$40,000 were made in each of the years ended March 31, 2023 and 2022. The annual minimum royalty is creditable against royalties owed during the same calendar year.

In addition to the annual royalties noted above, CURF is 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 defends the technology by litigation, it can offset any royalties due by legal expenses incurred. As of December 31, 2023, the Company's legal expenses exceeded royalties owed from the upfront payment and sales-based royalties related to the license agreement. Therefore, no royalty expense to CURF was recorded for the nine months ended December 31, 2023. No royalty expense related to sales-based royalties has been recorded to date.

Note 7. 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.

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

The Company regularly reviews contingencies to determine the adequacy of its accruals and related disclosures. During the period presented, the Company has not recorded any accrual for loss contingencies associated with any claims or legal proceedings; determined that an unfavorable outcome is probable or reasonably possible; or determined that the amount or range of any possible loss is reasonably estimable. However, the outcome of legal proceedings and claims brought against the Company is subject to significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, 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 8. Leases

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

Operating Leases

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

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

The table below summarizes the Company's lease liabilities and corresponding right-of-use assets as of December 31, 2023 (in thousands except the year and percentage):

	December 31, 2023
ASSETS	
Operating lease right-of-use assets	\$ 1,403
Total lease right-of-use assets	<u>\$ 1,403</u>
LIABILITIES	
Current	
Operating lease liability	\$ 502
Noncurrent	
Operating lease liability, net of current portion	\$ 999
Total lease liabilities	<u>\$ 1,501</u>
Weighted average remaining lease term:	3.08
Weighted average discount rate:	6%

Variable lease expense was approximately \$39,000 and \$114,000 for the three and nine months ended December 31, 2023, respectively, and approximately \$34,000 and \$110,000 for the three and nine months ended December 31, 2022, respectively. Operating lease expense was approximately \$125,000 and \$377,000 for the three and nine months ended December 31, 2023, respectively, and approximately \$114,000 and \$373,000 for the three and nine months ended December 31, 2022, respectively.

Cash flows associated with the Company's operating lease for the three and nine months ended December 31, 2023, were approximately \$125,000 and \$377,000, respectively, and approximately \$59,000 and \$304,000 for the three and nine months ended December 31, 2022, respectively.

Future lease payments relating to the Company's operating lease liabilities as of December 31, 2023, are as follows (in thousands):

Fiscal year ending March 31, 2024	\$ 129
Fiscal year ending March 31, 2025	523
Fiscal year ending March 31, 2026	538
Fiscal year ending March 31, 2027	460
Total future lease payments	<u>1,650</u>
Less: Imputed interest	(149)
Total lease obligations	<u>1,501</u>
Less: Current obligations	(502)
Noncurrent lease obligations	<u>\$ 999</u>

Note 9. Concentrations

Credit risk and significant customers

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments. The Company maintains cash balances at various financial institutions located within the United States. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. Balances may exceed federally insured limits. The Company is also potentially subject to concentrations of credit risk in its revenues and accounts receivable. However, the Company only receives royalty revenue from one licensee and has not historically experienced any accounts receivable write-downs.

Note 10. Related Parties

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

Viscient Biosciences (“Viscient”) is an entity for which Keith Murphy, the Company’s Executive Chairman, serves as the Chief Executive Officer and President. Dr. Jeffrey Miner, the Company’s former Chief Scientific Officer, is also the Chief Scientific Officer of Viscient, and Thomas Jurgensen, the Company’s former General Counsel, previously served as outside legal counsel to Viscient through his law firm, Optima Law Group, APC.

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 include, but are 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. The Company evaluated the accounting for the Intercompany Agreement and concluded that any services provided by Viscient to the Company will be expensed as incurred, and any compensation for services provided by the Company to Viscient will be considered a reduction of personnel related expenses. Any services provided to Viscient do not fall under Topic 606 as the Intercompany Agreement is not a contract with a customer. For the three and nine months ended December 31, 2023 and 2022, the Company incurred no consulting expenses from Viscient. Additionally, for the three and nine months ended December 31, 2023, the Company provided approximately \$3,000 and \$13,000 of histology services to Viscient, respectively, and \$17,000 and \$44,000 for the three and nine months ended December 31, 2022, respectively.

Note 11. 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 has 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 estimates that it will incur approximately \$0.4 million of cash expenditures in connection with the reduction in force, which relate to severance pay, and are expected to be incurred through the quarter ending March 31, 2024. The Company anticipates annual cost savings of \$1.5 million resulting from the reduction in force.

Approximately \$0.4 million of restructuring charges were recorded during the nine months ended December 31, 2023, and no restructuring charges were recorded during the three months ended December 31, 2023.

(in thousands)	Three Months Ended December 31, 2023	Nine Months Ended December 31, 2023
Severance for Involuntary Employee Terminations	\$ —	\$ 380
Total Restructuring Expense	\$ —	\$ 380

The following table summarizes the activity and balances of the restructuring reserve (in thousands):

	Severance for Involuntary Employee Terminations
Balance at March 31, 2023	\$ —
Increase to reserve	380
Utilization of reserve:	
Payments	(263)
Balance at December 31, 2023	\$ 117

Note 12. Subsequent Events

Between January 1, 2024 and February 8, 2024, the Company issued 201,319 shares of common stock in ATM offerings under the 2021 ATM Prospectus Supplement for net proceeds of approximately \$0.2 million.



1,562,500 shares of Common Stock
Pre-Funded Warrants to Purchase up to 5,000,000 Shares of Common Stock
Common Warrants to Purchase up to 6,562,500 Shares of Common Stock
Up to 11,562,500 Shares of Common Stock Underlying the Pre-Funded Warrants and Common Warrants

Common Stock

PROSPECTUS

Jones 

May 8, 2024
