UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-Q

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

For the quarterly period ended June 30, 2024

OR

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

For the transition period from _____ to

Commission File Number 001-35996

Organovo Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**27-1488943**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11555 Sorrento Valley Rd, Suite 100, San Diego, CA 92121	**(858) 224-1000**
(Address of principal executive offices and zip code)	**(Registrant's telephone number, including area code)**

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of August 1, 2024, a total of 15,364,076 shares of the registrant's Common Stock, $0.001 par value, were outstanding.

ORGANOVO HOLDINGS, INC.

INDEX

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2024	March 31, 2024
	(Unaudited)	
Assets		
Current Assets		
Cash and cash equivalents	$ 6,187	$ 2,901
Accounts receivable	48	33
Inventory	408	297
Prepaid expenses and other current assets	640	705
Total current assets	7,283	3,936
Fixed assets, net	601	669
Restricted cash	143	143
Operating lease right-of-use assets	1,194	1,299
Prepaid expenses and other assets, net	249	302
Total assets	$ 9,470	$ 6,349
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 1,119	$ 627
Accrued expenses	404	727
Operating lease liability, current portion	510	506
Total current liabilities	2,033	1,860
Operating lease liability, net of current portion	775	888
Total liabilities	2,808	2,748
Commitments and Contingencies (Note 7)		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 14,373,076 and 10,077,726 shares issued and outstanding at June 30, 2024 and March 31, 2024, respectively	14	10
Additional paid-in capital	349,662	343,261
Accumulated deficit	(343,013)	(339,669)
Treasury stock, 46 shares at cost	(1)	(1)
Total stockholders' equity	6,662	3,601
Total Liabilities and Stockholders' Equity	$ 9,470	$ 6,349

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 June 30, 2024	Three Months Ended June 30, 2023
Revenues		
Royalty revenue	$ 25	$ 75
Product revenue	14	—
Total Revenues	39	75
Cost of revenues	2	—
Research and development expenses	1,402	1,666
Selling, general and administrative expenses	2,021	2,604
Total costs and expenses	3,425	4,270
Loss from Operations	(3,386)	(4,195)
Other Income		
Gain on investment in equity securities	—	12
Interest income	44	157
Total Other Income	44	169
Income Tax Expense	(2)	(2)
Net Loss	$ (3,344)	$ (4,028)
Net loss per common share—basic and diluted	$ (0.23)	$ (0.46)
Weighted average shares used in computing net loss per common share—basic and diluted	14,663,693	8,717,232
Comprehensive loss:		
Net loss	$ (3,344)	$ (4,028)
Comprehensive loss	$ (3,344)	$ (4,028)

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 Months Ended June 30, 2024							
	Common Stock			Treasury Stock				
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
Balance at March 31, 2024	**10,078**	**$ 10**	**$ 343,261**	**—**	**$ (1)**	**$ (339,669)**	**$ —**	**$ 3,601**
Issuance of common stock under employee and director stock option, RSU, and purchase plans	1	—	—	—	—	—	—	—
Issuance of common stock from exercise of pre-funded warrants	1,379	1	—	—	—	—	—	1
Issuance of common stock from public offering, net	2,915	3	6,245	—	—	—	—	6,248
Stock-based compensation expense	—	—	156	—	—	—	—	156
Net loss	—	—	—	—	—	(3,344)	—	(3,344)
Balance at June 30, 2024 (Unaudited)	**14,373**	**$ 14**	**$ 349,662**	**—**	**$ (1)**	**$ (343,013)**	**$ —**	**$ 6,662**

	Three Months Ended June 30, 2023							
	Common Stock			Treasury Stock				
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
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**

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)

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023
Cash Flows From Operating Activities		
Net loss	$ (3,344)	$ (4,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on investment in equity securities	—	(12)
Accretion on investments	(22)	(60)
Depreciation and amortization	70	67
Stock-based compensation	156	475
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(15)	3
Inventory	(111)	—
Prepaid expenses and other assets	118	149
Accounts payable	492	157
Accrued expenses	(323)	(2,061)
Operating lease right-of-use assets and liabilities, net	(4)	(1)
Net cash used in operating activities	(2,983)	(5,311)
Cash Flows From Investing Activities		
Purchases of fixed assets	—	(15)
Purchases of investments	(1,480)	(4,939)
Maturities of investments	1,500	5,000
Liquidation of equity securities	—	718
Net cash provided by investing activities	20	764
Cash Flows From Financing Activities		
Proceeds from issuance of common stock, net	6,249	—
Net cash provided by financing activities	6,249	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	3,286	(4,547)
Cash, cash equivalents, and restricted cash at beginning of period	3,044	15,444
Cash, cash equivalents, and restricted cash at end of period	$ 6,330	$ 10,897
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 6,187	$ 10,754
Restricted cash	143	143
Total cash, cash equivalents, and restricted cash	$ 6,330	$ 10,897
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 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 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 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 2025. The Company released Phase 2 data for FXR314 for the treatment of metabolic function-associated steatohepatitis (“MASH”) in April 2024 that is supportive of ongoing development, and the Company believes FXR314 has a commercial opportunity in MASH, most likely in combination therapy. The Company is exploring the potential for combination therapies using FXR314 and currently approved mechanisms in preclinical animal studies and the Company's IBD disease models.

The Company's second focus 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. The Company 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.

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

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 subsidiary, Organovo, Inc.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not necessarily include all information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at March 31, 2024 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 subsidiary. 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, 2024, 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, 2025 (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 June 30, 2024, the Company had cash and cash equivalents of approximately $6.2 million, restricted cash of approximately $0.1 million and an accumulated deficit of approximately $343.0 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 agreement for its facilities. The Company also had negative cash flows from operations of approximately $3.0 million during the three months ended June 30, 2024.

Through June 30, 2024, 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 three months ended June 30, 2024, the Company issued 1,352,600 shares of its common stock through its ATM facility, for net proceeds of approximately $1.7 million.

Additionally, on May 8, 2024, the Company priced a best efforts public offering (the "Offering") of: (i) 1,562,500 shares of its common stock and accompanying common warrants ("Common Warrants") to purchase up to 1,562,500 shares of common stock at a combined public offering price of $0.80 per share and accompanying Common Warrant to purchase one share of common stock and (ii) pre-funded warrants ("Pre-Funded Warrants") to purchase 5,000,000 shares of common stock and accompanying Common Warrants to purchase up to 5,000,000 shares of common stock at a combined public offering price of $0.799 per Pre-Funded Warrant and accompanying Common Warrant to purchase one share of common stock. The closing of the Offering occurred on May 13, 2024. The Company received net proceeds of approximately $4.5 million from the Offering, after deducting the estimated offering expenses payable by the Company, including the Placement Agent fees.

On July 18, 2024, the Company received a written notice (the "Notice") from the Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the last 30 consecutive business days, the Company no longer meets the requirement to maintain a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided with an initial period of 180 calendar days, or until January 14, 2025, to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of the Company's common stock must be at least $1 per share for a minimum of ten consecutive business days during this 180-day period. The Notice provides that the Nasdaq staff will provide written confirmation to the Company if the Company regains compliance with Rule 5550(a)(2). If the Company does not regain compliance with Rule 5550(a)(2) by January 14, 2025, the Company may be eligible for an additional compliance period of 180 calendar days. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice to Nasdaq of its intention to cure the bid price deficiency during the second compliance period. However, if it appears to the

Nasdaq staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq would notify the Company that its securities will be subject to delisting. In the event of such a notification, the Company may appeal the Nasdaq staff's determination to delist its securities, but there can be no assurance the Nasdaq staff would grant any request for continued listing.

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 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. As of June 30, 2024 and March 31, 2024, 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.

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.

Inventory

Inventories are stated at the lower of cost or net realizable value. Inventory as of June 30, 2024 and March 31, 2024 consisted of approximately $0.4 million and $0.3 million in finished goods, respectively, which is related to Mosaic. Please refer to "Note 11. Business Segment Information" for further information.

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 2023 Employee Stock Purchase Plan ("2023 ESPP"), the assumed vesting of restricted stock units ("RSUs"), the exercise of warrants, and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the three months ended June 30, 2024 and 2023 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 11.1 million at June 30, 2024 and 1.7 million at June 30, 2023.

Revenue recognition

Royalty revenue

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

The Company considered a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the Company is a principal vs. agent, whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company evaluates each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, sales-based royalty payments have been identified as variable consideration which must be evaluated to determine if it has been constrained and, therefore, excluded from the transaction price. Please refer to "Note 6: Collaborative Research, Development, and License Agreements" for further information.

Product revenue, net

The Company's product-based division, Mosaic, produces high-quality cell-based products for use in Organovo's R&D and for use by life science customers. The Company recognizes product revenue when the performance obligation is satisfied, which is at the point in time the customer obtains control of the Company's product, typically upon delivery. Product revenues are recorded at the transaction price under Topic 606. The Company provides no right of return to its customers except in cases where a customer obtains authorization from the Company for the return. To date, there have been no product returns.

Recent Accounting Pronouncements

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

In December 2023, the FASB issued Accounting Standards Update ("ASU") 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The update requires a public business entity to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. Adoption of the ASU allows for either the prospective or retrospective application of the amendment and is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company has not yet completed its assessment of the impact of ASU 2023-09 on the Company's Consolidated Financial Statements.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. The ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of this guidance.

Note 3. Investments and Fair Value Measurement

Investments in debt securities

As of June 30, 2024, the Company held $1.5 million of investments in debt securities (which are included in the $6.2 million of cash and cash equivalents). For the three months ended June 30, 2024, there was less than $0.1 million of interest income related to the investments in debt securities. As the investments in debt securities consist of U.S. Treasury bills from active markets, the fair value is measured using level 1 inputs.

The following table summarizes the Company's investments in debt securities that are measured at fair value as of June 30, 2024 and March 31, 2024, respectively (in thousands):

	Amortized costs basis	Gross unrealized gains	Gross unrealized losses	Fair value
As of June 30, 2024				
Investment in debt securities	$ 1,490	$ —	$ —	$ 1,490
As of March 31, 2024				
Investment in debt securities	$ 997	$ 1	$ —	$ 998

Note 4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2024	March 31, 2024
Accrued compensation	$ 265	$ 536
Accrued legal and professional fees	57	93
Other accrued expenses	82	98
	$ 404	$ 727

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 June 30, 2024, 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. 333-252224), declared effective by the SEC on January 29, 2021 (the “2021 Shelf”), which registered $150.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that expired on January 29, 2024. On January 26, 2024, the Company filed a new shelf registration statement on Form S-3 (File No. 333-276722) to register $150.0 million of the Company's common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the "2024 Shelf"). The 2024 Shelf was declared effective by the SEC on February 8, 2024 and replaced the 2021 Shelf at that time.

On March 16, 2018, the Company entered into a Sales Agreement (“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 were issued pursuant to the 2021 Shelf until it was replaced by the 2024 Shelf.

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, share 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 transactions will be issued pursuant to the 2024 Shelf.

During the three months ended June 30, 2024, the Company issued 1,352,600 shares of common stock in ATM offerings for net proceeds of approximately $1.7 million, all of which were sold pursuant to the 2024 Shelf. As of June 30, 2024, the Company has sold an aggregate of 1,389,002 shares of common stock in ATM offerings under the 2024 ATM Prospectus, with gross proceeds of approximately $1.8 million and net proceeds of approximately $1.8 million. As of June 30, 2024, there was approximately $100.0 million available for future offerings under the 2024 Shelf, and approximately $0.8 million available for future offerings through the Company’s ATM program under the 2024 ATM Prospectus.

May 2024 Best Efforts Public Offering

On May 8, 2024, the Company priced a best efforts public offering (the “Offering”) of: (i) 1,562,500 shares of its common stock and accompanying common warrants (“Common Warrants”) to purchase up to 1,562,500 shares of common stock at a combined public offering price of $0.80 per share and accompanying Common Warrant to purchase one share of common stock and (ii) pre-funded warrants (“Pre-Funded Warrants”) to purchase 5,000,000 shares of common stock and accompanying Common Warrants to purchase up to 5,000,000 shares of common stock at a combined public offering price of $0.799 per Pre-Funded Warrant and accompanying Common Warrant to purchase one share of common stock. In connection with the Offering, the Company entered into Securities Purchase Agreements with the purchasers of the securities in the Offering on May 8, 2024.

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

The per share exercise price for the Common Warrants is $0.80, subject to adjustment as provided therein. The Common Warrants were immediately exercisable, subject to certain beneficial ownership limitations, and will expire on the date that is five years following the original issuance date. If a registration statement covering the issuance of the shares of common stock issuable upon exercise of the Common Warrants is not available for the issuance, then the holders may exercise the Common Warrants by means of a "cashless exercise."

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

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

Restricted Stock Units

The following table summarizes the Company's RSUs activity for the three months ended June 30, 2024:

	Number of Shares		Weighted Average Price
Unvested at March 31, 2024	122,642	$	1.75
Granted	—	$	—
Vested	(1,250)	$	10.27
Cancelled / forfeited	—	$	—
Unvested at June 30, 2024	121,392	$	1.66

Stock Options

During the three months ended June 30, 2024, under the 2022 Plan, 144,227 stock options were granted at various exercise prices.

The following table summarizes the Company's stock option activity from March 31, 2024 to June 30, 2024:

	Options Outstanding		Weighted Average Exercise Price		Aggregate Intrinsic Value
Outstanding at March 31, 2024	698,007	$	4.26	$	—
Options granted	144,227	$	0.99	$	—
Options cancelled / forfeited	(6,912)	$	3.30	$	—
Options expired	—	$	—	$	—
Outstanding at June 30, 2024	835,322	$	3.70	$	—
Vested and Exercisable at June 30, 2024	435,188	$	5.40	$	—

The weighted average remaining contractual term of stock options exercisable and outstanding at June 30, 2024 was approximately 7.11 years.

Warrants

In connection with the Offering described above, the Company issued Common Warrants to purchase up to 1,562,500 shares of common stock at a combined public offering price of $0.80 per share and accompanying Common Warrant to purchase one share of common stock and (ii) Pre-Funded Warrants to purchase 5,000,000 shares of common stock and accompanying Common Warrants to purchase up to 5,000,000 shares of common stock at a combined public offering price of $0.799 per Pre-Funded Warrant and accompanying Common Warrant to purchase one share of common stock. The Company has determined that these warrants should be classified as equity instruments since they do not require the Company to repurchase the underlying common stock and do not require

the Company to issue a variable amount of common stock. In addition, these warrants are indexed to common stock and do not have any antidilution rights.

The following table summarizes the Company's Common Warrant activity from March 31, 2024 to June 30, 2024:

	Number of Warrants		Exercise Price
Outstanding at March 31, 2024	—	$	—
Issued	6,562,500	$	0.80
Exercised	—	$	0.80
Outstanding at June 30, 2024	6,562,500	$	0.80

The following table summarizes the Company's Pre-Funded Warrants activity from March 31, 2024 to June 30, 2024:

	Number of Warrants		Exercise Price
Outstanding at March 31, 2024	—	$	—
Issued	5,000,000	$	0.001
Exercised	(1,379,000)	$	0.001
Outstanding at June 30, 2024	3,621,000	$	0.001

Employee Stock Purchase Plan

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. 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 commenced on March 1, 2024.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consisted of the following at June 30, 2024:

Common stock issuable pursuant to options outstanding and reserved under the 2012 Plan	428,296
Common stock reserved under the 2012 Plan	—
Common stock issuable pursuant to options outstanding and reserved under the 2022 Plan	357,026
Common stock reserved under the 2022 Plan	1,569,724
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	3,750
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
Common stock issuable pursuant to outstanding pre-funded warrants	3,621,000
Common stock issuable pursuant to outstanding common warrants	6,562,500
Total at June 30, 2024	12,755,938

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 June 30, 2024	Three Months Ended June 30, 2023
Research and development	$ 26	$ 107
General and administrative	130	368
Total	$ 156	$ 475

The total unrecognized compensation cost related to unvested stock option grants as of June 30, 2024 was approximately $0.5 million and the weighted average period over which these grants are expected to vest is 2.38 years.

The total unrecognized compensation cost related to unvested RSUs as of June 30, 2024 was $0.1 million, which will be recognized over a weighted average period of 0.49 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 June 30, 2024	Three Months Ended June 30, 2023
Dividend yield	—	—
Volatility	101.69%	98.51%
Risk-free interest rate	4.47%	3.95%
Expected life of options	6 years	6 years
Weighted average grant date fair value	$ 0.80	$ 1.45

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 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 June 30, 2024	Three Months Ended June 30, 2023*
Dividend yield	—	—
Volatility	95.20%	0.00%
Risk-free interest rate	5.27%	0.00%
Expected term	6 months	—
Grant date fair value	$ 0.39	$ —

*There were no participants in the ESPP for the purchase period beginning March 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

BICO Group AB

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. For the three months ended June 30, 2024, the Company recorded $31,000 of royalty revenue based on sales-based royalties from the License Agreement. Royalty revenue presented on the Statements of Operations and Other Comprehensive Loss is $25,000 for the three months ended June 30, 2024, due to a decrease adjustment related to the prior quarter.

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.

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

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 expired 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, 2024 and 2023. The annual minimum royalty is creditable against royalties owed during the same calendar year. As the licensed patents expired in May 2024, there will be no further royalty payments owed.

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 June 30, 2024, 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 three months ended June 30, 2024 and 2023, respectively. 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 June 30, 2024 (in thousands except the year and percentage):

	June 30, 2024
ASSETS	
Operating lease right-of-use assets	$ 1,194
Total lease right-of-use assets	$ 1,194
LIABILITIES	
Current	
Operating lease liability	$ 510
Noncurrent	
Operating lease liability, net of current portion	$ 775
Total lease liabilities	$ 1,285
Weighted average remaining lease term:	2.58
Weighted average discount rate:	6%

Variable lease expense was approximately $1,000 and $36,000 for the three months ended June 30, 2024 and 2023, respectively. Operating lease expense was approximately $126,000 for the three months ended June 30, 2024 and 2023, respectively.

Cash flows associated with the Company's operating lease for the three months ended June 30, 2024 and 2023 was approximately $130,000 and $126,000, respectively.

Future lease payments relating to the Company's operating lease liabilities as of June 30, 2024, are as follows (in thousands):

Fiscal year ending March 31, 2025	$ 393
Fiscal year ending March 31, 2026	538
Fiscal year ending March 31, 2027	460
Total future lease payments	1,391
Less: Imputed interest	(106)
Total lease obligations	1,285
Less: Current obligations	(510)
Noncurrent lease obligations	$ 775

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.

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 months ended June 30, 2024 and 2023, the Company incurred no consulting expenses from Viscient. Additionally, for the three months ended June 30, 2024, and 2023, the Company provided approximately zero and $10,000 of histology services to Viscient, respectively.

Note 11. Business Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing performance. The Company's operating segments were identified in fiscal 2024 and did not impact prior periods. The Company's operating segments are as follows:

Research & Development

The research and development ("R&D") segment consists of the Company's drug development efforts. The Company's current clinical focus is in advancing FXR314 in IBD, including UC and CD. The Company plans to start a Phase 2a clinical trial in UC in the calendar year 2025. The Company released Phase 2 data for FXR314 for the treatment of MASH in April 2024 that are supportive of ongoing development, and believes FXR314 has a commercial opportunity in MASH, most likely in combination therapy. The Company is exploring the potential for combination therapies using FXR314 and currently approved mechanisms in preclinical animal studies and its IBD disease models.

The Company's second focus 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. The Company 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 the disease 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.

Mosaic Cell Sciences

The Mosaic Cell Sciences segment, which began operations in February 2024, consists of our Mosaic Cell Sciences division ("Mosaic") which will serve as a key source of certain of the primary human cells that the Company utilizes in its research and development efforts. The Company believes Mosaic can help optimize its supply chain, reduce operating expenses related to cell sourcing and procurement, and ensure that the cellular raw materials it uses are of the highest quality and are derived from tissues that are ethically sourced in full compliance with state and federal guidelines. Mosaic provides the Company with qualified human cells for use in its clinical research and development programs. In addition to supplying the Company with primary human cells, Mosaic offers human cells for sale to life science customers, both directly and through distribution partners, which the Company expects to offset costs and over time become a profit center that offsets overall R&D spending by the Company.

Business Segment Information

The Company's R&D segment generates royalty revenue related to its IP. The Company's Mosaic segment generates product revenue as part of its core operations. Segment revenues consisted of the following (in thousands):

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023
R&D		
Royalty revenue	$ 25	$ 75
Mosaic		
Product revenue	14	—
Total segment revenue	$ 39	$ 75
Total company revenue	$ 39	$ 75

Operating segment costs and expenses consisted of the following (in thousands):

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023
R&D		
Research and development expenses	$ 1,175	$ 1,666
Mosaic		
Cost of revenues	2	—
Research and development expenses	227	—
Selling, general, and administrative expenses	67	—
Total segment costs and expenses	$ 1,471	$ 1,666
Other selling, general, and administrative expenses	1,954	2,604
Total company costs and expenses	$ 3,425	$ 4,270

The R&D segment's identifiable assets are its fixed assets. The Mosaic segment's identifiable assets are its fixed assets and inventory. Other Company assets are comprised of all other assets that are not distinctly identifiable to a segment. Operating segment assets consisted of the following (in thousands):

	June 30, 2024	March 31, 2024
R&D		
Fixed assets, net	$ 377	$ 423
Mosaic		
Fixed assets, net	172	183
Inventory	408	297
Total segment assets	$ 957	$ 903
Other company assets	8,513	5,446
Total company assets	$ 9,470	$ 6,349

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

The following management's discussion and analysis of financial condition and results of operations should be read in conjunction with our historical consolidated financial statements and the related notes thereto included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2024. This management's discussion and analysis contains forward-looking statements, such as statements related to our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions such as "will," "may," "could," "should," or similar expressions, identify certain of these forward-looking statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties, including those described in this Quarterly Report on Form 10-Q, as well as the risk factors disclosed in our Annual Report on the Form 10-K for the fiscal year ended March 31, 2024, filed with the Securities and Exchange Commission on May 31, 2024, and discussed in the section titled "Risk Factors" under Part II, Item 1A in this Quarterly Report on Form 10-Q, that could cause our actual results or events to differ materially from those expressed or implied by such forward-looking statements. Unless the context otherwise requires, the terms "Organovo," the "Company", "we", "us" and "our" in this Quarterly Report on Form 10-Q refer to Organovo Holdings, Inc. and its wholly owned subsidiary, Organovo, Inc.

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

Basis of Presentation

The unaudited condensed consolidated financial statements included in this Form 10-Q have been prepared in accordance with the Securities and Exchange Commission (the "SEC") instructions to Quarterly Reports on Form 10-Q. Accordingly, the unaudited condensed consolidated financial statements presented elsewhere in this Form 10-Q and discussed below are unaudited and do not contain all the information required by U.S. generally accepted accounting principles ("GAAP") to be included in a full set of financial statements. The audited financial statements for the year ended March 31, 2024, filed with the SEC on Form 10-K on May 31, 2024, include a summary of our significant accounting policies and should be read in conjunction with this Form 10-Q. In the opinion of management, all material adjustments necessary to present fairly the results of operations for such periods have been included in this Form 10-Q. All such adjustments are of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results of operations for the entire year.

Overview

We are a 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 2025. 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

Mosaic Cell Sciences Division

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. Mosaic provides the Company with qualified human cells for use in its clinical research and development programs. In addition to supplying the Company with primary human cells, Mosaic offers 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.

Nasdaq Minimum Bid Notice

On July 18, 2024, we received a written notice (the "Notice") from the Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer meet the requirement to maintain a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided with an initial period of 180 calendar days, or until January 14, 2025, to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least $1 per share for a minimum of ten consecutive business days during this 180-day period. The Notice provides that the Nasdaq staff will provide written confirmation to us if we regain compliance with Rule 5550(a)(2).

If we do not regain compliance with Rule 5550(a)(2) by January 14, 2025, we may be eligible for an additional compliance period of 180 calendar days. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice to Nasdaq of our intention to cure the bid price deficiency during the second compliance period. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or we are otherwise not eligible, Nasdaq would notify us that our securities will be subject to delisting. In the event of such a notification, we may appeal the Nasdaq staff's determination to delist our securities, but there can be no assurance the Nasdaq staff would grant any request for continued listing.

The Notice had no immediate effect on the listing or trading of our common stock and our common stock will continue to trade on the Nasdaq Capital Market under the symbol "ONVO". We intend to monitor the closing bid price of our common stock and consider our available options if our common stock does not trade at a level likely to result in us regaining compliance with Rule 5550(a)(2) by January 14, 2025, including effecting a reverse stock split, which would be subject to the prior approval of our stockholders. There can be no assurance that we will be able to regain compliance with Nasdaq's minimum bid price requirement or that we will maintain our compliance with the other listing requirements necessary for us to maintain the listing of our common stock on the Nasdaq Capital Market.

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, 2024. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our condensed consolidated financial statements, refer to Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Note 1. Description of Business and Summary of Significant Accounting Policies" in the Notes to Consolidated Financial Statements contained in our Annual Report on Form 10-K for the year ended March 31, 2024, filed with the SEC on May 31, 2024.

Results of Operations

Comparison of the three months ended June 30, 2024, and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023 (in thousands, except %):

	Three Months Ended June 30,		Increase (decrease)	
	2024	2023	$	%
Royalty revenue	$ 25	$ 75	$ (50)	(67%)
Product revenue	$ 14	$ —	$ 14	100%
Cost of revenues	$ 2	$ —	$ 2	100%
Research and development	$ 1,402	$ 1,666	$ (264)	(16%)
Selling, general and administrative	$ 2,021	$ 2,604	$ (583)	(22%)
Other income	$ 44	$ 169	$ (125)	(74%)

Revenues

For the three months ended June 30, 2024 and 2023, total revenue was less than $0.1 million and $0.1 million, respectively. Royalty 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 in fiscal 2025. We expect quarterly sales of royalty bearing products by the licensee to remain consistent with the first quarter of fiscal 2025 going forward. Product revenue is related to the sale of human cells developed by Mosaic. The first quarter of fiscal 2025 is the first quarter of product sales since the inception of Mosaic. We expect product revenue to increase going forward.

Cost of Revenues

For the three months ended June 30, 2024 and 2023, total cost of revenues was less than $0.1 million and zero, respectively, and is related to the sale of finished goods inventory by Mosaic.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2024 and 2023 (in thousands, except %):

	Three Months Ended June 30, 2024	% of total	Three Months Ended June 30, 2023	% of total	Increase (decrease) $	Increase (decrease) %
Research and development	$ 1,318	94%	$ 1,505	91%	$ (187)	(12%)
Non-cash stock-based compensation	26	2%	107	6%	(81)	(76%)
Depreciation and amortization	58	4%	54	3%	4	7%
Total research and development expenses	**$ 1,402**	**100%**	**$ 1,666**	**100%**	**$ (264)**	**(16%)**

For the three months ended June 30, 2024, total research and development expenses were $1.4 million, a decrease of $0.3 million, or approximately 16%, from the prior year period. Our average full-time research and development staff decreased from an average of eighteen full-time employees for the three months ended June 30, 2023 to an average of fifteen full-time employees for the three months ended June 30, 2024. Our fiscal 2025 operations resulted in a $0.2 million decrease in personnel related costs which includes stock-based compensation, a $0.1 million decrease in facilities costs, a $0.1 million decrease in lab expenses, offset by a $0.1 million increase in consulting 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 June 30, 2024 and 2023 (in thousands, except %):

	Three Months Ended June 30, 2024	% of total	Three Months Ended June 30, 2023	% of total	Increase (decrease) $	Increase (decrease) %
Selling, general and administrative	$ 1,879	93%	$ 2,223	86%	$ (344)	(15%)
Non-cash stock-based compensation	130	6%	368	14%	(238)	(65%)
Depreciation and amortization	12	1%	13	0%	(1)	(8%)
Total selling, general and administrative expenses	**$ 2,021**	**100%**	**$ 2,604**	**100%**	**$ (583)**	**(22%)**

For the three months ended June 30, 2024, total selling, general and administrative expenses were approximately $2.0 million, a decrease of $0.6 million, or approximately 22%, compared to the prior year period. Our average full-time general and administrative staff of five employees remained the same for each of the three months ended June 30, 2024 and 2023. However, in fiscal 2024 one of the staff was our former General Counsel who was an Executive Officer included in a reduction in force during the second quarter of fiscal 2024. Subsequently, a sales associate for the Mosaic Cell Sciences segment was hired in the fourth quarter of fiscal 2024. Our fiscal 2025 operations resulted in a $0.3 million decrease in personnel related expenses which includes stock-based compensation, a $0.1 million decrease in consulting expenses, and a $0.2 million decrease in legal and other corporate costs, which includes a $0.3 decrease in legal expenses, and a $0.1 million decrease in audit and tax expense, offset by a $0.2 million increase in investor relations expenses.

Other Income

Other income was less than $0.1 million and $0.2 million for the three months ended June 30, 2024 and 2023, respectively, which was related to interest income.

.

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 2025. We released Phase 2 data for FXR314 for the treatment of metabolic function-associated steatohepatitis (“MASH”) in April 2024 that is supportive of ongoing development, and we believe FXR314 has a commercial opportunity in MASH, most likely in combination therapy. 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 June 30, 2024, we had cash and cash equivalents of approximately $6.2 million, restricted cash of approximately $0.1 million and an accumulated deficit of approximately $343.0 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 agreement for its facilities. We had negative cash flow from operations of approximately $3.0 million during the three months ended June 30, 2024. At March 31, 2024, we had cash and cash equivalents of approximately $2.9 million, restricted cash of approximately $0.1 million and an accumulated deficit of approximately $339.7 million.

At June 30, 2024, we had total current assets of approximately $7.3 million and current liabilities of approximately $2.0 million, resulting in working capital of $5.3 million. At March 31, 2024, we had total current assets of approximately $3.9 million and current liabilities of approximately $1.9 million, resulting in working capital of $2.0 million.

The following table summarizes the primary sources and uses of cash for the three months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	$ (2,983)	$ (5,311)
Investing activities	20	764
Financing activities	6,249	—
Net increase in cash, cash equivalents, and restricted cash	$ 3,286	$ (4,547)

Operating activities

Net cash used in operating activities for the three months ended June 30, 2024, was approximately $3.0 million as compared to $5.3 million used in operating activities for the three months ended June 30, 2023. This $2.3 million decrease in operating cash usage can be attributed primarily to the $2.0 million cash payment in fiscal 2024 for acquired in-process research and development assets.

Investing activities

Net cash provided by investing activities was less than $0.1 million for the three months ended June 30, 2024, which consisted of interest income. Net cash provided by investing activities was $0.8 million for the three months ended June 30, 2023, which consisted of the purchases of investments of $4.9 million, the maturities of investments of $5.0 million, the liquidation of equity securities of $0.7 million, and fixed asset purchases of less than $0.1 million.

Financing activities

Net cash provided by financing activities was $6.2 million and zero for the three months ended June 30, 2024 and 2023, respectively. Financing activities consisted of the sale of common stock through at-the-market (“ATM”) share offerings and a public offering of common stock and accompanying common warrants and pre-funded warrants. Refer to “Operations funding requirements” below for further information regarding financing activities.

Operations funding requirements

Through June 30, 2024, 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, 2025 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. 333-252224), declared effective by the SEC on January 29, 2021 (the "2021 Shelf"), which registered $150.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that expired on January 29, 2024. On January 26, 2024, we filed a new shelf registration statement on Form S-3 (File No. 333-276722) to register $150.0 million of common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the "2024 Shelf"). The 2024 Shelf was declared effective by the SEC on February 8, 2024 and replaced the 2021 Shelf at that time.

On March 16, 2018, we 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, 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 were issued pursuant to our 2021 Shelf until it was replaced by the 2024 Shelf.

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

During the three months ended June 30, 2024, we issued 1,352,600 shares of common stock in ATM offerings for net proceeds of approximately $1.7 million, all of which were sold pursuant to the 2024 Shelf. As of June 30, 2024, we have sold an aggregate of 1,389,002 shares of common stock in ATM offerings under the 2024 ATM Prospectus, with gross proceeds of approximately $1.8 million and net proceeds of approximately $1.8 million. As of June 30, 2024, there was approximately $100.0 million available for future offerings under the 2024 Shelf, and approximately $0.8 million available for future offerings through our ATM program under the 2024 ATM Prospectus.

On May 8, 2024, the we priced a best efforts public offering (the "Offering") of: (i) 1,562,500 shares of our common stock and accompanying common warrants ("Common Warrants") to purchase up to 1,562,500 shares of common stock at a combined public offering price of $0.80 per share and accompanying Common Warrant to purchase one share of common stock and (ii) pre-funded warrants ("Pre-Funded Warrants") to purchase 5,000,000 shares of common stock and accompanying Common Warrants to purchase up to 5,000,000 shares of common stock at a combined public offering price of $0.799 per Pre-Funded Warrant and accompanying Common Warrant to purchase one share of common stock. The closing of the Offering occurred on May 13, 2024. We received net proceeds of approximately $4.5 million from the Offering, after deducting the offering expenses payable by us including the placement agent fees.

Having insufficient funds may require us to relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could 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.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

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

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

Changes in Internal Control over Financial Reporting

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

Inherent Limitations on Effectiveness of Controls

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

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 7 of the Notes to the Unaudited Condensed Consolidated Financial Statements within this Form 10-Q for a discussion of our legal proceedings and contingencies.

ITEM 1A. RISK FACTORS

Investment in our common stock involves a substantial degree of risk and should be regarded as speculative. As a result, the purchase of our common stock should be considered only by persons who can reasonably afford to lose their entire investment. Before you elect to purchase our common stock, you should carefully consider the risk and uncertainties described below in addition to the other information incorporated herein by reference. Additional risks and uncertainties of which we are unaware or which we currently believe are immaterial could also materially adversely affect our business, financial condition or results of operations. If any of the risks or uncertainties discussed in this Quarterly Report 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, 2024, filed with the SEC on May 31, 2024.

Risk Factor Summary

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

- ***We will incur substantial additional operating losses over the next several years as our 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 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 that is focused on developing FXR314 in inflammatory bowel disease ("IBD"), including ulcerative colitis ("UC"), based on demonstration of clinical promise in three-dimensional human tissues as well as strong preclinical data. Our current clinical focus is in advancing FXR314 in IBD, including UC and Crohn's disease. 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 ("ATM") offering will result in dilution to our existing stockholders.

We currently have an effective shelf registration statement on Form S-3 filed with the Securities and Exchange Commission (the “SEC”), which we may use to offer from time to time any combination of debt securities, common and preferred stock and warrants. On March 16, 2018, we entered into the Sales Agreement pursuant to which we have the ability to sell shares of our common stock to the public through an ATM offering. As of June 30, 2024, we have issued and sold pursuant to the Sales Agreement an aggregate of 6,724,018 shares of our common stock for gross proceeds of approximately $48.7 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 May 23, 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 $3,094,641. 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 may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Currently, we are focused on developing FXR314 in IBD, including UC, based on demonstration of clinical promise in 3D human tissues as well as strong preclinical data. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business. Additionally, the potentially addressable patient population for our product candidates may be limited, or may not be amenable to treatment with our product candidates. Our spending on current and future research and development programs and

product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

In some cases, there may be only one or few providers of such services, including clinical data management or manufacturing services. In addition, the cost of such services could be significantly increased over time. We may rely on third parties and collaborators to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these third parties and collaborators for clinical development activities reduces our control over these activities. Our reliance on these parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with Good Clinical Practice ("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 inseverable 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.

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 June 30, 2024 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 June 30, 2024 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 $3.4 million and $4.2 million for the three months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of $343.0 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. A bill to amend the existing UK framework has been reintroduced (in a different form) by the new UK Government and was announced as a bill which will be introduced into Parliament at the King's Speech on July 17, 2024. At this time, there is no specific clarity on the provisions of the bill, or the extent to which it will amend the UK framework, beyond general descriptions on its intended purpose. Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection 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, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, Texas and others have adopted privacy laws, which take effect from July 1, 2024 through 2026. Some state laws also minimize what data can be collected from consumers and how businesses may use and disclose it. These state privacy laws also require businesses to make disclosures to consumers about data collection, use and sharing practices. In addition, some of these laws (including the California Privacy Rights Act), along with other standalone health privacy laws, subject health-related information to additional safeguards and disclosures and some specifically regulate consumer health data, such as the Washington My Health My Data Act, which became effective in 2023 and 2024. 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). 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. No services were provided to Viscient during the three months ended June 30, 2024.

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.

On July 18, 2024, we received a written notice (the "Notice") from the Listing Qualifications Staff of the Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer meet the requirement to maintain a minimum bid price of $1 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided with an initial period of 180 calendar days, or until January 14, 2025, to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least $1 per share for a minimum of ten consecutive business days during this 180-day period. The Notice provides that the Nasdaq staff will provide written confirmation to us if we regain compliance with Rule 5550(a)(2).

If we do not regain compliance with Rule 5550(a)(2) by January 14, 2025, we may be eligible for an additional compliance period of 180 calendar days. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice to Nasdaq of our intention to cure the bid price deficiency during the second compliance period. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or we are otherwise not eligible, Nasdaq would notify us that our securities will be subject to delisting. In the event of such a notification, we may appeal the Nasdaq staff's determination to delist our securities, but there can be no assurance the Nasdaq staff would grant any request for continued listing.

The Notice had no immediate effect on the listing or trading of our common stock and our common stock will continue to trade on the Nasdaq Capital Market under the symbol "ONVO". We intend to monitor the closing bid price of our common stock and consider our available options if our common stock does not trade at a level likely to result in us regaining compliance with Rule 5550(a)(2) by January 14, 2025, including effecting a reverse stock split, which would be subject to the prior approval of our stockholders. There can be no assurance that we will be able to regain compliance with Nasdaq's minimum bid price requirement or that we will maintain our compliance with the other listing requirements necessary for us to maintain the listing of our common stock on the Nasdaq Capital Market.

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 markers or broker-dealers for our common stock; and
- the availability of information concerning the trading prices and volume of shares of our common stock.

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

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

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

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

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- our ability to execute on our new strategic plan;
- reduced government funding for research and development activities;
- actual or anticipated variations in our operating results;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- sales of our common stock or other securities in the open market;

- degree of coverage of securities analysts and reports and recommendations issued by securities analysts regarding our business;
- volume fluctuations in the trading of our common stock; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. The trading price of our common stock is, and is likely to continue to be, volatile. For example, during the quarter ended June 30, 2024, our closing stock price ranged from $0.75 to $1.35 per share. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

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

We are authorized to issue 200,000,000 shares of common stock and 25,000,000 shares of preferred stock. As of June 30, 2024, there were an aggregate of 14,373,076 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 2,476,438 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, 45,000 shares of common stock that may be issued through our 2023 Employee Stock Purchase Plan ("ESPP"), and 10,183,500 shares of our common stock that may be issued upon the exercise of outstanding warrants.

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

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

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

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

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

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

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our Certificate of Incorporation, Bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain

control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delaying or impeding a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Risks Related to Our Intellectual Property

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

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

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

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

As previously disclosed, we have recommenced certain historical operations and are now focusing our future efforts on developing highly customized 3D human tissues as living, dynamic models for healthy and diseased human biology for drug development. 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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

During the fiscal quarter ended June 30, 2024, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(a) of Regulation S-K.

ITEM 6. EXHIBITS

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

Exhibit No.	Description
3.1	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.2	Certificate of Amendment of Certificate of Incorporation of Organovo Holdings, Inc. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 27, 2018).
3.3	Certificate of Second Amendment of Certificate of Incorporation of Organovo Holdings, Inc. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the SEC on August 17, 2020).
3.4	Amended and Restated Bylaws of Organovo Holdings, Inc., effective as of July 13, 2023 (incorporated by reference to Exhibit 3.4 the Company's Annual Report on Form 10-K, as filed with the SEC on July 14, 2023).
4.1	Form of Common Warrant (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 13, 2024).
4.2	Form of Pre-Funded Warrant (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the SEC on May 13, 2024).
10.1	Placement Agency Agreement, dated May 8, 2024, between the Company and JonesTrading Institutional Services LLC (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 13, 2024).
10.2^	Form of Securities Purchase Agreement, dated May 8, 2024 (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on May 13, 2024).
31.1	Certification of Keith Murphy, Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.*
31.2	Certification of Thomas Hess, Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.*
32.1	Certification of Keith Murphy, Executive Chairman, and Thomas Hess, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.**
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).*
101.SCH	Inline XBRL Taxonomy Extension Schema.*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.*
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).*

* Filed herewith.

** Furnished herewith.

^ Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORGANOVO HOLDINGS, INC.

Date: August 5, 2024

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

Date: August 5, 2024

By: */s/ Thomas Hess*
Name: Thomas Hess
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Keith Murphy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Organovo Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

Dated: August 5, 2024

/s/ Keith Murphy

Keith Murphy
Executive Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Thomas Hess, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Organovo Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

Dated: August 5, 2024

/s/ Thomas Hess

Thomas Hess
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Organovo Holdings, Inc. (the "Company") for the period ended June 30, 2024, as filed with the Securities and Exchange Commission (the "Report"), I, Keith Murphy, Executive Chairman and I, Thomas Hess, Chief Financial Officer of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

Date: August 5, 2024

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

/s/ Thomas Hess
Thomas Hess
Chief Financial Officer
(Principal Financial Officer)

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

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