

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

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended March 31, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Transition Period from ____ to
Commission File No. 001-35996

ORGANOVO HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

11555 Sorrento Valley Rd, Suite 100

San Diego, CA

(Address of principal executive offices)

27-1488943

(IRS Employer Identification No.)

92121

(Zip code)

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ONVO	The Nasdaq Capital Market

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on the closing stock price as reported on the Nasdaq Capital Market on September 30, 2022, the last trading day of the registrant's second fiscal quarter, was \$16,721,329. For purposes of this computation only, shares of common stock held by each executive officer, director, and 10% or greater stockholders have been excluded in that such persons may be deemed affiliates.

The number of outstanding shares of the registrant's common stock, as of June 1, 2023 was 8,716,953.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required for Part III of this report is incorporated herein by reference to the definitive proxy statement for the 2023 annual meeting of the registrant's stockholders, expected to be filed within 120 days of the end of the registrant's fiscal year.

Auditor Firm Id: 199

Auditor Name: Mayer Hoffman McCann P.C.

Auditor Location: San Diego, CA

Organovo Holdings, Inc.
Annual Report on Form 10-K
For the Year Ended March 31, 2023
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Important Information Regarding Forward-Looking Statements

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

PART I

Item 1. Business.

Overview

Organovo Holdings, Inc. (“Organovo Holdings,” “we,” “us,” “our,” the “Company” and “our Company”) is a biotechnology company that focuses on building high fidelity, 3D tissues that recapitulate key aspects of human disease. We use these models to identify gene targets responsible for driving the disease and intend to initiate drug discovery programs around these validated targets. We are initially focusing on the intestine and have ongoing 3D tissue development efforts in ulcerative colitis (“UC”) and Crohn’s disease (“CD”). We intend to add additional tissues/diseases/targets to our portfolio over time. 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.

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

Our NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. We believe that the use of our bioprinting platform as well as complementary 3D technologies will allow us to develop an understanding of disease biology that leads to validated novel drug targets and therapeutics to those targets to treat disease.

The majority of our current focus is on inflammatory bowel disease (“IBD”), including CD and UC. 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 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. Using these disease models, we intend to identify and validate novel therapeutic targets. After finding therapeutic drug targets, we will focus on developing novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these drug candidates towards an Investigational New Drug (“IND”) filing and potential future clinical trials. We may also form partnerships around the development of targets or therapeutics for the treatment of IBD.

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

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 commercial opportunity.

We hold a large and diverse patent portfolio related to our bioprinting platform and complementary 3D technologies. The strength of this patent portfolio, the fact that it was created early in the bioprinting revolution and growth in the bioprinting industry have made for an attractive business opportunity for us. We are now beginning to invest resources to explore and expand business and revenue opportunities from the leveraging of our patent portfolio.

Our Platform Technology

Our 3D human tissue platform is multifaceted. We approach each tissue agnostic to specific technologies, and intend to apply the best 3D technology to a given disease. We are developing novel disease models using high throughput systems, bioprinted and flow/stretch capable 3D systems as appropriate. Our proprietary NovoGen Bioprinters® and related technologies for preparing bio-inks and bioprinting multicellular tissues with complex architecture are grounded in over a decade of peer-reviewed scientific publications, deriving originally from research led by Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of Biological Physics at the University of Missouri-Columbia (“MU”). We have a broad portfolio of intellectual property rights covering the principles, enabling instrumentation, applications, tissue constructs and methods of cell-based printing, including exclusive licenses to certain patented and patent pending technologies from MU and Clemson University. We own or exclusively license more than 160 patents and pending applications worldwide covering specific tissue designs, uses, and methods of manufacture.

The NovoGen Bioprinter® Platform

Our NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. A custom graphic user interface (“GUI”) facilitates the 3D design and execution of scripts that direct precision movement of multiple

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

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

Research Collaborations

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

Intellectual Property

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

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

We solely own or hold exclusive licenses to 32 issued U.S. patents and more than 115 issued international patents in foreign jurisdictions including Australia, Canada, China, Denmark, France, Great Britain, Germany, Ireland, Japan, South Korea, Sweden, the Netherlands and Switzerland. We solely or jointly own or hold exclusive licenses to 17 pending U.S. patent applications and more than 5 pending international applications in foreign jurisdictions including Australia, Canada, China, the European Patent Office, Japan and South Korea. These patent families relate to our bioprinting technology and our engineered tissue products and services, including our various uses in areas of tissue creation, *in vitro* testing, utilization in drug discovery, and *in vivo* therapeutics.

In connection with the recent acquisition of the FXR program from Metacrine, we acquired the related patent portfolio by way of assignment. This includes filings on the lead candidate, FXR314, and selected filings on the prior candidate (no longer in development), FXR125. With respect to this FXR portfolio, we solely own 6 issued patents and 14 international patents in jurisdictions, including Australia, China, Eurasia, India, Israel, Mexico, Japan and South Africa. We solely own 8 pending U.S. patent applications and more than 50 pending international applications in foreign jurisdictions, including Argentina, Australia, Brazil, Chile, Canada, Eurasia, Europe, Israel, India, Japan, South Korea, Mexico, Philippines, Singapore, South Africa, Hong Kong and Taiwan. These patent families relate to FXR125 and FXR314, including generic coverage, species coverage, methods of use, formulations and polymorph crystals.

In-Licensed Intellectual Property

In 2009 and 2010, we obtained world-wide exclusive licenses to intellectual property owned by MU and the Medical University of South Carolina, which now includes 7 issued U.S. patents, 2 pending U.S. applications and 16 issued international patents. Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of Biophysics at MU, was one of the co-inventors of all of these works (collectively, the "Forgacs Intellectual Property"). The Forgacs Intellectual Property provides us with intellectual property rights relating to cellular aggregates, the use of cellular aggregates to create engineered tissues, and the use of cellular aggregates to

create engineered tissue with no scaffold present. The intellectual property rights derived from the Forgas Intellectual Property also enables us to utilize our NovoGen Bioprinter[®] to create engineered tissues.

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

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

The patent rights we obtained through these exclusive licenses are not only foundational within the field of 3D bioprinting and FXR agonist therapies but provide us with favorable priority dates. We are required to make ongoing royalty payments under these exclusive licenses based on net sales of products and services that rely on the intellectual property we in-licensed. For additional information regarding our royalty obligations see “Note 5. Collaborative Research, Development, and License Agreements” in the Notes to the Consolidated Financial Statements included in this Annual Report.

Company Owned Intellectual Property

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

With respect to our bioprinting platform, we have 8 issued U.S. patents and 14 issued foreign patents directed to our NovoGen Bioprinter[®] and methods of bioprinting: U.S. Patent Nos. 8,931,880; 9,149,952; 9,227,339; 9,315,043; 9,499,779; 9,855,369; 10,174,276, 10,967,560, 11,577,450, 11,577,451 and 11,413,805; Australia Patent Nos. 2011318437, 2015202836, 2016253591, 2013249569, and 2014296246; Canada Patent No. 2,812,766; China Patent Nos. ZL201180050831.4 and ZL201480054148.1; European Patent Nos. 2838985, 2629975, and 3028042; Japan Patent Nos. 6333231, 6566426 and 6842918, and Russian Patent No. 2560393. These issued patents and pending patent applications carry remaining patent terms ranging from over 12 years to just over 6 years. We have additional U.S. continuation applications pending in these families as well foreign counterpart applications in multiple countries.

Our ExVive[™] Human Liver Tissue is protected by U.S. Patent Nos. 9,222,932, 9,442,105, 10,400,219 and 11,127,774; Australia Patent Nos. 2014236780 and 2017200691; and Canada Patent No. 2,903,844. Our ExVive[™] Human Kidney Tissue is protected by U.S. Patent Nos. 9,481,868, 10,094,821 and 10,962,526; Australian Patent No. 2015328173, Canadian Patent No. 2,962,778, European Patent No. 3204488 and Japan Patent No. 7021177. These issued patents and pending patent applications carry remaining patent terms ranging from over 14 years to just over 11 years. We have additional U.S. patent applications pending in these families, as well as foreign counterpart applications in multiple countries. We currently have pending numerous patent applications in the U.S. and globally that are directed to additional features on bioprinters, additional tissue types, their methods of fabrication, and specific applications.

Our U.S. Patent Nos. 9,855,369 and 9,149,952, which relate to our bioprinter technology, were the subject of IPR proceedings filed by Cellink AB and its subsidiaries (collectively, “BICO Group AB”), one of our competitors. Likewise, U.S. Patent Nos. 9,149,952, 9,855,369, 8,931,880, 9,227,339, 9,315,043 and 10,967,560 (all assigned to Organovo, Inc.) and U.S. Patent Nos. 7,051,654, 8,241,905, 8,852,932 and 9,752,116 (assigned to Clemson University and the University of Missouri, respectively) were implicated in a declaratory judgment complaint filed against Organovo, Inc., our wholly owned subsidiary, by BICO Group AB and certain of its subsidiaries in the United States District Court for the District of Delaware. All of these matters have since been settled in a favorable manner for the Company. Specifically, on February 23, 2022, we announced an agreement of a non-exclusive license for BICO Group AB and its affiliate companies to Organovo’s foundational patent portfolio in 3D bioprinting. For more information regarding these proceedings, see the section titled Part I, Item 3 of this Annual Report on Form 10-K.

With respect to our FXR agonist program covering FXR314 and FXR125, we have 6 issued U.S. patents and 14 issued foreign patents directed to composition of matter protection (generic and specific) for FXR314 and FXR125, as well claims directed to methods of treatment of GI diseases, formulations of FXR314 and polymorphs of the FXR314 molecule including United States Patent Nos. 11,214,538, 10,705,712, 10,927,082, 10,961,198, 11,136,071 and 11,084,817, granted Australian Patent Nos. 2016323992 and 2018236275, Chinese Patent Nos. 201680066917 and 269065, Eurasian Patent Nos. 040003 and 040704, Israeli Patent Nos. 258011, 296068 and 296065, Indian Patent No. 380510, Japanese Patent Nos. 6905530 and 717709, Mexican Patent Nos. 386,752 and 397265 and South African Patent No. 2018/01750. In addition, we have 8 pending U.S. patent applications and over 50 pending foreign patent applications, including U.S. Patent Application Nos. 18/156,069, 17/532,618, 18/174,393, 17/349,757, 17/276,787, 17/906,580, 17/906,582 and 17/906,585 and over 50 pending international patent applications in a number of countries including, Australia, Brazil, Canada, Chile, China, the Eurasian Patent Office, the European Patent Office, Israel, India, Japan, South Korea, Mexico, Singapore,

Philippines and Hong Kong. These issued patents and pending patent applications carry remaining patent terms ranging from over 18 years to just over 15 years.

Employees and Human Capital

As of June 1, 2023, we had 24 employees, of which 15 are full-time. We have also retained some of our former employees as consultants, in addition to a number of expert consultants in specific scientific and operational areas. Our employees are not represented by labor unions or covered under any collective bargaining agreements. We consider our relationship with our employees to be good.

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

Corporate Information

We are operating the business of our subsidiaries, including Organovo, Inc., our wholly-owned subsidiary, which we acquired in February 2012. Organovo, Inc. was incorporated in Delaware in April 2007. Our common stock has traded on The Nasdaq Stock Market LLC under the symbol “ONVO” since August 8, 2016 and our common stock currently trades on the Nasdaq Capital Market. Prior to that time, it traded on the NYSE MKT under the symbol “ONVO” and prior to that was quoted on the OTC Market.

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

Available Information

Our investor relations website is located at <http://ir.organovo.com>. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Reports filed with the Securities and Exchange Commission (the “SEC”) pursuant to the Exchange Act, including annual and quarterly reports, and other reports we file, are available free of charge, through our website. The content of our website is not intended to be incorporated by reference into this Annual Report or in any other report or document that we file. We make them available on our website as soon as reasonably possible after we file them with the SEC. The reports we file with the SEC are also available on the SEC’s website (<http://www.sec.gov>).

Item 1A. Risk Factors.

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

Risk Factor Summary

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

- *We will incur substantial additional operating losses over the next several years as our 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. Separately, our independent registered public accounting firm has included in its opinion for the year ended March 31, 2023 an explanatory paragraph expressing substantial doubt in our ability to continue as a going concern, which may hinder our ability to obtain future financing.*
- *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 biotechnology company focusing 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 focusing our efforts on utilizing our 3D bioprinting technology to develop human tissues and disease models for drug discovery and development. Our success will depend upon the viability of our platform technology and any disease models we develop, as well as on our ability to determine which drug candidates we should pursue. Our success will also depend on our ability to select an appropriate development strategy for any drug candidates we 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.

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 is critical to our success. Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. If we are unable to attract and retain high quality personnel, our ability to pursue our 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. Our existing cash, cash equivalents and interest thereon is expected to be sufficient to fund our projected operating requirements for at least the next 12 months. We have based these estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect if our operating plans change. 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 \$28.3 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 Jones Trading Institutional Services LLC on March 16, 2018 (the "Sales Agreement"). Any shares of common stock issued in the at-the-market 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 up to \$28.3 million of additional shares of our common stock to the public through an "at the market" offering. 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 June 1, 2023, 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. Although we would still maintain the ability to raise funds through other means, such as through the filing of a registration statement on Form S-1 or in private placements, the rules and regulations of the SEC or any other regulatory agencies may restrict our ability to conduct certain types of financing activities, or may affect the timing of and amounts we can raise by undertaking such activities.

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

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future results.

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

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

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

- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure to obtain sufficient enrollment in clinical trials or participants may fail to complete clinical trials;
- clinical trials of our drug candidates that may produce negative or inconclusive results, and as a result we, or any pharmaceutical company with who we enter into a partnering or development agreement, may decide, or regulators may require, additional clinical trials;
- suspension or termination of clinical research, either by us, any third party with whom we enter into a partnering or development agreement, regulators or institutional review boards, for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- additional or unanticipated clinical trials required by regulators or institutional review boards to obtain approval or any drug candidates may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving any drug candidates, or such requirements may not be as anticipated;
- the cost of clinical trials for any drug candidates may be greater than anticipated;
- the supply or quality of any drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate or may be delayed; and
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;

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

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

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

In some cases, there may be only one or few providers of such services, including clinical data management or manufacturing services. In addition, the cost of such services could be significantly increased over time. We may rely on third parties and collaborators to enroll qualified patients and conduct, supervise and monitor our clinical trials. Our reliance on these third parties and collaborators for clinical development activities reduces our control over these activities. Our reliance on these parties, however, does not relieve us of our regulatory responsibilities, including ensuring that our clinical trials are conducted in accordance with Good Clinical Practice (“GCP”) regulations and the investigational plan and protocols contained in the regulatory agency applications. In addition, these third parties may not complete activities on schedule or may not manufacture under Current Good Manufacturing Practice (“cGMP”) conditions. Preclinical or clinical studies may not be performed or completed in accordance with Good Laboratory Practices (“GLP”) regulatory requirements or our trial design. If these third parties or collaborators do not successfully carry out their contractual duties or meet expected deadlines, obtaining regulatory approval for manufacturing and commercialization of our drug candidates may be delayed or prevented. We may rely substantially on third-party data managers for our clinical trial data. There is no assurance that these third parties will not make errors in the design, management or retention of our data or data systems. There is no assurance these third parties will pass FDA or regulatory audits, which could delay or prohibit regulatory approval.

In addition, we will exercise limited control over our third-party partners and vendors, which makes us vulnerable to any errors, interruptions or delays in their operations. If these third parties experience any service disruptions, financial distress or other business disruption, or difficulties meeting our requirements or standards, it could make it difficult for us to operate some aspects of our business.

The near and long-term viability of our drug discovery and development efforts will depend on our ability to successfully establish strategic relationships.

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

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

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance ("ESG") factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies.

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

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

As widely reported, in the past several years, global credit and financial markets have experienced volatility and disruptions, 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. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. 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.

The impact of the Russian invasion of Ukraine 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 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 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, the continuing conflict has resulted and may continue to result 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 may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

Risks Related to Government Regulation

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

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

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

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

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

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

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

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

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

Current and future legislation may increase the difficulty and cost of commercializing our drug candidates and may affect the prices we may obtain if our drug candidates are approved for commercialization.

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

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

In addition, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which shall take effect in 2023. Under the Inflation Reduction Act of 2022, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the government for the difference. The new law also caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at \$2,000 a year.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the “PPACA”), was enacted. The PPACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers’ rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of “average manufacturer price”, which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services (“CMS”), which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the “donut hole.” Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

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

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The U.S. Department of Health and Human Services has started soliciting feedback on some of these measures and, at the same time, is implementing others under its existing authority. For example, in May

2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While any proposed measures will require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our drug candidates, if approved for commercialization.

In Europe, the United Kingdom formally withdrew from the European Union on January 31, 2020, and entered into a transition period that ended on December 31, 2020. A significant portion of the regulatory framework in the United Kingdom is derived from the regulations of the European Union. We cannot predict what consequences the recent withdrawal of the United Kingdom from the European Union will have on the regulatory frameworks of the United Kingdom or the European Union, or on our future operations, if any, in these jurisdictions, and the United Kingdom is in the process of negotiating trade deals with other countries. Additionally, the United Kingdom's withdrawal from the European Union may increase the possibility that other countries may decide to leave the European Union again.

Risks Related to Our Capital Requirements, Finances and Operations

Management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern. Separately, our independent registered public accounting firm has included in its opinion for the year ended March 31, 2023 an explanatory paragraph expressing substantial doubt in our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our financial statements as of March 31, 2023 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Management has performed an analysis and concluded that substantial doubt exists about our ability to continue as a going concern. Separately, our independent registered public accounting firm included in its opinion for the year ended March 31, 2023 an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, obtain government grants, reduce expenditures and generate significant revenue. Our financial statements as of March 31, 2023 do not include any adjustments that might result from the outcome of this uncertainty. The reaction of investors to the inclusion of a going concern statement by management and our auditors, and our potential inability to continue as a going concern, in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances.

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

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

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

We have generated operating losses each year since we began operations, including \$17.7 million and \$11.5 million for the years ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of \$325.0 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 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 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, certain of our executives also provide 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 officers 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 and could also lead to legislative and regulatory changes and 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. 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. 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 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. For example, four other states have adopted such laws, taking effect from January 1, 2023 (in Virginia) and throughout the next year in Utah, Colorado, and Connecticut. Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. This is particularly true with respect to data security incidents, and sensitive personal information, including health and biometric data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and business.

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

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

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

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

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

Keith Murphy, our Executive Chairman, is the Chief Executive Officer, Chairman and principal stockholder of Viscient, a private company that he founded in 2017 that is focused on drug discovery and development utilizing 3D tissue technology and multi-omics (genomics, transcriptomics, metabolomics). Jeffrey N. Miner and our Chief Scientific Officer, is a co-founder, the Chief Scientific Officer and a significant stockholder of Viscient. In addition, Adam Stern, Douglas Jay Cohen and David Gobel (through the Methuselah Foundation and the Methuselah Fund), members of our Board, have invested funds through a convertible promissory note in Viscient, but do not serve as an employee, officer or director of Viscient. Additional members of our Research and Development organization also work at Viscient, and we expect that additional employees or consultants of ours will also be employees of or consultants to Viscient. We use certain Viscient-owned facilities and equipment and allow Viscient to use certain of our facilities and equipment. During fiscal 2023, we provided services to Viscient, and we expect to continue to provide services to Viscient and enter into additional agreements with Viscient in the future.

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

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

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

Risks Related to Our Common Stock and Liquidity Risks

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

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

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

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

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

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

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

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

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

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

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

We are authorized to issue 200,000,000 shares of common stock and 25,000,000 shares of preferred stock. As of March 31, 2023, there were an aggregate of 11,426,737 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 2,650,405 shares of our common stock that may be issued upon the vesting of restricted stock units, the exercise of outstanding stock options, or is available for issuance under our equity incentive plans, and 58,426 shares of common stock that may be issued through our Employee Stock Purchase Plan ("ESPP").

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

To protect our products and technologies, we, and our collaborators and licensors, must prosecute and maintain existing patents, obtain new patents and pursue other intellectual property protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. 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.

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 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

In November 2020, we entered into a sixty-two month lease agreement for our long term permanent premises, consisting of approximately 8,051 square feet of lab and office space. In November 2021, we amended the permanent lease agreement to add an additional 2,892 square of office space in the same building. In December 2021, we took occupancy of our permanent lab and office space, located at 11555 Sorrento Valley Road, San Diego, CA 92121. See “Note 7. Leases” of the Notes to the Consolidated Financial Statements contained within this Annual Report for a further discussion of properties.

Item 3. Legal Proceedings.

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

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

We are not involved in any material legal proceedings or legal matters at this time. See “Note 8. Commitments and Contingencies” of the Notes to the Consolidated Financial Statements contained within this Annual Report for a further discussion of potential commitments and contingencies related to legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information for Common Stock

Our common stock is traded on the Nasdaq Capital Market under the symbol “ONVO.”

Holders of Record

As of March 31, 2023, we had 8,716,906 outstanding shares of common stock and approximately 81 holders of record of our common stock. The number of beneficial owners is substantially greater than the number of record holders because a large portion of our common stock is held of record through brokerage firms in “street name.”

Dividend Policy

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

We satisfy certain U.S. federal and state tax withholding obligations due upon the vesting of restricted stock unit awards by automatically withholding from the shares being issued in connection with such award a number of shares of our common stock with an aggregate fair market value on the date of vesting equal to the minimum tax withholding obligations. The following table sets forth information with respect to shares of our common stock repurchased by us to satisfy certain tax withholding obligations during the three months ended March 31, 2023:

	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid Per Share (or Unit)
January 1, 2023 - January 31, 2023	—	\$ —
February 1, 2023 - February 28, 2023	34 (1)	\$ 2.64
March 1, 2023 - March 31, 2023	—	\$ —
Total	<u>34</u>	<u>\$ 2.64</u>

(1) Represents shares of our common stock withheld from employees for the payment of taxes.

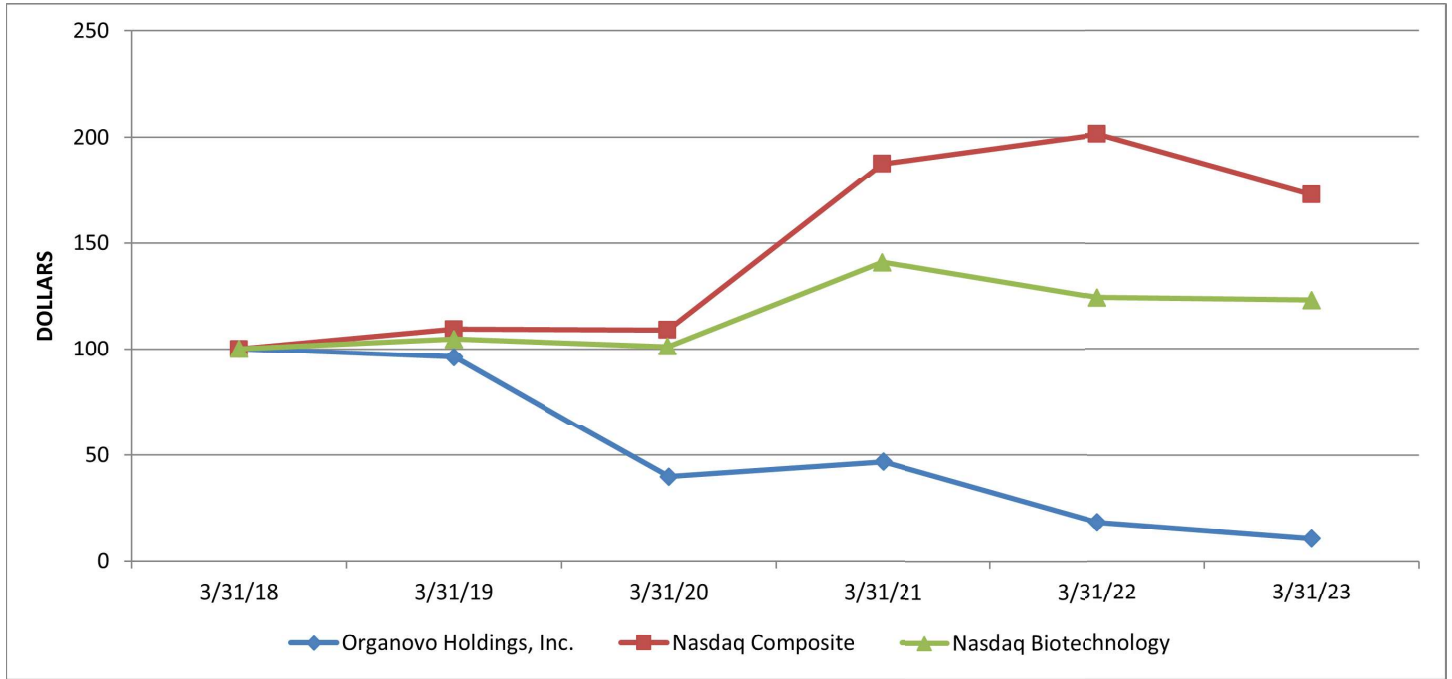
Performance Graph

This performance graph is furnished and shall not be deemed “filed” with the SEC or subject to Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended.

The graph set forth below compares the cumulative total stockholder return data on our common stock with the cumulative return data of (i) the Nasdaq Stock Market Composite Index, and (ii) the Nasdaq Biotechnology Index over the five-year period ending March 31, 2023. This graph assumes the investment of \$100 on March 31, 2018 in our common stock and each of the comparative indices and assumes the reinvestment of dividends. No cash dividends have been declared or paid on our common stock.

The comparisons in the graph and related information is not intended to forecast or be indicative of possible future performance of our common stock, and we do not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
 Among Organovo Holdings, Inc.,
 the Nasdaq Composite Index, and the Nasdaq Biotechnology Index



* \$100 invested on March 31, 2018 in stock or index, including reinvestment of dividends.

Securities Authorized for Issuance under Equity Compensation Plans

Information about securities authorized for issuance under equity compensation plans is set forth in Part III, Item 12. “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” of this Annual Report.

Item 6. [Reserved]

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

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

Overview

We are a biotechnology company that is focusing on building high fidelity, 3D tissues that recapitulate key aspects of human disease. We use these models to identify gene targets responsible for driving the disease and intend to initiate drug discovery programs around these validated targets. We are initially focusing on the intestine and have ongoing 3D tissue development efforts in ulcerative colitis (“UC”) and Crohn’s disease (“CD”). We intend to add additional tissues/diseases/targets to our portfolio over time. 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.

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

Our NovoGen Bioprinters® are automated devices that enable the fabrication of 3D living tissues comprised of mammalian cells. We believe that the use of our bioprinting platform as well as complementary 3D technologies will allow us to develop an understanding of disease biology that leads to validated novel drug targets, and therapeutics to those targets to treat disease.

The majority of our current focus is on inflammatory bowel disease (“IBD”), including CD and UC. 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 current understanding of intestinal tissue models and IBD 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. Using these disease models, we intend to identify and validate novel therapeutic targets. After finding therapeutic drug targets, we will focus on developing novel small molecule, antibody, or other therapeutic drug candidates to treat the disease, and advance these drug candidates towards an Investigational New Drug (“IND”) filing and potential future clinical trials. We may also form partnerships around the development of targets or therapeutics for the treatment of IBD.

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

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 commercial opportunity.

We hold a large and diverse patent portfolio related to our bioprinting platform and complementary 3D technologies. The strength of this patent portfolio, the fact that it was created early in the bioprinting revolution and growth in the bioprinting industry have made for an attractive business opportunity for us. We are now beginning to invest resources to explore and expand business and revenue opportunities from the leveraging of our patent portfolio.

Critical Accounting Policies, Estimates, and Judgments

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). Any reference in this annual report to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments used in preparing our financial statements and related disclosures, none of which are considered critical. All estimates affect reported amounts of assets, liabilities, revenues and expenses, as well as disclosures of contingent assets and liabilities. These

estimates and judgments are also based on historical experience and other factors that are believed to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

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

Stock-based compensation

For purposes of calculating stock-based compensation, we estimate the fair value of stock options and shares acquirable under our 2022 Equity Incentive Plan (“2022 Plan”), Amended and Restated 2012 Equity Incentive Plan (the “2012 Plan”), our 2016 Employee Stock Purchase Plan (the “ESPP”) or our 2021 Inducement Equity Plan (the “Inducement Plan”) using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. Expected volatility is based on the Company-specific historical volatility rate. For certain options granted with vesting criteria contingent on market conditions, we engage with valuation specialists to calculate fair value and requisite service periods using Monte Carlo simulations. For certain options granted with vesting criteria contingent on pre-defined Company performance criteria, we periodically assess and adjust the expense based on the probability of achievement of such performance criteria. For shares acquirable under our ESPP, we use our Company-specific volatility rate. The expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts. If factors change and we employ different assumptions, our stock-based compensation expense may differ significantly from what we have recorded in the past.

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

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

Revenue

We assess whether our license agreements are considered a contract with a customer under ASC Topic 606, Revenue from Contracts with Customers (“Topic 606”) or an arrangement with a collaborator subject to guidance under ASC Topic 808, Collaborative Arrangements (“Topic 808”). These agreements can include one or more of the following: (i) non-refundable upfront fees and (ii) royalties based on specified percentages of net product sales. At contract inception, we assess the goods or services agreed upon within each contract and assess whether each good or service is distinct and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

For the year ended March 31, 2023, the performance obligations assessed were sales-based royalties on a quarterly basis. We evaluate the performance obligation to determine if it can be satisfied at a point in time or over time. For agreements that include sales-based royalties, we estimate and recognize revenue in the period the underlying sales occur. Key factors considered in the estimate include sales of products that include the underlying licensed IP and the location of customers related to the jurisdictions of the licensed IP. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Differences in the allocation of the transaction price between delivered and undelivered performance obligations can impact the timing of revenue recognition but do not change the total revenue recognized under any agreement.

Results of Operations

Comparison of the Years Ended March 31, 2023 and 2022

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

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

Revenues

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

Research and Development Expenses

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

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

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

Selling, General and Administrative Expenses

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

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

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

increased to an average of five full-time employees for the year ended March 31, 2023. Year over year, we had an increase in personnel related costs of approximately \$0.4 million, an increase in consulting costs of approximately \$0.3 million, an increase in depreciation and amortization of approximately \$0.1 million. These increases were offset by a \$1.2 million decrease in general corporate costs, mostly attributable to a decrease in legal costs related to litigation regarding patent enforcement that occurred and ended in fiscal 2022.

Other Income (Expense)

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

Financial Condition, Liquidity and Capital Resources

Going forward, we intend to leverage our proprietary technology platform to develop therapeutic drugs. Our initial plan is to focus 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. As of March 31, 2023, we had cash and cash equivalents of approximately \$15.3 million and an accumulated deficit of \$325.0 million. As of March 31, 2022, we had cash and cash equivalents of \$28.7 million and an accumulated deficit of \$307.7 million. We had negative cash flows from operations of \$12.4 million and \$8.5 million for the years ended March 31, 2023 and 2022, respectively.

As of March 31, 2023, we had total current assets of approximately \$17.0 million and current liabilities of approximately \$3.7 million, resulting in working capital of \$13.3 million. At March 31, 2022, we had total current assets of approximately \$29.5 million and current liabilities of approximately \$1.4 million, resulting in working capital of \$28.1 million.

The following table sets forth a summary of the primary sources and uses of cash for the years ended March 31, 2023 and 2022 (in thousands):

	Year Ended March 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	\$ (12,408)	\$ (8,453)
Investing activities	(966)	(409)
Financing activities	—	205
Net decrease in cash, cash equivalents, and restricted cash	\$ (13,374)	\$ (8,657)

Operating activities

Net cash used in operating activities was approximately \$12.4 million and \$8.5 million for the years ended March 31, 2023 and 2022, respectively. The \$3.8 million increase in operating cash usage, for the year ended March 31, 2023, can be attributed primarily to an increase in our research and development activities. Operating cash usage includes \$2.0 million of cash outflows for acquired IPR&D of Metacrine's FXR drug compound, related research data, and IP.

Investing activities

Net cash used in investing activities was \$1.0 million and \$0.4 million for the years ended March 31, 2023 and 2022, respectively. The net cash used in investing activities for the year ended March 31, 2023 was attributed to \$0.4 million of fixed asset purchases, \$0.7 million of purchases of equity securities, net of sales, which was slightly offset by \$0.1 million of investment income. The net cash used in investing activities for the year ended March 31, 2022 was related to the purchase of fixed assets.

Financing activities

Net cash provided by financing activities was zero and \$0.2 million for the years ended March 31, 2023 and 2022, respectively. The net cash provided for the year ended March 31, 2022, was primarily driven by at-the-market ("ATM") share offerings. Refer to "Operations funding requirements" below for further information regarding financing activities.

Operations funding requirements

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

Our ongoing cash requirements include research and development expenses, compensation for personnel, consulting fees, legal and accounting support, insurance premiums, facilities, maintenance of our intellectual property portfolio, license and collaboration agreements, listing on the Nasdaq Capital Market, and other miscellaneous fees to support our operations. We expect our total operating expense for the fiscal year ending March 31, 2024 to be between \$12.0 million and \$14.0 million. Based on our current operating plan and available cash resources, we will need substantial additional funding to support future operating activities. We have concluded that the prevailing conditions and ongoing liquidity risks faced by us raise substantial doubt about our ability to continue as a going concern for at least one year following the date these financial statements are issued. The accompanying consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

We previously had an effective shelf registration statement on Form S-3 (File No. 333-222929) (the "2018 Shelf") that registered \$100.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that was set to expire on February 22, 2021. On January 19, 2021, we filed a shelf registration statement on Form S-3 (File No. 333-252224) to register \$150.0 million of common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the "2021 Shelf") and a related prospectus. The 2021 Shelf registration statement was declared effective by the SEC on January 29, 2021 and replaced the 2018 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 "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 are issued pursuant to our 2021 Shelf.

During the year ended March 31, 2023, we sold no shares of common stock in ATM offerings. As of March 31, 2023, we have sold an aggregate of 1,580,862 shares of common stock in ATM offerings under the ATM Prospectus Supplement, for gross proceeds of approximately \$21.7 million. As of March 31, 2023, there was approximately \$100.0 million available in future offerings under the 2021 Shelf, and approximately \$28.3 million available for future offerings through our ATM program under the ATM Prospectus Supplement.

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

As of March 31, 2023, we had 8,716,906 total issued and outstanding shares of common stock.

On October 12, 2022, our stockholders and the Board of Directors ("Board") approved the 2022 Plan, and it became effective on that date. The 2022 Plan replaced the 2012 Plan on the effective date. Upon the effective date, we ceased granting awards under the 2012 Plan and any shares remaining available for future issuance under the 2012 Plan were cancelled and are no longer available for future issuance. The 2012 Plan continues to govern awards previously granted under it. At the time the Board approved the 2022 Plan, an aggregate of 1,363,000 shares of our common stock was initially reserved for issuance under the 2022 Plan. We committed to reducing the new 2022 Plan share reserve by the number of shares that were granted under the 2012 Plan and the Inducement Plan between July 25, 2022 and October 12, 2022. From July 25, 2022 to October 12, 2022, we issued 126,262 shares of common stock under the 2012 Plan. As a result, the number of shares reserved for future issuance under the 2022 Plan is 1,236,738 shares of common stock as of March 31, 2023. We also committed to reducing the aggregate number of shares of common stock issuable pursuant to the Inducement Plan from 750,000 shares to 51,000 shares (which includes 50,000 shares of its common stock issuable pursuant to an outstanding option to purchase common stock with an exercise price of \$2.75 per share, leaving only 1,000 shares available for future issuance under the Inducement Plan) and the share reserve was reduced effective October 12, 2022.

The 2022 Plan provides for the issuance of up to 1,236,738 shares of our common stock, of which 1,071,471 shares remain available for issuance as of March 31, 2023, to executive officers, directors, advisory board members, employees and consultants. The 2012 Plan, as amended, provided for the issuance of up to 2,327,699 shares of our common stock, of which no shares remain available for issuance as of March 31, 2023. Additionally, 75,000 shares of common stock have been reserved for issuance under the ESPP, of which 58,426 shares remain available for future issuance as of March 31, 2023. Finally, 51,000 shares of common stock have been reserved for issuances under our Inducement Plan, of which 1,000 remain available for future issuance as of March 31, 2023. In

aggregate, issued and outstanding common stock and shares issuable under outstanding equity awards or reserved for future issuance under the 2022 Plan, the 2012 Plan, the Inducement Plan, and the ESPP total 11,426,737 shares of common stock as of March 31, 2023.

Effect of Inflation and Changes in Prices

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

Recent Accounting Pronouncements

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

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

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

Item 8. Consolidated Financial Statements.

Organovo Holdings, Inc.

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

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

Going Concern Uncertainty

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

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters.

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2011.

San Diego, California
July 13, 2023

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

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

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

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS

(in thousands except for share and per share data)

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

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

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

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

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

ORGANOVO HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

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

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

Organovo Holdings, Inc.

Notes to Consolidated Financial Statements

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

Nature of operations and basis of presentation

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

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

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

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

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

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

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

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on the basis that we are a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. As of March 31, 2023, the Company had cash and cash equivalents of approximately \$15.3 million, restricted cash of approximately \$0.1 million and an accumulated deficit of approximately \$325.0 million. The restricted cash was pledged as collateral for a letter of credit that the Company is required to maintain as a security deposit under the terms of the lease agreements for its facilities. The Company also had negative cash flows from operations of approximately \$12.4 million during the year ended March 31, 2023.

Through March 31, 2023, the Company has financed its operations primarily through the sale of common stock through public and at-the-market (“ATM”) offerings, the private placement of equity securities, from revenue derived from the licensing of intellectual property, products and research-based services, grants, and collaborative research agreements, and from the sale of convertible notes. During the year ended March 31, 2023, the Company issued zero shares of its common stock through its ATM facility.

Based on our current operating plan and available cash resources, we will need substantial additional funding to support future operating activities. We have concluded that the prevailing conditions and ongoing liquidity risks faced by us raise substantial doubt

about our ability to continue as a going concern for at least one year following the date these financial statements are issued. The accompanying consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern. As the Company continues its operations and is focusing its efforts on drug discovery and development, the Company will need to raise additional capital to implement this business plan. The Company cannot predict with certainty the exact amount or timing for any future capital raises. The Company will seek to raise additional capital through debt or equity financings, or through some other financing arrangement. However, the Company cannot be sure that additional financing will be available if and when needed, or that, if available, it can obtain financing on terms favorable to its stockholders. Any failure to obtain financing when required will have a material adverse effect on the Company's business, operating results, and financial condition.

Use of estimates

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

Investments

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

Investments in debt securities consist of investments in U.S. Treasury bills. As of March 31, 2023, all investments that have original maturities of three months or less are classified as cash equivalents on the Consolidated Balance Sheets. Prior to March 31, 2023, the Company classified certain investments as held-to-maturity. All investments previously classified as held-to-maturity matured prior to March 31, 2023. As of March 31, 2023, all investments are classified as available-for-sale, as the sale of such investments may be required prior to maturity to implement management strategies. Available-for-sale debt securities are recorded at fair value. Any unrealized gains and losses are included in accumulated other comprehensive income as a component of stockholders' equity until realized. As U.S. Treasury bills are risk-free, any declines in fair value are considered temporary.

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

Fair value measurement

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

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

Financial instruments

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

Cash and cash equivalents

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

Restricted cash

As of March 31, 2023 and 2022, the Company had approximately \$0.1 million of restricted cash, respectively, deposited with a financial institution. The entire amount was held in certificates of deposit to support a letter of credit agreement related to the Company's facility leases entered into in November 2020 and amended in November 2021.

Fixed assets and depreciation

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

Impairment of long-lived assets

In accordance with authoritative guidance, the Company reviews its long-lived assets, including fixed assets and other assets, for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be fully recoverable. To determine recoverability of its long-lived assets, the Company evaluates whether future undiscounted net cash flows will be less than the carrying amount of the assets and adjusts the carrying amount of its assets to fair value. Management has determined that no impairment of long-lived assets occurred as of March 31, 2023 and 2022.

Research and development

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

Acquired in-process research and development

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

FXR Program

In March 2023, the Company acquired Metacrine's FXR program for \$4.0 million. The FXR program was determined to have no alternative future use, and therefore was considered acquired in-process research and development and fully expensed. For the year ended March 31, 2023, the Company paid a \$2.0 million upfront payment, and the remaining \$2.0 million will be paid in the next fiscal year (see detail in "Note 4. Accrued Expenses") upon final transfer of the drug compounds, related data, and IP.

Income taxes

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

Revenue recognition

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

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

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

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

Stock-based compensation

The Company accounts for stock-based compensation in accordance with the ASC Topic 718, *Compensation — Stock Compensation*, which establishes accounting for equity instruments exchanged for employee and non-employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award (determined using either the Black-Scholes or Monte Carlo option-pricing models, depending on the complexity of the equity grant), and is recognized as an expense, under the straight-line method, over the employee’s requisite service period (generally the vesting period of the equity grant).

Comprehensive income (loss)

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

Net loss per share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options and warrants, shares reserved for purchase under the Company’s 2016 Employee Stock Purchase Plan (“ESPP”), the assumed release of restriction of restricted stock units (“RSUs”), and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the years ended March 31, 2023 and 2022 as the Company reported a net loss for each respective period and the effect would have been anti-dilutive.

Common stock equivalents excluded from computing diluted net loss per share were approximately 1.6 million shares and 1.2 million shares for the years ended March 31, 2023 and 2022, respectively.

Note 2. Investments and fair value measurement

Investments in debt securities

As of March 31, 2023, the Company held \$4.9 million of investments in debt securities (which are included in the \$15.3 million of cash and cash equivalents). For the year ended March 31, 2023, there was \$0.3 million of interest income related to the investments in debt securities. There were less than \$0.1 million of unrealized gains recorded on investments in debt securities for the year ended March 31, 2023. As the investments in debt securities consist of U.S. Treasury bills from active markets, the fair value is measured using level 1 inputs.

The following table summarizes the Company's investments in debt securities that are measured at fair value as of March 31, 2023 (in thousands):

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

Investments in equity securities

For the year ended March 31, 2023, there was \$1.1 million of equity securities purchased, and \$0.4 million of equity securities sold. As of March 31, 2023, the fair value of investment in equity securities was \$0.7 million, resulting in less than a \$0.1 million

unrealized gain on investment in equity securities. As the investments in equity securities consist of common stock from active markets, the fair value is measured using level 1 inputs.

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

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

Note 3. Fixed Assets

Fixed assets consisted of the following (in thousands):

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

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

Note 4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

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

Note 5. Collaborative Research, Development, and License Agreements

License Agreements

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

As part of the License Agreement, BICO Group AB agreed to pay the Company a one time, nonrefundable upfront fee of \$1,500,000. Based on Topic 606, the Company concluded that the performance obligation related to this upfront fee consisted of the Company

filing stipulations of dismissal of all legal matters noted above, as well as the Company granting the non-exclusive license of the aforementioned patents within five days of receiving the upfront payment. The conditions of the performance obligation were satisfied, and therefore the Company recognized revenue of \$1,500,000 on February 22, 2022, the executed date of the License Agreement.

Additionally, as part of the License Agreement, BICO Group AB agreed to pay the Company ongoing sales-based royalties (based on percentages of BICO Group AB's net sales) for the use of the granted license. The sales-based royalties became effective beginning on February 22, 2022, the effective date of the License Agreement, and continue until the expiration of the last surviving licensed patent. As the sales-based royalties are required to be paid 45 days after the end of every quarter, there is variable consideration that must be estimated to determine royalty revenue within a given reporting period. Sales-based royalties that occurred prior to fiscal 2023 were recognized as revenue on a one quarter lag due to constraints on the estimates of variable consideration. During fiscal 2023, the Company began to estimate sales-based royalties earned each quarter. For the year ended March 31, 2023, the Company recorded \$370,000 of royalty revenue based on sales-based royalties from the License Agreement. This recognized revenue is related to sales-based royalties earned from February 22, 2022 through March 31, 2023.

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

University of Missouri

In March 2009, the Company entered into a license agreement with the Curators of the University of Missouri to in-license certain technology and intellectual property relating to self-assembling cell aggregates and to intermediate cellular units. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company is required to pay the University of Missouri royalties ranging from 1% to 3% of net sales of covered tissue products, and of the fair market value of covered tissues transferred internally for use in the Company's commercial service business, depending on the level of net sales achieved by the Company each year. The Company paid the minimum annual royalty of \$25,000 in January 2022 for its respective calendar year, which is credited against royalties due during the subsequent twelve months. No payments have been made in excess of the minimum annual royalties in the years ended March 31, 2023 and 2022.

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

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

Clemson University

In May 2011, the Company entered into a license agreement with Clemson University Research Foundation to in-license certain technology and intellectual property relating to ink-jet printing of viable cells. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company is required to pay the university royalties ranging from 1.5% to 3% of net sales of covered tissue products and the fair market value of covered tissues transferred internally for use in the Company's commercial service business, depending on the level of net sales reached each year. The license agreement terminates upon expiration of the patents licensed, which are expected to expire in May 2024, and is subject to certain conditions as defined in the license agreement. Minimum annual royalty payments of \$20,000 were due for each of the two years beginning with calendar 2014, and \$40,000 per year beginning with calendar 2016. Royalty payments of \$40,000 were made in each of the years ended March 31, 2023 and 2022. The annual minimum royalty is creditable against royalties owed during the same calendar year.

In addition to the annual royalties noted above, the University is owed 40% of all payments including but not limited to, upfront payments, license fees, issue fees, maintenance fees, and milestone payments received from third parties, including sublicensees, in consideration for sublicensing rights to licensed products. However, per the agreement, in the event that the Company defends the technology by litigation, it can offset any royalties due by legal expenses incurred. As of March 31, 2023, the Company's legal

expenses exceeded royalties owed from the upfront payment and sales-based royalties related to the License Agreement. Therefore, no royalty expense to Clemson University was recorded for the year ended March 31, 2023. No royalty expense related to sales-based royalties has been recorded to date.

Capitalized License Fees

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

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

The above license fees, net of accumulated amortization, are included in Other Assets in the accompanying consolidated balance sheets and are being amortized over the life of the related patents. Amortization expense of licenses was approximately \$82,000 and \$14,000 for the years ended March 31, 2023 and 2022, respectively. At March 31, 2023, the weighted average remaining amortization period for all licenses was approximately 2 years. The annual amortization expense of licenses for the next five years is estimated to be approximately \$3,000 per year.

The Salk Institute for Biological Studies

In March 2023, the Company acquired the FXR Agonist program from Metacrine. All patent rights related to this program have been assigned to the Company in connection with the acquisition. In addition, the Company assumed and was assigned a license agreement with the Salk Institute for Biological Studies (hereafter “Salk”) that provides certain payments to Salk upon the successful development and commercialization of the lead compound, FXR314. The Company is required to pay Salk royalties ranging from 1% to 1.125% of net sales of therapeutics based on FXR314. In addition, the Company is required to make certain milestone payments based on the successful initiation and/or completion of certain development milestones, including \$500,000 within 45 days of the dosing of the first patient in a phase III clinical trial, \$1,000,000 within 45 days of FDA approval of the first Licensed Product and \$1,500,000 within 45 days of the first commercial sale of a Licensed Product in the Territory. There are also reduced milestone payments application to a second or third licensed product, if any. Should the company sublicense the a licensed product to a third party, then it must pay a 3.5% of sublicensing revenue attributable to such a sublicense.

Note 6. Stockholders’ Equity

Preferred stock

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

Common stock

In January 2012, the Board approved the 2012 Plan. The 2012 Plan authorized the issuance of up to 327,699 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, RSUs, performance units, performance shares, and other stock or cash awards. The Board and stockholders of the Company approved an amendment to the 2012 Plan in August 2013 to increase the number of shares of common stock that may be issued under the 2012 Plan by 250,000 shares. In August 2015, the Board and stockholders of the Company approved an amendment to the 2012 Plan to further increase the number of shares of common stock that may be issued under the 2012 Plan by 300,000 shares. In July 2018, the Board and stockholders of the Company approved an amendment to the 2012 Plan to further increase the number of shares of common stock that may be issued under the 2012 Plan by 550,000 shares. In October 2021, the Board and stockholders of the Company approved an amendment to the 2012 Plan to further increase the number of shares of common stock that may be issued under the 2012 Plan by 900,000, bringing the aggregate shares issuable under the 2012 Plan to 2,327,699. The 2012 Plan as amended and restated became effective on July 26, 2018 and terminates ten years after such date.

In March 2021, the Board approved the Inducement Plan. The Inducement Plan authorized the issuance of up to 750,000 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, RSUs, performance units, performance shares, and other stock or cash awards. In February 2022, 50,000 incentive stock options were issued under the Inducement Plan.

On October 12, 2022, the Company's stockholders and the Board approved the 2022 Plan, and it became effective on that date. The 2022 Plan replaced the 2012 Plan on the effective date. Upon the effective date, the Company ceased granting awards under the 2012 Plan and any shares remaining available for future issuance under the 2012 Plan were cancelled and are no longer available for future issuance. The 2012 Plan continues to govern awards previously granted under it. At the time the Board approved the 2022 Plan, an aggregate of 1,363,000 shares of the Company's common stock was initially reserved for issuance under the 2022 Plan. The Company committed to reducing the new 2022 Plan share reserve by the number of shares that were granted under the 2012 Plan and the Inducement Plan between July 25, 2022 and October 12, 2022. From July 25, 2022 to October 12, 2022, the Company issued 126,262 shares of its common stock under the 2012 Plan. As a result, the number of shares reserved for future issuance under the 2022 Plan is 1,236,738 shares of common stock. The Company also committed to reducing the aggregate number of shares of its common stock issuable pursuant to the Inducement Plan from 750,000 shares to 51,000 shares (which includes 50,000 shares of its common stock issuable pursuant to an outstanding option to purchase common stock with an exercise price of \$2.75 per share, leaving only 1,000 shares available for future issuance under the Inducement Plan) and the share reserve was reduced effective October 12, 2022.

The Company previously had an effective shelf registration statement on Form S-3 (File No. 333-222929) and the related prospectus previously declared effective by the SEC on February 22, 2018 (the "2018 Shelf"), which registered \$100.0 million of common stock, preferred stock, warrants and units, or any combination of the foregoing, that was set to expire on February 22, 2021. On January 19, 2021, the Company filed a shelf registration statement on Form S-3 (File No. 333-252224) to register \$150.0 million of the Company's common stock, preferred stock, debt securities, warrants and units, or any combination of the foregoing (the "2021 Shelf") and a related prospectus. The 2021 Shelf was declared effective by the SEC on January 29, 2021 and replaced the 2018 Shelf at that time.

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

Restricted stock units

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

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

Stock options

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

On March 8, 2021, the Company granted 120,000 and 25,000 stock options, respectively, to its Executive Chairman and its Chief Scientific Officer under the 2012 Plan. On October 7, 2021, the Company granted an additional 120,000 and 25,000 stock options, respectively, to the aforementioned officers. These stock options have unique vesting criteria based on market conditions, more specifically the Company's stock price. As these market condition based stock options require significant estimates and assumptions to calculate their fair value, the Company engaged with valuation specialists to calculate the fair value and requisite service periods using Monte Carlo simulations. The stock options will be expensed over their determined requisite service periods. As of March 31, 2023, half of the aforementioned stock options were fully expensed over their requisite service periods. However, to date, none of the stock options have vested.

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

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

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

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

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

Employee Stock Purchase Plan

In June 2016, the Board, and in August 2016, its stockholders subsequently approved, the ESPP. The Company reserved 75,000 shares of common stock for issuance thereunder. The ESPP permits employees after five months of service to purchase common stock through payroll deductions, limited to 15 percent of each employee’s compensation up to \$25,000 per employee per year. Shares under the ESPP are purchased at 85 percent of the fair market value at the lower of (i) the closing price on the first trading day of the six-month purchase period or (ii) the closing price on the last trading day of the six-month purchase period. The initial offering period commenced in September 2016. During the year ended March 31, 2023, 1,009 shares were issued under the ESPP. At March 31, 2023, there were 58,426 shares remaining available for the purchase under the ESPP.

Common stock reserved for future issuance

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

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

Stock-based compensation expense and valuation information

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

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

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

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

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

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

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

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

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

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

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

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

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

Note 7. Leases

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

Operating Leases

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

On November 23, 2020, the Company entered into two lease agreements, pursuant to which the Company temporarily leased approximately 3,212 square feet of lab and office space (the "Temporary Lease") in San Diego and permanently leased approximately 8,051 square feet of office space (the "Permanent Lease") in San Diego once certain tenant improvements for the Company's permanent premises were completed by the landlord and the premises were ready for occupancy. Additionally, on November 17, 2021, the Permanent Lease was amended to add an additional 2,892 square feet of office space in the same building. The Temporary Lease commenced on November 27, 2020 and served as temporary premises until the Permanent Lease was ready for occupancy. The Permanent Lease commenced on December 17, 2021 and is intended to serve as the Company's permanent premises for approximately sixty-two months. Monthly rental payments are approximately \$40,900 with 3% annual escalators.

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

The Company determined that the Permanent Lease is considered an operating lease under ASC 842, and therefore upon the lease commencement date of December 17, 2021, recognized lease liabilities and corresponding right-of-use assets of \$2.3 million. The Company aggregates all lease and non-lease components for each class of underlying assets into a single lease component. As the Permanent Lease did not have a discount rate implicit in the lease, the Company estimated its incremental borrowing rate to discount the lease payments based on information available at the lease commencement. The Company records operating lease expense on a straight-line basis over the life of the lease (referred to as "operating lease expense"). Variable lease expenses associated with the Company's leases, such as payments for additional monthly fees to cover the Company's share of certain facility expenses (common area maintenance, or CAM) are expensed as incurred.

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

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

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

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

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

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

Note 8. Commitments and Contingencies

Legal matters

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

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

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

significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, if one or more legal matters were resolved against the Company in a reporting period, the Company's consolidated financial statements for that reporting period could be materially adversely affected.

Note 9. Income Taxes

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

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

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets are as follows as of March 31, 2023 and 2022 (in thousands, except percentages):

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

A full valuation allowance has been established to offset the deferred tax assets as management cannot conclude that realization of such assets is more likely than not. Under the Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research tax credit carryforwards to offset taxable income may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such limitations have been triggered as of March 31, 2023. Until this analysis is completed, the Company has removed the deferred tax assets related to net operating losses from its deferred tax asset schedule. Further, until a study is completed and any limitation known, approximately \$1.6 million and \$1.5 million for the years ended March 31, 2023 and 2022, respectively, would be considered as an uncertain tax position if netted against the deferred tax asset. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. The valuation allowance increased by approximately \$1,875,000 and decreased by approximately \$1,941,000 for the years ended March 31, 2023 and 2022, respectively.

The Company had federal and state net operating loss carryforwards of approximately \$210.5 million and \$40.9 million, respectively, as of March 31, 2023. Federal net operating loss carryforwards of approximately \$66.8 million will carryforward indefinitely and be available to offset up to 80% of future taxable income each year subject to revisions made by the Coronavirus Aid, Relief, and

Economic Security Act (the “CARES Act”). The remaining federal net operating losses will begin to expire in 2028, unless previously utilized. The state net operating loss carryforwards (“NOLs”) will begin to expire in 2028, unless previously utilized.

The Company had federal and state research tax credit carryforwards of approximately \$4.7 million and \$4.3 million at March 31, 2023, respectively. The federal research tax credit carryforwards begin expiring in 2028. The state research tax credit carryforwards do not expire.

The Company did not record any accruals for income tax accounting uncertainties for the year ended March 31, 2023.

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

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

The Company is subject to tax in the United States and in California. As of March 31, 2023, the Company’s tax years from inception are subject to examination by the tax authorities due to the generation of net operating losses. The Company is not currently under examination by any jurisdiction.

Note 10. Concentrations

Credit risk and significant customers

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

Note 11. Related Parties

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

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

On December 28, 2020, the Company entered into an intercompany agreement (the “Intercompany Agreement”) with Viscient and Organovo, Inc., the Company’s wholly-owned subsidiary, which included an asset purchase agreement for certain lab equipment. Pursuant to the Intercompany Agreement, the Company agreed to provide Viscient certain services related to 3D bioprinting technology, which includes, but is not limited to, histology services, cell isolation, and proliferation of cells and Viscient agreed to provide the Company certain services related to 3D bioprinting technology, including bioprinter training, bioprinting services, and qPCR assays, in each case on payment terms specified in the Intercompany Agreement and as may be further determined by the parties. In addition, the Company and Viscient each agreed to share certain facilities and equipment and, subject to further agreement, to each make certain employees available for specified projects for the other party at prices to be determined in good faith by the parties. The Company evaluated the accounting for the Intercompany Agreement and concluded that any services provided by Viscient to the Company will be expensed as incurred, and any compensation for services provided by the Company to Viscient will be considered a reduction of personnel related expenses. Any services provided to Viscient do not fall under Topic 606 as the Intercompany Agreement is not a contract with a customer. For the years ended March 31, 2023 and 2022, the Company incurred approximately zero and \$47,000 in consulting expenses from Viscient, respectively. Additionally, for the years ended March 31, 2023 and 2022, the Company provided approximately \$59,000 and \$48,000 of histology services to Viscient, respectively.

Note 12. Defined Contribution Plan

The Company has a defined contribution 401(k) plan covering substantially all employees. During the year ended March 31, 2015, the 401(k) plan was amended (the “Amended Plan”) to include an employer matching provision. Under the terms of the Amended Plan, the Company will make matching contributions on up to the first 6% of compensation contributed by its employees. Amounts expensed under the Company’s 401(k) plan for the years ended March 31, 2023 and 2022 were approximately \$10,000 and \$25,000, respectively.

Note 13. Recent Accounting Pronouncements

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

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

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

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

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management's annual report on internal control over financial reporting is set forth below.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our system of internal control over financial reporting is designed to provide reasonable assurance to our management and the Board regarding the preparation and fair presentation of our consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, under the supervision of our Executive Chairman and our Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of March 31, 2023. In making this assessment, we used the framework included in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the criteria set forth in *Internal Control — Integrated Framework* (2013), our management concluded that our internal control over financial reporting was effective as of March 31, 2023.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the fourth quarter of the fiscal year ended March 31, 2023, to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Executive Chairman and our Chief Financial Officer, 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.

Item 9B. Other Information.

On July 12, 2023, the Board approved and adopted an amendment and restatement of our amended bylaws (as so amended and restated, the "Amended and Restated Bylaws"), effective as of such date.

The amendments effected by the Amended and Restated Bylaws address the universal proxy rules promulgated by the U.S. Securities and Exchange Commission, as set forth in Rule 14a-19 of the Securities Exchange Act of 1934, as amended (the "1934 Act"). The amendments require any stockholder providing advance notice of director nominations to comply with Rule 14a-19 of the 1934 Act,

including applicable notice and solicitation requirements. We will disregard such nominations if the stockholder fails to timely provide reasonable evidence of its compliance with Rule 14a-19 of the 1934 Act.

The amendments also enhance disclosure requirements and procedural mechanics in connection with director nominations and business proposals by stockholders (other than proposals to be included in our proxy statement pursuant to Rule 14a-8 of the 1934 Act). The amendments require, among other information, additional background information and disclosures regarding proposing stockholders, proposed nominees and business, and other persons related to a stockholder's solicitation of proxies. Further, a stockholder may not nominate a greater number of director candidates than there are director seats subject to election by stockholders at an annual meeting, and the Board may require any nominee to submit to interviews with the Board. In addition, any stockholder directly or indirectly soliciting proxies from other stockholders must use a proxy card color other than white, with the white proxy card being reserved for exclusive use by the Board.

The amendments also eliminate the requirement that we make a stockholder list available during a meeting of stockholders, consistent with recent amendments to the General Corporation Law of the State of Delaware, and make various other conforming, technical and non-substantive changes.

The foregoing description of the amendments effected by the Amended and Restated Bylaws does not purport to be complete and is qualified in its entirety by reference to the complete text of the Amended and Restated Bylaws, which is attached hereto as Exhibit 3.4 and incorporated herein by reference.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information relating to our directors, executive officers and corporate governance, including our Code of Business Conduct, will be included in the proxy statement for the 2023 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference. The full text of our Code of Business Conduct, which is the code of ethics that applies to all of our officers, directors and employees, can be found in the "Investors" section of our website accessible to the public at www.organovo.com.

Item 11. Executive Compensation.

Information relating to executive compensation will be included in the proxy statement for the 2023 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference.

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

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

Plan category	(A) Number of securities to be issued upon exercise/vesting of outstanding options, warrants, units and rights	(B) Weighted-average exercise price of outstanding options, warrants, units and rights	(C) Number of securities available for future issuance under Equity Compensation Plans (excluding securities reflected in column (A))
Equity compensation plans approved by security holders (1)	1,528,934 (2)	\$ 6.62	1,129,897 (3)
Equity compensation plans not approved by security holders (4)	50,000 (5)	\$ 2.75	1,000 (6)

- (1) Includes the 2008 Plan, the 2012 Plan, the 2022 Plan, and the ESPP.
- (2) Includes stock options to purchase 1,401,217 shares of common stock with a per share weighted-average exercise price of \$6.62. Also includes 127,717 restricted stock units with no exercise price.
- (3) Includes 58,426 shares of common stock available for purchase under the ESPP as of March 31, 2023.
- (4) Includes the Inducement Award Agreements and the Inducement Plan
- (5) Includes 50,000 stock options with a per share exercise price of \$2.75 granted pursuant to the Inducement Plan
- (6) Includes 1,000 shares of common stock reserved for issuance pursuant to the Inducement Plan.

Information relating to the beneficial ownership of our common stock will be included in the proxy statement for the 2023 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference.

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

Information relating to certain relationships and related transactions and director independence will be included in the proxy statement for the 2023 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

Information relating to principal accountant fees and services will be included in the proxy statement for the 2023 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our most recently completed fiscal year, which is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

- (a) The following documents have been filed as part of this Annual Report:
1. Consolidated Financial Statements: The information required by this item is included in Item 8 of Part II of this annual report.
 2. Financial Statement Schedules: Financial statement schedules required under the related instructions are not applicable for the years ended March 31, 2023 and 2022 and have therefore been omitted.
 3. Exhibits: The exhibits listed in the Exhibit Index attached to this report are filed or incorporated by reference as part of this annual report.
- (b) The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
2.1	<u>Agreement and Plan of Merger and Reorganization, dated as of December 13, 2019, by and among the Company, Opal Merger Sub, Inc. and Tarveda Therapeutics, Inc. (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 16, 2019).</u>
2.2	<u>First Amendment to Merger Agreement, dated as of January 26, 2020, by and among the Company, Opal Merger Sub, Inc. and Tarveda Therapeutics, Inc. (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 29, 2020).</u>
3.1	<u>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).</u>
3.2	<u>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).</u>
3.3	<u>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).</u>
3.4*	<u>Amended and Restated Bylaws of Organovo Holdings, Inc., effective as of July 12, 2023.</u>
4.1*	<u>Description of Securities.</u>
10.1+	<u>Organovo, Inc. 2008 Equity Incentive Plan (incorporated by reference from Exhibit 10.14 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).</u>
10.2+	<u>Organovo Holdings, Inc. Amended and Restated 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 6, 2021).</u>
10.3+	<u>Form of Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.16 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).</u>
10.4+	<u>Form of Indemnification Agreement (incorporated by reference from Exhibit 10.17 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).</u>
10.5†	<u>License Agreement dated as of March 24, 2009, by and between Organovo, Inc. and the Curators of the University of Missouri (incorporated by reference from Exhibit 10.23 to the Company's Current Report on Form 8-K, as filed with the SEC on May 11, 2012).</u>
10.6†	<u>License Agreement dated as of March 12, 2010 by and between the Company and the Curators of the University of Missouri (incorporated by reference from Exhibit 10.24 to the Company's Current Report on Form 8-K, as filed with the SEC on May 11, 2012).</u>
10.7†	<u>License Agreement dated as of May 2, 2011, by and between the Company and Clemson University Research Foundation (incorporated by reference from Exhibit 10.25 to the Company's Current Report on Form 8-K, as filed with the SEC on May 11, 2012).</u>
10.8+	<u>Form of Non-Employee Director Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 9, 2015).</u>
10.9+	<u>Form of Executive Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 9, 2015).</u>
10.10+	<u>Organovo Holdings, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2015).</u>
10.11+	<u>Amendment to the Organovo Holdings, Inc. Severance and Change in Control Plan, dated May 19, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 20, 2020).</u>
10.12+	<u>Form of Organovo Holdings, Inc. Severance and Change in Control Plan Participation Agreement (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 9, 2015).</u>

Exhibit No.	Description
10.13+	<u>Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement (Retention Form) under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).</u>
10.14+	<u>Form of Employee Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).</u>
10.15+	<u>Form of Non-Employee Director Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).</u>
10.16+	<u>Organovo Holdings, Inc. 2016 Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 18, 2016).</u>
10.17+	<u>Organovo Holdings, Inc. Inducement Award Stock Option Agreement, dated April 24, 2017 (incorporated by reference from Exhibit 99.1 to the Company's Registration Statement on Form S-8 (File No. 333-217437), as filed with the SEC on April 24, 2017).</u>
10.18+	<u>Organovo Holdings, Inc. Inducement Award Performance-Based Restricted Stock Unit Agreement, dated April 24, 2017 (incorporated by reference from Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-217437), as filed with the SEC on April 24, 2017).</u>
10.19+	<u>Organovo Holdings, Inc. Inducement Award Stock Option Agreement, dated August 14, 2018 (incorporated by reference from Exhibit 99.1 to the Company's Registration Statement on Form S-8 (File No. 333-226837), as filed with the SEC on August 14, 2018).</u>
10.20+	<u>Organovo Holdings, Inc. Inducement Award Restricted Stock Unit Agreement, dated August 14, 2018 (incorporated by reference from Exhibit 99.2 to the Company's Registration Statement on Form S-8 (File No. 333-226837), as filed with the SEC on August 14, 2018).</u>
10.21+	<u>Consulting Agreement, dated September 15, 2020, by and between Organovo and Multi Dimensional Bio Insight LLC. (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 5, 2020).</u>
10.22+	<u>Consulting Agreement, dated August 25, 2020, by and between Organovo and Danforth Advisors (incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 5, 2020).</u>
10.23+	<u>Amendment No. 5 dated October 4, 2021 to Consulting Agreement dated August 25, 2021 by and between Company and Danforth Advisors LLC (incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on October 6, 2021).</u>
10.24+	<u>Offer Letter, dated September 15, 2020, between the Company and Jeffrey N. Miner (incorporated by reference from Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 5, 2020).</u>
10.25+	<u>Engagement Agreement, dated July 23, 2020, by and between Organovo and Optima Law Group of San Diego (incorporated by reference from Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on November 5, 2020).</u>
10.26	<u>Lease Agreement dated November 23, 2020, between Organovo Holdings, Inc. and San Diego Inspire 1, LLC (Permanent Lease Agreement 176640186.8) (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on November 25, 2020).</u>
10.27	<u>Amended and Restated Lease Agreement dated November 23, 2020, between Organovo, Inc., as Tenant, and San Diego Inspire 2, LLC, as Landlord, as amended by First Amendment to Amended & Restated Lease, dated November 17, 2021, between San Diego Inspire 2, LLC, as Landlord, and Organovo, Inc., as Tenant (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 19, 2021).</u>
10.28#	<u>Intercompany Agreement, dated December 28, 2020, by and among Organovo Holdings, Inc., Organovo, Inc. and Viscient Biosciences, Inc. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 31, 2020).</u>

Exhibit No.	Description
10.29+	Offer Letter, dated December 28, 2020, between the Company and Tom Jurgensen (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on February 8, 2021).
10.30	Sales Agreement, dated March 16, 2018, by and among Organovo Holdings, Inc., H.C. Wainwright & Co., LLC and Jones Trading Institutional Services LLC. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 16, 2018).
10.31+	Organovo Holdings, Inc. 2021 Inducement Equity Incentive Plan (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on March 10, 2021).
10.32+	Form of Stock Option Agreement under the Organovo Holdings, Inc. 2021 Inducement Equity Incentive Plan (incorporated by reference from Exhibit 4.2 to the Company's Registration Statement on Form S-8 (File No. 333-254714), as filed with the SEC on March 25, 2021).
10.33+	Form of Restricted Stock Unit Agreement under the Organovo Holdings, Inc. 2021 Inducement Equity Incentive Plan (incorporated by reference from Exhibit 4.3 to the Company's Registration Statement on Form S-8 (File No. 333-254714), as filed with the SEC on March 25, 2021).
10.34*	Settlement and Patent License Agreement, dated February 22, 2022, by and between Organovo Holdings, Inc. and BICO Group AB.
10.35+	Organovo Holdings, Inc. 2022 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 14, 2022)
10.36+	Form of Global Stock Option Award Agreement under the Organovo Holdings, Inc. 2022 Equity Incentive Plan (incorporated by reference from Exhibit 4.2 to the Company's Registration Statement on Form S-8 (No. 333-268001), filed with the SEC on October 25, 2022).
10.37+	Form of Global Restricted Stock Unit Award Agreement under the Organovo Holdings, Inc. 2022 Equity Incentive Plan (incorporate3 by reference from Exhibit 4.2 to the Company's Registration Statement on Form S-8 (No. 333-268001), filed with the SEC on October 25, 2022).
10.38*	Purchase Agreement, dated March 10, 2023, by and between Organovo Holdings, Inc. and Metacrine, Inc.
21.1*	Subsidiaries of Organovo Holdings, Inc.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on signature page hereto).
31.1*	Certification of Chief Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer a Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certifications Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and to 18 U.S.C. Section 1350.
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ Designates management contracts and compensation plans.

† This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the redaction pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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

SIGNATURES

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

ORGANOVO HOLDINGS, INC.

By: /s/ Keith Murphy

Keith Murphy
Executive Chairman

Date: July 13, 2023

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

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

Signature	Title	Date
/s/ Keith Murphy Keith Murphy	Executive Chairman (Principal Executive Officer)	July 13, 2023
/s/ Thomas Hess Thomas Hess	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	July 13, 2023
/s/ Adam Stern Adam Stern	Director	July 13, 2023
/s/ Douglas Cohen Douglas Cohen	Director	July 13, 2023
/s/ David Gobel David Gobel	Director	July 13, 2023
/s/ Vaidehi Joshi Vaidehi Joshi	Director	July 13, 2023
/s/ Alison Milhous Alison Milhous	Director	July 13, 2023

**AMENDED AND RESTATED BYLAWS OF
ORGANOVO HOLDINGS, INC.**

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BYLAWS OF ORGANOVO HOLDINGS, INC.

ARTICLE I - CORPORATE OFFICES

1.1 REGISTERED OFFICE

The registered office of Organovo Holdings, Inc. shall be fixed in the corporation's certificate of incorporation, as the same may be amended from time to time.

1.2 OTHER OFFICES

The corporation's board of directors may at any time establish other offices at any place or places where the corporation is qualified to do business.

ARTICLE II - MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the board of directors. The board of directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the General Corporation Law of the State of Delaware (as amended, the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the corporation's then-principal executive office.

2.2 ANNUAL MEETING

The annual meeting of stockholders shall be held each year. The board of directors shall designate the date and time of the annual meeting. In the absence of such designation the annual meeting of stockholders shall be held on the second Tuesday of May of each year at 10:00 a.m. However, if such day falls on a legal holiday, then the meeting shall be held at the same time and place on the next succeeding business day. At the annual meeting, directors shall be elected and any other proper business, brought in accordance with Section 2.4 of these bylaws, may be transacted.

2.3 SPECIAL MEETING

(i) A special meeting of the stockholders, other than those required by statute, may be called at any time by the board of directors, chairperson of the board of directors, chief executive officer or president (in the absence of a chief executive officer), but a special meeting may not be called by any other person or persons. The board of directors may cancel, postpone or reschedule any previously scheduled special meeting at any time, before or after the notice for such meeting has been sent to the stockholders.

(ii) The notice of a special meeting shall include the purpose for which the meeting is called. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the board of directors, chairperson of the board of directors, chief executive officer or president (in the absence of a chief executive officer). Nothing contained in this Section 2.3(ii) shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the board of directors may be held.

2.4 ADVANCE NOTICE PROCEDURES

(i) *Advance Notice of Stockholder Business at Annual Meeting.* At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be

properly brought before an annual meeting, business must be brought: (A) pursuant to the corporation's proxy materials with respect to such meeting, (B) by or at the direction of the board of directors, or (C) by a stockholder of the corporation who (1) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(i) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has timely complied in proper written form with the notice procedures set forth in this Section 2.4(i). In addition, for business to be properly brought before an annual meeting by a stockholder, such business must be a proper matter for stockholder action pursuant to these bylaws and applicable law. Except for proposals properly made in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (as so amended and inclusive of such rules and regulations, the "**1934 Act**"), clause (C) above shall be the exclusive means for a stockholder to bring business before an annual meeting of stockholders.

(a) To comply with clause (C) of Section 2.4(i) above, a stockholder's notice must set forth all information required under this Section 2.4(i) and must be timely received by the secretary of the corporation. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the corporation not later than 5:00 p.m. Pacific Time on the forty-fifth (45th) day nor earlier than 9:00 a.m. Pacific Time on the seventy-fifth (75th) day before the one-year anniversary of the date on which the corporation first mailed its proxy materials or a notice of availability of proxy materials (whichever is earlier) for the preceding year's annual meeting; *provided, however*, that in the event that no annual meeting was held in the previous year or if the date of the annual meeting is advanced by more than thirty (30) days prior to or delayed by more than sixty (60) days after the one (1)-year anniversary of the date of the previous year's annual meeting, then, for notice by the stockholder to be timely, it must be so received by the secretary not earlier than 5:00 p.m. Pacific Time on the one hundred twentieth (120th) day prior to such annual meeting and not later than 5:00 p.m. Pacific Time on the later of (i) the ninetieth (90th) day prior to such annual meeting, or (ii) the tenth (10th) day following the day on which Public Announcement (as defined below) of the date of such annual meeting is first made. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described in this Section 2.4(i)(a). "**Public Announcement**" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act.

(b) To be in proper written form, a stockholder's notice to the secretary must set forth as to each matter of business the stockholder intends to bring before the annual meeting: (1) a brief description of the business intended to be brought before the annual meeting and the reasons for conducting such business at the annual meeting, (2) the name and address, as they appear on the corporation's books, of the stockholder proposing such business and any Stockholder Associated Person (as defined below), (3) the class, series and number of shares of stock and debt instruments of the corporation that are, directly or indirectly, held of record or are beneficially owned by the stockholder or any Stockholder Associated Person and any derivative positions held or beneficially held by the stockholder or any Stockholder Associated Person as of the date of delivery of such notice, (4) any (i) agreement, arrangement or understanding (including, without limitation and regardless of the form of settlement, any derivative, long or short positions, profit interests, forwards, futures, swaps, options, warrants convertible securities, stock appreciation or similar rights, hedging or other transaction or series of transactions and borrowed or loaned shares of stock) that has been entered into by or on behalf of such stockholder or any Stockholder Associated Person with respect to any securities of the corporation (any of the foregoing, a "**Derivative Instrument**"), including the full notional amount of any securities that, directly or indirectly, underlie any Derivative Instrument and (ii) other agreement, arrangement or understanding the effect or intent of which is to create or mitigate loss to, or to manage the risk or benefit from share price changes for, or to increase or decrease the voting power of, such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, (5) any right to dividends on the corporation's securities beneficially owned by the stockholder or any Stockholder Associated Person that are separated or separable from the underlying security, (6) any material interest of the stockholder or a Stockholder Associated Person in such business, (7) a representation and undertaking that the stockholder is a holder of record of stock of the corporation as of the date of delivery of such notice and intends to appear in person or by proxy at the annual meeting to bring such business before the annual meeting, (8) any other information relating to the stockholder or any Stockholder Associated Person or others acting in concert with them, or the proposed business that, in each case, would be required to be disclosed in a proxy statement or other filings required to be made in connection with the solicitation of proxies in support of such proposal pursuant to Section 14 of the 1934 Act and (9) a statement whether either such stockholder or any Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of the voting power of the corporation's voting shares required under applicable law

to carry the proposal (such information provided and statements made as required by clauses (1) through (9), a “**Business Solicitation Statement**”). In addition, to be in proper written form, a stockholder’s notice to the secretary must be supplemented not later than ten (10) days following the record date for the determination of stockholders entitled to notice of the meeting, and ten (10) days following the record date for the determination of stockholders entitled to vote at the meeting (if that record date is different than the record date for the determination of stockholders entitled to notice of the meeting), to disclose the information contained in clauses (3) and (4) above as of the applicable record date. For purposes of this Section 2.4, a “**Stockholder Associated Person**” of any stockholder shall mean (i) any person controlling, directly or indirectly, or acting in concert with, such stockholder, (ii) any beneficial owner of shares of stock of the corporation owned of record or beneficially by such stockholder and on whose behalf the proposal or nomination, as the case may be, is being made or (iii) any person controlling, controlled by or under common control with such person referred to in the preceding clauses (i) and (ii).

(c) Without exception, no business shall be conducted at any annual meeting except in accordance with the provisions set forth in this Section 2.4(i) and, if applicable, Section 2.4(ii) hereof. In addition, business proposed to be brought by a stockholder may not be brought before the annual meeting if such stockholder or a Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Business Solicitation Statement applicable to such business or if the Business Solicitation Statement applicable to such business contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that business was not properly brought before the annual meeting and in accordance with the provisions of this Section 2.4(i), and, if the chairperson should so determine, he or she shall so declare at the annual meeting that any such business not properly brought before the annual meeting shall not be conducted.

(ii) *Advance Notice of Director Nominations at Annual Meetings.* Notwithstanding anything in these bylaws to the contrary, only persons who are nominated in accordance with the procedures set forth in this Section 2.4(ii) shall be eligible for election or re-election as directors at an annual meeting of stockholders. Nominations of persons for election or re-election to the board of directors of the corporation shall be made at an annual meeting of stockholders only (A) by or at the direction of the board of directors or (B) by a stockholder of the corporation who (1) was a stockholder of record at the time of the giving of the notice required by this Section 2.4(ii), on the record date for the determination of stockholders entitled to notice of the annual meeting and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has complied with the notice procedures set forth in this Section 2.4(ii). In addition to any other applicable requirements, for a nomination to be made by a stockholder, the stockholder must have given timely notice thereof in proper written form to the secretary of the corporation.

(a) To comply with clause (B) of Section 2.4(ii) above, (1) a nomination to be made by a stockholder must set forth all information required under this Section 2.4(ii) and must be received by the secretary of the corporation at the then-principal executive offices of the corporation at the time set forth in, and in accordance with, the final three sentences of Section 2.4(i)(a) above, (2) the stockholder must have complied in all respects with the requirements of Section 14 of the 1934 Act, including, without limitation, the requirements of Rule 14a-19 under the 1934 Act (“**Rule 14a-19**”) (as such rule and regulations thereunder may be amended from time to time by the Securities and Exchange Commission (the “**SEC**”), including any SEC Staff interpretations relating thereto) and (3) the board of directors or an executive officer designated thereby shall have determined that the stockholder has satisfied the requirements of this clause (2) of Section 2.4(ii)(a), including without limitation the satisfaction of any undertaking delivered under Section 2.4(ii)(b) below. In no event may a stockholder provide notice with respect to a greater number of director candidates than there are director seats subject to election by stockholders at the annual meeting.

(b) To be in proper written form, such stockholder’s notice to the secretary must set forth:

(1) as to each person (a “**nominee**”) whom the stockholder proposes to nominate for election or re-election as a director: (A) the name, age, business address and residence address of the nominee, (B) the principal occupation or employment of the nominee, (C) the class, series and number of shares of the corporation that are held of record or are beneficially owned by the nominee and any Derivative Instruments held or beneficially held by the nominee, including the full notional amount of any securities that, directly or indirectly, underlie any such Derivative Instruments, (D) any other agreement, arrangement or understanding that has been made

the effect or intent of which is to create or mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of the nominee with respect to the corporation's securities, (E) a description of all compensatory, payment, indemnification or other arrangements or understandings between or among the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nominations are to be made by the stockholder or concerning the nominee's potential service on the board of directors (such arrangement or understanding, a "**Third-Party Compensation Arrangement**"), (F) a description of any agreement, arrangement or understanding between the nominating stockholder or the Stockholder Associated Person, on the one hand, and the nominee, on the other hand, related to any subject matter that will be material in such nominating stockholder's solicitation of stockholders (including, without limitation, matters of social, labor, environmental and governance policy), regardless of whether such agreement, arrangement or understanding relates specifically to the corporation, (G) a description of any direct or indirect material interest in any material contract or agreement between or among any nominating stockholder or Stockholder Associated Person, on the one hand, and each nominee or his or her respective associates or any other participants in such solicitation, on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K if such nominating stockholder or Stockholder Associated Person were the "registrant" for purposes of such rule and the nominee were a director or executive officer of such registrant, (H) a completed and signed questionnaire, representation and agreement as provided in Section 2.4(ii)(c) and (I) any other information relating to the nominee that would be required to be disclosed about such nominee if proxies were being solicited for the election or re-election of the nominee as a director, or that is otherwise required, in each case pursuant to Section 14 under the 1934 Act; and

(2) as to such stockholder giving notice, (A) the information required to be provided pursuant to clauses (2) through (8) of Section 2.4(i)(b) above, and the supplement referenced in the second sentence of Section 2.4(i)(b) above (except that the references to "business" in such clauses shall instead refer to nominations of directors for purposes of this paragraph), (B) a written representation to the corporation that such stockholder has complied in all respects with the requirements of Section 14 of the 1934 Act, including, without limitation, the requirements of Rule 14a-19 (as such rule and regulations thereunder may be amended from time to time by the SEC, including any SEC Staff interpretations relating thereto), (C) a written undertaking by such stockholder giving notice or, if the notice is given on behalf of a beneficial owner on whose behalf the nomination is made, by such beneficial owner, that such stockholder or beneficial owner will deliver to beneficial owners of shares representing at least 67% of the voting power of the stock entitled to vote generally in the election of directors either (x) at least 20 calendar days before the annual meeting, a copy of its definitive proxy statement for the solicitation of proxies for its nominee or (y) at least 40 calendar days before the annual meeting, a Notice of Internet Availability of Proxy Materials that would satisfy the requirements of Rule 14a-16(d) of the 1934 Act, (D) a description of any agreement, arrangement or understanding (whether oral or written) between any nominating stockholder, on the one hand, and a Stockholder Associated Person, on the other hand, related to any subject matter that will be material in the nominating stockholder's solicitation of stockholders (including, without limitation, matters of social, labor, environmental and governance policy), regardless of whether such agreement, arrangement or undertaking relates specifically to the corporation, (E) with respect to each Stockholder Associated Person, the information that would be disclosed with respect to them under Item 5(b) of Schedule 14A under the 1934 Act, assuming that each such person was deemed a "participant" as defined in paragraphs (a)(ii), (iii), (iv), (v) and (vi) of Instruction 3 to Item 4 of Schedule 14A and (F) such other information as may be reasonably requested by the corporation to facilitate disclosure to stockholders of all material facts that, in the reasonable discretion of the corporation, are relevant for stockholders to make an informed decision on the director election proposal, including information regarding any Stockholder Associated Person (such information provided and statements made as required by clauses (A) to (F) above, a "**Nominee Solicitation Statement**").

(c) To be eligible to be a nominee of any stockholder for election or re-election as a director of the corporation, the nominee must provide to the secretary, in accordance with the applicable time periods prescribed for delivery of notice under Section 2.4(ii)(a) above or Section 2.4(iii) below: (1) a signed and completed written questionnaire (in the form provided by the secretary at the written request of the nominating stockholder, which form will be provided by the secretary within ten (10) days of receiving such request) containing information regarding such nominee's background, qualifications, stock ownership, independence and such other information as may reasonably be required by the corporation to determine the eligibility of such nominee to serve as a director of the corporation or to serve as an independent director of the corporation and (2) a written representation and undertaking executed by the nominee (in the form provided by the secretary at the written request of the nominating

stockholder, which form will be provided by the secretary within ten (10) days of receiving such request) whereby the nominee (i) consents to being named as a nominee of such stockholder, (ii) consents to serving as a director of the corporation if elected and intends to serve a full term on the board of directors, (iii) agrees to be named in any proxy materials, including the associated proxy cards, relating to the corporation's next annual meeting or special meeting, as applicable, pursuant to Rule 14a-19, (iv) acknowledges that as a director of the corporation, the nominee will owe fiduciary duties under Delaware law with respect to the corporation and its stockholders, (v) unless previously disclosed to the corporation, a statement that such nominee is not, and will not become, a party to any voting agreement, arrangement, commitment, assurance or understanding with any person or entity as to how such nominee, if elected as a director, will vote on any issue (a "**Voting Commitment**") or any Voting Commitment that could limit or interfere with such nominee's ability to comply, if elected as a director of the corporation, with such nominee's fiduciary duties under applicable law; (vi) unless previously disclosed to the corporation, a statement that such nominee is not, and will not become, a party to any Third-Party Compensation Arrangement; (vii) a statement that if such nominee is elected as a director, such nominee would be in compliance, and will continue to comply, with all applicable rules of any securities exchanges upon which the corporation's securities are listed, the corporation's corporate governance, conflict of interest, confidentiality, stock ownership and trading guidelines, and other policies and guidelines applicable to directors and in effect during such person's term in office as a director (and, if requested by any nominee, the secretary will provide to such nominee all such policies and guidelines then in effect) and (viii) a statement that such nominee will provide facts, statements and other information in all communications with the corporation and its stockholders that are or will be true and correct in all material respects and that do not and will not omit to state any fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading in any material respect.

(d) At the request of the board of directors, any person nominated by a stockholder for election or re-election as a director must furnish to the secretary of the corporation (1) such information required to be set forth in the stockholder's notice of nomination of such person as a director as of a date subsequent to the date on which the notice of such person's nomination was given, (2) such other information as may reasonably be required by the corporation to determine the eligibility of such proposed nominee to serve as an independent director or audit committee financial expert of the corporation under applicable law, securities exchange rule or regulation, or any publicly disclosed corporate governance guideline or committee charter of the corporation and (3) such other information that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee. If requested by the corporation, any supplemental information required under this paragraph shall be provided by such stockholder within ten (10) days after it has been requested by the corporation. In addition, the board of directors may require any nominee to submit to interviews with the board of directors or any committee thereof, and such nominee shall make himself or herself available for any such interviews within ten (10) days following any reasonable request therefor from the board of directors or any committee thereof. In the absence of the furnishing of any such information of the kind specified in this Section 2.4(ii)(d) if requested, such stockholder's nomination shall not be considered in proper form pursuant to this Section 2.4(ii).

(e) Without exception, no person shall be eligible for election or re-election as a director of the corporation at an annual meeting of stockholders unless nominated in accordance with the provisions set forth in this Section 2.4(ii). In addition, no later than five (5) business days prior to the annual meeting or any adjournment, rescheduling, postponement or other delay thereof, a stockholder nominating individuals for election or re-election as a director will provide the corporation with reasonable evidence that such stockholder has met the requirements of Rule 14a-19. Notwithstanding anything to the contrary in these bylaws, unless otherwise required by law, if any stockholder (x) provides notice pursuant to Rule 14a-19 and (y) subsequently (1) notifies the corporation that such stockholder no longer intends to solicit proxies in support of director nominees other than the corporation's director nominees in accordance with Rule 14a-19, (2) fails to comply with the requirements of Rule 14a-19 or (3) fails to timely provide such reasonable evidence, update, supplement or additional information sufficient to satisfy the corporation that such requirements have been met, such stockholder's nomination(s) shall be deemed null and void and the corporation shall disregard any proxies or votes solicited for any nominee proposed by such stockholder, notwithstanding that such proxies may have been received by the corporation and counted for the purposes of determining quorum. A nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee or any other information provided to the corporation by or on behalf of such nominee contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson

of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that a nomination was not made in accordance with the provisions prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the annual meeting, and the defective nomination shall be disregarded.

(iii) *Advance Notice of Director Nominations for Special Meetings.*

(a) For a special meeting of stockholders at which directors are to be elected or re-elected pursuant to Section 2.3 hereof, nominations of persons for election to the board of directors shall be made only (1) by or at the direction of the board of directors or (2) by any stockholder of the corporation who (A) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(iii), on the record date for the determination of stockholders entitled to notice of the special meeting and on the record date for the determination of stockholders entitled to vote at the special meeting and (B) delivers a timely written notice of the nomination to the secretary of the corporation that includes the information set forth in Sections 2.4(ii)(b) and (ii)(c) above. To be timely, such notice must be received by the secretary at the then-principal executive offices of the corporation not later than 5:00 p.m. Pacific Time on the later of the ninetieth (90th) day prior to such special meeting or the tenth (10th) day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the board of directors to be elected or re-elected at such meeting. A person shall not be eligible for election or re-election as a director at a special meeting unless the person is nominated (i) by or at the direction of the board of directors or (ii) by a stockholder in accordance with the notice procedures set forth in this Section 2.4(iii). In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. Any person nominated in accordance with this Section 2.4(iii) is subject to, and must comply with, the provisions of Section 2.4(ii)(c).

(b) The chairperson of the special meeting shall, if the facts warrant, determine and declare at the meeting that a nomination or business was not made in accordance with the procedures prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the meeting, and the defective nomination or business shall be disregarded.

(iv) *Other Requirements and Rights.*

(a) A stockholder shall update and supplement its notice to the corporation of its intent to propose business at an annual meeting, and a nominee shall further update and supplement the materials delivered pursuant to this Section 2.4, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.4 shall be true and correct as of the record date for stockholders entitled to notice of the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the secretary at the principal executive offices of the corporation not later than five (5) business days after the record date for stockholders entitled to notice of the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the date of the meeting and, if practical, any adjournment or postponement thereof (and, if not practical, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof).

(b) For the avoidance of doubt, the obligation to update and supplement, or provide additional information or evidence, as set forth in these bylaws shall not limit the corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines pursuant to these bylaws or enable or be deemed to permit a stockholder who has previously submitted notice pursuant to these bylaws to amend or update any nomination or to submit any new nomination. No disclosure pursuant to these bylaws will be required with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is the stockholder submitting a notice pursuant to this Section 2.4 solely because such broker, dealer, commercial bank, trust company or other nominee has been directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner.

(c) Notwithstanding anything to the contrary in this Section 2.4, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear in person at the applicable meeting to present a nomination or other proposed business, such nomination will be disregarded or such proposed business will not be transacted, as the case may be, notwithstanding that proxies in respect of such nomination or business may have been received by the corporation and counted for purposes of determining a quorum. For purposes of this Section 2.4(iv), to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the applicable meeting, and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the applicable meeting.

(d) In addition to the foregoing provisions of this Section 2.4, a stockholder must also comply with all applicable requirements of state law and of the 1934 Act and the rules and regulations thereunder with respect to the matters set forth in this Section 2.4, including, with respect to business such stockholder intends to bring before the annual meeting that involves a proposal that such stockholder requests to be included in the corporation's proxy statement, the requirements of Rule 14a-8 (or any successor provision) under the 1934 Act. Nothing in this Section 2.4 shall be deemed to affect any right of: (1) a stockholder to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the 1934 Act or (2) the corporation to omit a proposal from the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the 1934 Act.

2.5 NOTICE OF STOCKHOLDERS' MEETINGS

Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in the DGCL, the certificate of incorporation or these bylaws, the written notice of any meeting of stockholders shall be given not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

2.6 QUORUM

The holders of one-third of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. Where a separate vote by a class or series or classes or series is required, one-third of the outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter, except as otherwise provided by law, the certificate of incorporation or these bylaws.

If, however, such quorum is not present or represented at any meeting of the stockholders, then either (i) the chairperson of the meeting, or (ii) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.7 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the

meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the board of directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 213(a) of the DGCL and Section 2.11 of these bylaws, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting as of the record date fixed for notice of such adjourned meeting.

2.8 CONDUCT OF BUSINESS

The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business.

2.9 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

Except as otherwise required by law, the certificate of incorporation or the bylaws, (i) shareholder action (except for bylaw amendments, which will require a majority of shares entitled to vote, and election of directors) will be based on the affirmative vote of a majority of the votes cast and (ii) broker non-votes and abstentions will be considered for purposes of establishing a quorum but will not be considered as votes cast for or against a proposal or director nominee.

Except as otherwise required by law, the certificate of incorporation or these bylaws, directors shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of shares of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series, except as otherwise provided by law, the certificate of incorporation or these bylaws.

2.10 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Subject to the rights of the holders of any series of preferred stock, any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders; *provided, however*, that stockholders may take action by written consent if the action to be effected by written consent and the taking of such action by written consent are approved in advance by resolution of the board of directors.

2.11 RECORD DATES

In order that the corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the board of directors and which record date shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the board of directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the board of directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination.

If no record date is fixed by the board of directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at 5:00 p.m. Pacific Time on the day next preceding the day on which notice is given, or, if notice is waived, at 5:00 p.m. Pacific Time on the day next preceding the day on which the meeting is held.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the board of directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the provisions of Section 213 of the DGCL and this Section 2.11 at the adjourned meeting.

In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than sixty (60) days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at 5:00 p.m. Pacific Time on the day on which the board of directors adopts the resolution relating thereto.

2.12 PROXIES

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL.

A written proxy may be in the form of a telegram, cablegram, or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram, or other means of electronic transmission was authorized by the stockholder. Any stockholder directly or indirectly soliciting proxies from other stockholders must use a proxy card color other than white, which shall be reserved for exclusive use by the board of directors.

2.13 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The officer who has charge of the stock ledger of the corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; *provided, however*, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth (10th) day before the meeting date, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (i) on a reasonably accessible electronic network, *provided* that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the corporation's principal place of business. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. Such list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

2.14 INSPECTORS OF ELECTION

Before any meeting of stockholders, the board of directors shall appoint an inspector or inspectors of election to act at the meeting or its adjournment. The number of inspectors shall be either one (1) or three (3). If any person appointed as inspector fails to appear or fails or refuses to act, then the chairperson of the meeting may, and upon the request of any stockholder or a stockholder's proxy shall, appoint a person to fill that vacancy.

Such inspectors shall:

- (i) determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting, the existence of a quorum, and the authenticity, validity and effect of proxies;
- (ii) receive votes, ballots or consents;
- (iii) hear and determine all challenges and questions in any way arising in connection with the right to vote;
- (iv) count and tabulate all votes or consents;
- (v) determine when the polls shall close;
- (vi) determine the result; and
- (vii) do any other acts that may be proper to conduct the election or vote with fairness to all stockholders.

The inspectors of election shall perform their duties impartially, in good faith, to the best of their ability and as expeditiously as is practical. If there are three (3) inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all. Any report or certificate made by the inspectors of election is *prima facie* evidence of the facts stated therein.

ARTICLE III - DIRECTORS

3.1 POWERS

The business and affairs of the corporation shall be managed by or under the direction of the board of directors, except as may be otherwise provided in the DGCL or the certificate of incorporation.

3.2 NUMBER OF DIRECTORS

The board of directors shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time by resolution of the board of directors. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS

Except as provided in Section 3.4 of these bylaws, each director, including a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

If so provided in the certificate of incorporation, the directors of the corporation shall be divided into three classes.

3.4 RESIGNATION AND VACANCIES

Any director may resign at any time upon notice given in writing or by electronic transmission to the corporation. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is

irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the board of directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws, vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. If the directors are divided into classes, a person so elected by the directors then in office to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified.

If at any time, by reason of death or resignation or other cause, the corporation should have no directors in office, then any officer or any stockholder or an executor, administrator, trustee or guardian of a stockholder, or other fiduciary entrusted with like responsibility for the person or estate of a stockholder, may call a special meeting of stockholders in accordance with the provisions of the certificate of incorporation or these bylaws, or may apply to the Court of Chancery for a decree summarily ordering an election as provided in Section 211 of the DGCL.

If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the whole board of directors (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least 10% of the voting stock at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the DGCL as far as applicable.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

The board of directors may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the board of directors, or any committee designated by the board of directors, may participate in a meeting of the board of directors, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS

Regular meetings of the board of directors may be held without notice at such time and at such place as shall from time to time be determined by the board of directors.

3.7 SPECIAL MEETINGS; NOTICE

Special meetings of the board of directors for any purpose or purposes may be called at any time by the chairperson of the board of directors, the chief executive officer, the president, the secretary or a majority of the authorized number of directors.

Notice of the time and place of special meetings shall be:

- (i) delivered personally by hand, by courier or by telephone;
- (ii) sent by United States first-class mail, postage prepaid;
- (iii) sent by facsimile; or

(iv) sent by electronic mail,

directed to each director at that director's address, telephone number, facsimile number or electronic mail address, as the case may be, as shown on the corporation's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile or (iii) sent by electronic mail, it shall be delivered or sent at least 24 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four (4) days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the corporation's principal executive office) nor the purpose of the meeting.

3.8 QUORUM; VOTING

At all meetings of the board of directors, a majority of the total authorized number of directors shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the board of directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present. A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the required quorum for that meeting.

The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the board of directors, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, every reference in these bylaws to a majority or other proportion of the directors shall refer to a majority or other proportion of the votes of the directors.

3.9 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the board of directors, or of any committee thereof, may be taken without a meeting if all members of the board of directors or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the board of directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

3.10 FEES AND COMPENSATION OF DIRECTORS

Unless otherwise restricted by the certificate of incorporation or these bylaws, the board of directors shall have the authority to fix the compensation of directors.

3.11 REMOVAL OF DIRECTORS

Any director may be removed from office by the stockholders of the corporation only for cause.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

ARTICLE IV - COMMITTEES

4.1 COMMITTEES OF DIRECTORS

The board of directors may, by resolution passed by a majority of the authorized number of directors, designate one or more committees, each committee to consist of one or more of the directors of the corporation. The board of directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the board of directors or in these bylaws, shall have and may exercise all the powers and authority of the board of directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the corporation.

4.2 COMMITTEE MINUTES

Each committee shall keep regular minutes of its meetings and report the same to the board of directors when required.

4.3 MEETINGS AND ACTION OF COMMITTEES

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

- (i) Section 3.5 (place of meetings and meetings by telephone);
- (ii) Section 3.6 (regular meetings);
- (iii) Section 3.7 (special meetings and notice);
- (iv) Section 3.8 (quorum; voting);
- (v) Section 7.5 (waiver of notice); and
- (vi) Section 3.9 (action without a meeting)

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the board of directors and its members. *However:*

(i) the time of regular meetings of committees may be determined either by resolution of the board of directors or by resolution of the committee;

(ii) special meetings of committees may also be called by resolution of the board of directors;
and

(iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The board of directors may adopt rules for the governance of any committee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

4.4 SUBCOMMITTEES

Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the board of directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

ARTICLE V - OFFICERS

5.1 OFFICERS

The officers of the corporation shall be a president and a secretary. The corporation may also have, at the discretion of the board of directors, a chairperson of the board of directors, a vice chairperson of the board of directors, a chief executive officer, a chief financial officer or treasurer, one or more vice presidents, one or more assistant vice presidents, one or more assistant treasurers, one or more assistant secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS

The board of directors shall appoint the officers of the corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

5.3 SUBORDINATE OFFICERS

The board of directors may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers and agents as the business of the corporation may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the board of directors may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by an affirmative vote of the majority of the board of directors at any regular or special meeting of the board of directors or, except in the case of an officer chosen by the board of directors, by any officer upon whom such power of removal may be conferred by the board of directors.

Any officer may resign at any time by giving written notice to the corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the corporation under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES

Any vacancy occurring in any office of the corporation shall be filled by the board of directors or as provided in Section 5.3 hereof.

5.6 REPRESENTATION OF SHARES OF OTHER CORPORATIONS

The chairperson of the board of directors, the president, any vice president, the treasurer, the secretary or assistant secretary of this corporation, or any other person authorized by the board of directors or the president or a vice president, is authorized to vote, represent, and exercise on behalf of this corporation all rights incident to any and all shares of any other corporation or corporations standing in the name of this corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 AUTHORITY AND DUTIES OF OFFICERS

All officers of the corporation shall respectively have such authority and perform such duties in the management of the business of the corporation as may be designated from time to time by the board of directors or the stockholders and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the board of directors.

ARTICLE VI - STOCK

6.1 STOCK CERTIFICATES; PARTLY PAID SHARES

The shares of the corporation shall be represented by certificates, provided that the board of directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of the corporation by the chairperson of the board of directors or vice-chairperson of the board of directors, or the president or a vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The corporation shall not have power to issue a certificate in bearer form.

The corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly-paid shares, or upon the books and records of the corporation in the case of uncertificated partly-paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully-paid shares, the corporation shall declare a dividend upon partly-paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

6.2 SPECIAL DESIGNATION ON CERTIFICATES

If the corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the corporation shall issue to represent such class or series of stock; *provided, however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the corporation shall issue to represent such class or series of stock, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to this Section 6.2 or Sections 156, 202(a) or 218(a) of the DGCL or with respect to this Section 6.2 a statement that the corporation will furnish without charge to each stockholder who so requests the powers,

designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of certificates representing stock of the same class and series shall be identical.

6.3 LOST CERTIFICATES

Except as provided in this Section 6.3, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the corporation and cancelled at the same time. The corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

6.4 DIVIDENDS

The board of directors, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the corporation's capital stock. Dividends may be paid in cash, in property, or in shares of the corporation's capital stock, subject to the provisions of the certificate of incorporation.

The board of directors may set apart out of any of the funds of the corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the corporation, and meeting contingencies.

6.5 TRANSFER OF STOCK

Transfers of record of shares of stock of the corporation shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer.

6.6 STOCK TRANSFER AGREEMENTS

The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

6.7 REGISTERED STOCKHOLDERS

The corporation:

(i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;

(ii) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(iii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VII - MANNER OF GIVING NOTICE AND WAIVER

7.1 NOTICE OF STOCKHOLDERS' MEETINGS

Notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the corporation's records. An affidavit of the secretary or an assistant secretary of the corporation or of the transfer agent or other agent of the corporation that the notice has been given shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

7.2 NOTICE BY ELECTRONIC TRANSMISSION

Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any such consent shall be deemed revoked if:

(i) the corporation is unable to deliver by electronic transmission two consecutive notices given by the corporation in accordance with such consent; and

(ii) such inability becomes known to the secretary or an assistant secretary of the corporation or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

(i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;

(ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;

(iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and

(iv) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

An "**electronic transmission**" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

Notice by a form of electronic transmission shall not apply to Section 164, 296, 311, 312 or 324 of the DGCL.

7.3 NOTICE TO STOCKHOLDERS SHARING AN ADDRESS

Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the corporation under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to

stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any stockholder who fails to object in writing to the corporation, within sixty (60) days of having been given written notice by the corporation of its intention to send the single notice, shall be deemed to have consented to receiving such single written notice.

7.4 NOTICE TO PERSON WITH WHOM COMMUNICATION IS UNLAWFUL

Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the corporation is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

7.5 WAIVER OF NOTICE

Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE VIII - INDEMNIFICATION

8.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN THIRD PARTY PROCEEDINGS

Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL or any other applicable laws, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a “**Proceeding**”) (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director or officer of the corporation, or is or was a director or officer of the corporation serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys’ fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person’s conduct was unlawful. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person’s conduct was unlawful.

8.2 INDEMNIFICATION OF DIRECTORS AND OFFICERS IN ACTIONS BY OR IN THE RIGHT OF THE CORPORATION

Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL or any other applicable laws, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the

corporation to procure a judgment in its favor by reason of the fact that such person is or was a director or officer of the corporation, or is or was a director or officer of the corporation serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation; except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

8.3 SUCCESSFUL DEFENSE

To the extent that a present or former director or officer of the corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding described in Section 8.1 or 8.2 hereof, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

8.4 INDEMNIFICATION OF OTHERS

Subject to the other provisions of this Article VIII, the corporation shall have power to indemnify its employees and agents to the fullest extent not prohibited by the DGCL or any other applicable laws. The board of directors shall have the power to delegate to such person or persons the determination of whether employees or agents shall be indemnified.

8.5 ADVANCE PAYMENT OF EXPENSES

Expenses (including attorneys' fees) incurred by an officer or director of the corporation in defending any Proceeding shall be paid by the corporation in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of the person to repay such amounts if it shall ultimately be determined that the person is not entitled to be indemnified under this Article VIII or the DGCL. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents of the corporation or by persons serving at the request of the corporation as directors, officers, employees or agents of another corporation, partnership, joint venture, trust or other enterprise may be so paid upon such terms and conditions, if any, as the corporation deems appropriate. The right to advancement of expenses shall not apply to any claim for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding referenced in Section 8.6(ii) or 8.6(iii) hereof prior to a determination that the person is not entitled to be indemnified by the corporation.

Notwithstanding the foregoing, unless otherwise determined pursuant to Section 8.8 hereof, no advance shall be made by the corporation to an officer of the corporation (except by reason of the fact that such officer is or was a director of the corporation, in which event this paragraph shall not apply) in any Proceeding if a determination is reasonably and promptly made (i) by a majority vote of the directors who are not parties to such Proceeding, even though less than a quorum, (ii) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, that facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the corporation.

8.6LIMITATION ON INDEMNIFICATION

Subject to the requirements in Section 8.3 hereof and the DGCL, the corporation shall not be obligated to indemnify any person pursuant to this Article VIII in connection with any Proceeding (or any part of any Proceeding):

- (i) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;
- (ii) for an accounting or disgorgement of profits pursuant to Section 16(b) of the 1934 Act, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);
- (iii) for any reimbursement of the corporation by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the corporation, as required in each case under the 1934 Act (including any such reimbursements that arise from an accounting restatement of the corporation pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the “**Sarbanes-Oxley Act**”), or the payment to the corporation of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);
- (iv) initiated by such person, including any Proceeding (or any part of any Proceeding) initiated by such person against the corporation or its directors, officers, employees, agents or other indemnitees, unless (a) the board of directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (b) the corporation provides the indemnification, in its sole discretion, pursuant to the powers vested in the corporation under applicable law, (c) otherwise required to be made under Section 8.7 hereof or (d) otherwise required by applicable law; or
- (v) if prohibited by applicable law.

8.7DETERMINATION; CLAIM

If a claim for indemnification or advancement of expenses under this Article VIII is not paid in full within ninety (90) days after receipt by the corporation of the written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. The corporation shall indemnify such person against any and all expenses that are incurred by such person in connection with any action for indemnification or advancement of expenses from the corporation under this Article VIII, to the extent such person is successful in such action, and to the extent not prohibited by law. In any such suit, the corporation shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

8.8NON-EXCLUSIVITY OF RIGHTS

The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VIII shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person’s official capacity and as to action in another capacity while holding such office. The corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

8.9INSURANCE

The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability

asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of the DGCL.

8.10 SURVIVAL

The rights to indemnification and advancement of expenses conferred by this Article VIII shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

8.11 EFFECT OF REPEAL OR MODIFICATION

A right to indemnification or to advancement of expenses arising under a provision of the certificate of incorporation or a bylaw shall not be eliminated or impaired by an amendment to the certificate of incorporation or these bylaws after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.

8.12 CERTAIN DEFINITIONS

For purposes of this Article VIII, references to the "**corporation**" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article VIII with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued. For purposes of this Article VIII, references to "**other enterprises**" shall include employee benefit plans; references to "**finances**" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "**servicing at the request of the corporation**" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "**not opposed to the best interests of the corporation**" as referred to in this Article VIII.

ARTICLE IX - GENERAL MATTERS

9.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS

Except as otherwise provided by law, the certificate of incorporation or these bylaws, the board of directors may authorize any officer or officers, or agent or agents, to enter into any contract or execute any document or instrument in the name of and on behalf of the corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the board of directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

9.2 FISCAL YEAR

The fiscal year of the corporation shall be fixed by resolution of the board of directors and may be changed by the board of directors.

9.3SEAL

The corporation may adopt a corporate seal, which shall be adopted and which may be altered by the board of directors. The corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

9.4CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term “**person**” includes both a corporation and a natural person.

ARTICLE X - AMENDMENTS

These bylaws may be adopted, amended or repealed by the stockholders entitled to vote. However, the corporation may, in its certificate of incorporation, confer the power to adopt, amend or repeal bylaws upon the directors. The fact that such power has been so conferred upon the directors shall not divest the stockholders of the power, nor limit their power to adopt, amend or repeal bylaws.

A bylaw amendment adopted by stockholders which specifies the votes that shall be necessary for the election of directors shall not be further amended or repealed by the board of directors.

ARTICLE XI - EXCLUSIVE FORUM

Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another state or federal court located in the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the corporation, (2) any action asserting a claim of breach of a fiduciary duty owed by any director or officer or stockholder of the corporation to the corporation or the corporation’s stockholders, (3) any action arising pursuant to any provision of the DGCL, or these Bylaws or the corporation’s certificate of incorporation (as either may be amended from time to time), or (4) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the corporation shall be deemed to have notice of and consented to the provisions of this Article XI. Notwithstanding anything otherwise to the contrary herein, the provisions of this Article XI will not apply to suits brought to enforce a duty or liability created by the federal securities laws or any other claim for which the federal courts have exclusive jurisdiction.

ORGANOVO HOLDINGS, INC.

CERTIFICATE OF BYLAWS

The undersigned hereby certifies that he or she is the duly elected, qualified, and acting Secretary or Assistant Secretary of Organovo Holdings, Inc., a Delaware corporation and that the foregoing bylaws were adopted and ratified by the corporation's board of directors on July 12, 2023.

IN WITNESS WHEREOF, the undersigned has hereunto set his or her hand this 12th day of July, 2023.

/s/ Thomas Jurgensen
Thomas Jurgensen
Secretary

**DESCRIPTION OF ORGANOVO HOLDINGS, INC.'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

The following description of the common stock, par value \$0.001 per share, of Organovo Holdings, Inc. (“us,” “our,” “we,” or the “Company”), which is the only security of the Company registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), summarizes certain information regarding the common stock in our certificate of incorporation, as amended, our by-laws, as amended, and applicable provisions of Delaware general corporate law (the “DGCL”), and is qualified by reference to our certificate of incorporation, our certificate of amendment of certificate of incorporation, our by-laws and our amendment to bylaws, which are incorporated by reference as Exhibit 3.1, 3.2, 3.3, 3.4 and 3.5, respectively, to the Annual Report on Form 10-K for the fiscal year ending March 31, 2023.

Our authorized capital stock consists of 200,000,000 shares of common stock, par value \$0.001 per share and 25,000,000 shares of preferred stock, par value \$0.001 per share.

General

As of March 31, 2023, our certificate of incorporation, as amended (the “certificate of amendment”), authorizes us to issue up to (i) 200,000,000 shares of common stock, par value \$0.001 per share, and (ii) 25,000,000 shares of preferred stock, par value \$0.001 per share.

On August 18, 2020, we effected a 1-for-20 reverse stock split of our outstanding common stock. As a result of the reverse stock split, every twenty (20) shares of our pre-reverse split common stock were combined and reclassified into one (1) share of common stock. The reverse stock split had no effect on the number of authorized shares of common or preferred stock, or on the stated par value per share of our common stock.

The following is a summary of the material provisions of the common stock and preferred stock provided for in our Certificate of Incorporation and bylaws, as amended (the “bylaws”). For additional detail about our capital stock, please refer to our Certificate of Incorporation and bylaws.

Common Stock

Our common stock is listed on the Nasdaq Capital Market under the symbol “ONVO”.

Voting: Holders of our common stock are entitled to one vote for each share on all matters submitted to a stockholder vote, except matters that relate only to a series of our preferred stock.

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of common stock that are present in person or represented by proxy. Except as otherwise provided by law, amendments to the certificate of incorporation generally must be approved by a majority of the votes entitled to be cast by all outstanding shares of common stock. The certificate of incorporation does not provide for cumulative voting in the election of directors. The common stock holders will be entitled to such cash dividends as may be declared from time to time by our board of directors from funds available. Upon our liquidation, dissolution or winding up, the common stock holders will be entitled to receive pro rata all assets available for distribution to such holders.

Dividends: Subject to limitations under Delaware law and preferences that may apply to any then-outstanding shares of preferred stock, holders of common stock are entitled to share ratably in dividends, if any, as may be declared from time to time by our board of directors in its discretion from funds legally available therefor.

Dividends, if any, will be contingent upon our revenues and earnings, if any, and capital requirements and financial conditions. The payment of dividends, if any, will be within the discretion of our board of directors. We presently intend to retain all earnings, if any, and accordingly our board of directors does not anticipate declaring any dividends prior to a business combination.

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

Miscellaneous: Holders of our common stock have no pre-emptive rights, no conversion rights and there are no redemption provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. There are no restrictions presently on the repurchase or redemption of any shares of our preferred stock.

The issuance of preferred stock will affect, and may adversely affect, the rights of holders of common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock. The effects of issuing preferred stock could include one or more of the following:

- restricting dividends on the common stock;
- diluting the voting power of the common stock;
- impairing the liquidation rights of the common stock; or
- delaying or preventing changes in control or management of our company.

We have no present plans to issue any shares of preferred stock nor are any shares of our preferred stock presently outstanding.

Effect of Certain Provisions of our Certificate of Incorporation and Bylaws

Provisions of our certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, may have the effect of discouraging takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Classified Board. Our Certificate of Incorporation and our Bylaws provide that our board of directors is divided into three classes, consisting of two Class I directors, two Class II directors and two Class III directors. The directors designated as Class I directors have a term expiring at our annual meeting of stockholders in 2026. The directors designated as Class II directors have a term expiring at our annual meeting of stockholders in 2025, and the directors designated as a Class III directors have a term expiring at our annual meeting of stockholders in 2023. Directors for each class will be elected at the annual meeting of stockholders held in the year in which the term for that class expires and thereafter will serve for a term of three years. At any meeting of stockholders for the election of directors at which a quorum is present, the election will be determined by a plurality of the votes cast by the stockholders entitled to vote at the election. Under the classified board provisions, it will take at least two elections of directors for any individual or group to gain control of our board. Accordingly, these provisions could discourage a third party from initiating a proxy contest, making a tender offer or otherwise attempting to gain control of us.

Undesignated preferred stock. The authority of our board of directors to issue preferred stock could potentially be used to discourage attempts by third parties to obtain control of our company through a merger, tender offer, proxy contest, or otherwise by making it more difficult or more costly to obtain control of our company. Our board of directors may issue preferred stock with voting rights or conversion rights that, if exercised, could adversely affect the voting power of the holders of common stock.

Advanced Notice Requirement. Stockholder nominations of individuals for election to our board of directors and stockholder proposals of other matters to be brought before an annual meeting of our stockholders must comply with the advance notice procedures set forth in our bylaws. Generally, to be timely, such notice must be received at our principal executive offices no later than the date specified in our proxy statement released to stockholders in connection with the preceding year's annual meeting of stockholders, which date shall be not earlier than the 75th day, nor later than the close of business on the 45th day, prior to the one-year anniversary of the date on which we first mailed our proxy materials or a notice of availability of proxy materials (whichever is earlier) for the preceding year's annual meeting.

Special Meeting Requirements. Our bylaws provide that special meetings of our stockholders may only be called at the request of a majority of the authorized number of members of the board of directors, chairperson of the board of directors, chief executive officer, president or secretary. Only such business shall be considered at a special meeting as shall have been stated in the notice for such meeting.

No Stockholder Action by Written Consent Except with Prior Board Approval: Our Certificate of Incorporation and Bylaws provide that no action shall be taken by our stockholders except at an annual or special meeting of the stockholders called in accordance with the Bylaws, and no action shall be taken by our stockholders by written consent, except if the action to be effected by written consent and the taking of such action by written action is approved in advance by resolution of the board of directors.

No Cumulative Voting. Our certificate of incorporation does not include a provision for cumulative voting for directors.

Removal of Directors. Our certificate of incorporation and bylaws provide that the holders of our voting stock may only remove our directors for cause.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Size of Board and Vacancies. Our bylaws provide that the number of directors on our board of directors is fixed exclusively by our board of directors. Vacancies and newly created directorships resulting from any increase in our authorized number of directors will be filled by a majority of our board of directors then in office, although less than a quorum, or by a sole remaining director.

Indemnification. Our certificate of incorporation and our bylaws provide that we will indemnify our officers and directors against losses as they incur in investigations and legal proceedings resulting from their services to us, which may include service in connection with takeover defense measures.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 generally prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66^{2/3}% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, transfer, pledge or other disposition of 10% or more of either the assets or outstanding stock of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person who, together with affiliates and associates, beneficially owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

The provisions of Delaware law and our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions may make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Subsidiaries of Organovo Holdings, Inc.

- I. Organovo, Inc., a Delaware corporation
- II. Opal Merger Sub, Inc., a Delaware corporation

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statements Nos. 333-268001, 333-260910, 333-254714, 333-226839, 333-226837, 333-217437, 333-213345, 333-209395, 333-192248 and 333-181324 on Form S-8 and Registration Statements No. 333-252224 on Form S-3, of our report dated July 13, 2023, relating to the consolidated financial statements of Organovo Holdings, Inc. as of March 31, 2023 and 2022, and for each of the two years in the period ended March 31, 2023, included in this Annual Report on Form 10-K for the year ended March 31, 2023.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
July 13, 2023

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Keith Murphy, Executive Chairman of Organovo Holdings, Inc., certify that:

1. I have reviewed this annual report on Form 10-K 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 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(s) 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(s) 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: July 13, 2023

/s/ Keith Murphy
Keith Murphy
Executive Chairman

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Thomas Hess, Chief Financial Officer of Organovo Holdings, Inc., certify that:

1. I have reviewed this annual report on Form 10-K 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 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(s) 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(s) 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: July 13, 2023

/s/ Thomas Hess

Thomas Hess
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Annual Report on Form 10-K of Organovo Holdings, Inc. (the “Company”) for the year ended March 31, 2023, as filed with the Securities and Exchange Commission (the “Report”), Keith Murphy, Executive Chairman of the Company, and Thomas Hess, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: July 13, 2023

/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-K 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-K), irrespective of any general incorporation language contained in such filing.