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, 2022

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	**27-1488943**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification No.)*
11555 Sorrento Valley Rd, Suite 100 **San Diego, CA**	**92121**
(Address of principal executive offices)	*(Zip code)*

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

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

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

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, 2021, the last trading day of the registrant's second fiscal quarter, was $58,024,563. 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, 2022 was 8,710,703.

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 2022 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, 2022

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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; negative effects on our business due to COVID-19; 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 an early-stage 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.

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.

We recently completed a review and analysis of our full intellectual property portfolio to align it with our current business needs, strategies and objectives. Based on that review, a number of patents and patent applications in various countries were abandoned or allowed to lapse. The numbers provided herein are reflective of those changes.

We solely own or hold exclusive licenses to 26 issued U.S. patents and more than 95 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 23 pending U.S. patent applications and more than 20 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-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 Forgacs Intellectual Property also enables us to utilize our NovoGen Bioprinter® to create engineered tissues.

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

The patent rights we obtained through these exclusive licenses are not only foundational within the field of 3D bioprinting but provide us with favorable priority dates. We are required to make ongoing royalty payments under these exclusive licenses based on net sales of products and services that rely on the intellectual property we in-licensed. For additional information regarding our royalty obligations see "Note 4. 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 and 10,967,560; 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. 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; 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, MatTek Incorporated and Visikol, Inc. (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.

COVID-19

Global health concerns relating to the COVID-19 pandemic continue to weigh on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The extent to which COVID-19 impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the rise of vaccine-resistant variants, the duration of the outbreak, and any travel bans, restrictions or other limitations that may be imposed in the future. In particular, the continued COVID-19 pandemic could adversely impact various aspects of our operations, including among others, our ability to raise additional capital, the timing and ability to pursue our strategy, given the impact the pandemic may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners, and the ability to advance our research and development activities and pursue development of our pipeline products, each of which could have an adverse impact on our business and our financial results. Our employees and consultants have recently returned to working at our office and lab when necessary. We have developed guidelines and protocols to handle exposures and infections intended to keep disruptions to operations to a minimum.

Employees and Human Capital

As of June 1, 2022, we had 18 employees, of which 9 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.***
- ***We may be unable to continue as a going concern in the future.***
- ***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 COVID-19

We face risks related to health epidemics, including the COVID-19 pandemic, which could have a material adverse effect on our business and results of operations.

Global health concerns relating to the COVID-19 pandemic continue to weigh on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty. The continued COVID-19 pandemic could adversely impact our operations, including among others, the impact it may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners, and the ability to advance our research and development activities and pursue

development of any of our pipeline products, each of which could have an adverse impact on our business and our financial results. In particular, we require access to a constant, steady, reliable supply of human cells to support our development activities. The COVID-19 pandemic could negatively impact our ability to obtain a reliable supply of sufficient human cells or a supply at cost effective prices, which would harm our business and our results of operations and could cause us to be unable to support our drug development efforts.

In addition, the stock market has been unusually volatile during the COVID-19 pandemic and such volatility may continue. Our stock price has also experienced volatility during this time, including occasional significant increases and decreases. Such increases and decreases in our stock price may repeat or continue for the foreseeable future.

There are no comparable recent events which may provide guidance as to the effect of the COVID-19 pandemic, and, as a result, the ultimate impact of the COVID-19 pandemic, or any similar health epidemic that may occur in the future, is highly uncertain and subject to change. We do not yet know the full extent of COVID-19's impact on our business, our operations, or the global economy as a whole. However, the effects may have a material adverse impact on our future results of operations.

Risks Related to our Business

We have recommenced our operations as an early-stage 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.

Following the election of the new board of directors at our 2020 Annual Meeting of stockholders, we have recommenced operations and are focusing our efforts on utilizing our 3D bioprinting technology to develop human tissues and disease models for drug discovery and development. We have recommenced our operations as an early-stage company with an unproven business strategy, and may never achieve profitability. 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, including any impact to suppliers due to the COVID-19 pandemic, 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. Any shares of common stock issued in the at-the-market offering will result in dilution to our existing stockholders.

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;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution; and
- delays due to the recent COVID-19 pandemic, including with respect to the receipt of drug candidates or other materials, submission of New Drug Applications ("NDAs"), filing of Investigational New Drug ("INDs"), and starting any clinical trials for other indications or programs.

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, such as the COVID-19 pandemic, 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.

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

There have been public announcements by members of the U.S. Congress, regarding plans to repeal and replace the PPACA and Medicare. For example, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act of 2017, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to

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

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The U.S. Department of Health and Human Services has started soliciting feedback on some of these measures and, at the same time, is implementing others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While any proposed measures will require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our drug candidates, if approved for commercialization.

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

Risks Related to Our Capital Requirements, Finances and Operations

We may be unable to continue as a going concern in the future.

We have had recurring losses from operations since inception and will likely not generate meaningful revenue for the foreseeable future. We believe that our existing cash, cash equivalents and interest thereon will be sufficient to fund our projected operating requirements under our current operating plan for at least the next 12 months. However, if our operating plans change and our projected operating requirements increase, we may be unable to continue as a going concern. In this event, the perception that we may not be able to continue as a going concern may have an adverse impact on our business due to concerns about our ability to meet our future contractual obligations or pursue additional strategic transactions. Further, if we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation and dissolution could be significantly lower than the values reflected in our financial statements and an investor could lose all or part of its investment in our equity.

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 $11.5 million and $16.8 million for the years ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $307.7 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 COVID-19 pandemic or 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 loses associated with the strategic investments.

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

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

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

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

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 2022, we provided services to Viscient, and Viscient has previously purchased primary human cell-based products from our former subsidiary, Samsara Sciences, Inc. 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 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 OTCBB would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on stockholders:

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

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

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

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

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

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- continued macroeconomic conditions related to the COVID-19 pandemic;
- 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, 2022, there were an aggregate of 11,399,566 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 1,929,504 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 59,435 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 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, MatTek Incorporated and Visikol, Inc. (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 and Clemson University 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 and Clemson University 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 NovoGen Bioprinters and 3D tissue products fabricated using our NovoGen Bioprinters. Our rights to use these patents and patent applications and employ the inventions claimed in these licensed patents are subject to the continuation of and our compliance with the terms of our license agreements. If we were to breach the terms of these license agreements and the agreements were terminated as a result, our ability to continue to develop and commercialize our NovoGen Bioprinters and 3D tissue products and to operate our business could be adversely impacted.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ or engage individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims.

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 6. 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 previously disclosed the following actions (collectively, the "Actions"):

- In June 2021, the Company's U.S. Patent Nos. 9,855,369 and 9,149,952, which relate to its bioprinter technology, became the subject of IPR proceedings filed by Cellink AB and its subsidiaries, MatTek Incorporated and Visikol, Inc. (collectively, "BICO Group AB"). The Company filed a preliminary response to BICO Group AB's IPR petition in September 2021, and the Patent Trial and Appeal Board ("PTAB") denied institution of the proceedings in December 2021.

- Also in June 2021, U.S. Patent Nos. 9,149,952, 9,855,369, 8,931,880, 9,227,339 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent Nos. 7,051,654 and 9,752,116 (licensed exclusively to Organovo) were subject to a declaratory judgment complaint against the Company brought by BICO Group AB to obtain a declaration from the court that they do not infringe any claims of the noted patents (the "Action").

- Further, on July 28, 2021, the Company filed a complaint for patent infringement against BICO Group AB in the United States District Court for the Western District of Texas (the "Patent Complaint"). The Patent Complaint alleged that BICO Group AB has infringed U.S. Patent Nos. 9,149,952, 9,855,369 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent No. 9,752,116 (licensed exclusively to Organovo). The Company sought an injunction against continuing infringement of the foregoing patents by BICO Group AB and monetary damages. The Company later amended the complaint to add U.S. Patent No. 8,852,932. The case was transferred to the District of Delaware in December 2021 to be consolidated with BICO Group AB's declaratory judgment action.

- In addition, in September 2021, BICO Group AB filed two additional IPR proceedings against the Company's U.S. Patent Nos. 9,315,043 and 9,752,116 (exclusively licensed by the Company from the MUSC Foundation for Research and Development), which relate to its bioprinter technology. The Company filed preliminary responses to those proceedings in December 2021 and January 2022.

On February 22, 2022, the Company and BICO Group AB entered into a Settlement and Patent License Agreement fully and finally settling all matters between the parties regarding BICO Group AB's alleged infringement of the Company's patents. Concurrent with this settlement, the Delaware District Court action was dismissed and the remaining IPR proceeding was also dismissed.

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 7. 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, 2022, we had 8,710,627 outstanding shares of common stock and approximately 43 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, 2022:

	(a) Total Number of Shares (or Units) Purchased		(b) Average Price Paid Per Share (or Unit)
January 1, 2022 - January 31, 2022	—		$ —
February 1, 2022 - February 28, 2022	45	(1)	$ 3.04
March 1, 2022 - March 31, 2022	—		$ —
Total	45		$ 3.04

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

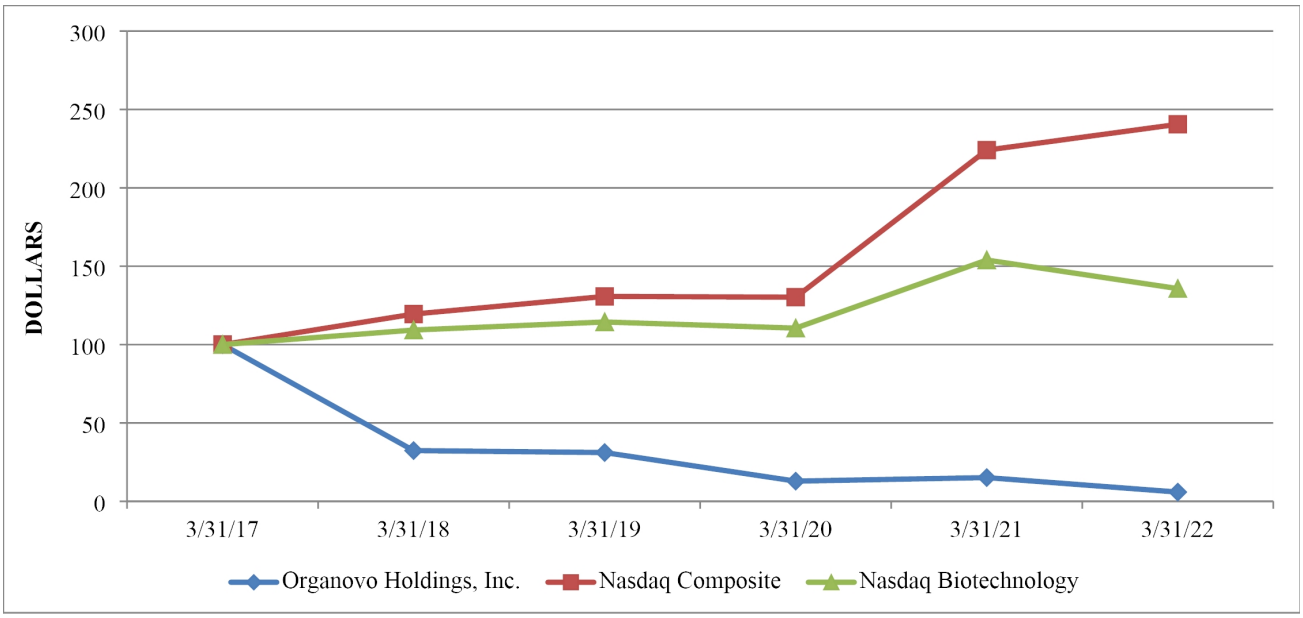
Performance Graph

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, 2022. This graph assumes the investment of $100 on March 31, 2017 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, 2017 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 an early-stage 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 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.

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.

COVID-19

Global health concerns relating to the COVID-19 pandemic continue to weigh on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The extent to which COVID-19 impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the rise of vaccine-resistant variants, the duration of the outbreak, and any travel bans, restrictions or other limitations that may be imposed in the future. In particular, the continued COVID-19 pandemic could adversely impact various aspects of our operations, including among others, our ability to raise additional capital, the timing and ability to pursue our revised strategy, given the impact the pandemic may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners and the ability to advance our research and development activities and pursue development of our pipeline products each of which could have an adverse impact on our business and our financial results. Our employees and consultants have recently returned to working at our office and lab when necessary. We have developed guidelines and protocols to handle exposures and infections intended to keep disruptions to operations to a minimum.

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, the most critical of which are those related to revenue recognition and the valuation of stock-based compensation expense. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Besides the estimates identified above that are considered critical, we make many other accounting estimates in preparing our financial statements and related disclosures. All estimates, whether or not deemed critical, 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, even for estimates and judgments that are not deemed critical.

Since March 31, 2021, the significant change to our critical accounting policies includes adding revenue recognition related items. 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 estimates, judgements, and 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 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. For stock options, prior to fiscal year 2020, we used a blend of historical volatility and implied volatility of comparable companies. As of April 1, 2019, we were using the Company-specific historical volatility rate as it was more reflective of market conditions and a better indicator of expected volatility. 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") and performance-based restricted stock units ("PBRSUs") 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. The expense for PBRSUs with pre-defined performance criteria is adjusted with the probability of achievement of such performance criteria at each period end.

All of the above accounting policies regarding stock-based compensation are considered critical, as they require significant estimates, judgements, and 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.

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.

As part of the accounting for these agreements, we must develop estimates and assumptions that require judgment of management to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. We evaluate each performance obligation to determine if it can be satisfied at a point in time or over time. 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.

For agreements that include license fees, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For agreements that include sales-based royalties, we recognize revenue in the period the underlying sales occur.

Results of Operations

Comparison of the Years Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the years ended March 31, 2022 and 2021 (in thousands, except percentages):

	Year Ended March 31,		Increase (decrease)	
	2022	2021	$	%
Revenues	$ 1,500	$ -	$ 1,500	100%
Research and development	$ 3,320	$ 1,103	$ 2,217	201%
Selling, general and administrative	$ 9,659	$ 15,723	$ (6,064)	(39%)
Other income	$ 33	$ 2	$ 31	1,550%

Revenues

We had $1.5 million of royalty revenue for the year ended March 31, 2022 compared to no revenue for the year ended March 31, 2021. 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”).

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended March 31, 2022 and 2021 (in thousands, except percentages):

	Year Ended March 31,		Increase (decrease)	
	2022	2021	$	%
Research and development	$ 2,787	$ 972	$ 1,815	187%
Non-cash stock-based compensation	419	105	314	299%
Depreciation and amortization	114	26	88	338%
Total research and development expenses	$ 3,320	$ 1,103	$ 2,217	201%

Research and development expenses increased by $2.2 million, or 201%, from approximately $1.1 million for the year ended March 31, 2021 to approximately $3.3 million for the year ended March 31, 2022 as we materially increased research and development activities following the change of control on September 15, 2020. Our full-time research and development staff increased from an average of two employees for the year ended March 31, 2021 to an average of nine employees for the year ended March 31, 2022. Research and development activities consisted of $1.6 million in personnel related costs, $0.8 million in lab expenses, $0.7 million in facility costs, and $0.2 million in consulting fees, depreciation, and other miscellaneous expenses. Going forward, in line with our renewed research and development efforts, we expect to hire additional employees and incur significantly more research and development expenses.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the years ended March 31, 2022 and 2021 (in thousands, except percentages):

	Year Ended March 31,		Increase (decrease)	
	2022	2021	$	%
Selling, general and administrative	$ 7,794	$ 10,257	$ (2,463)	(24%)
Non-cash stock-based compensation	1,837	5,451	(3,614)	(66%)
Depreciation and amortization	28	15	13	87%
Total selling, general and administrative expenses	$ 9,659	$ 15,723	$ (6,064)	(39%)

Selling, general and administrative expenses decreased approximately $6.0 million, or 39%, from $15.7 million for the year ended March 31, 2021 to approximately $9.7 million for the year ended March 31, 2022. Overall, the decrease year over year is due to the change in business operations from fiscal 2021 to fiscal 2022. During the year ended March 31, 2021, the majority of our costs were for personnel and general corporate costs, as we were in the midst of a strategic alternatives process and at the time we had an average of five full-time employees, three of whom were executives. A change in control occurred in September 2020, which triggered the resignations and related severance costs for the three executives. This included the accelerated vesting of any outstanding share based compensation. During the year ended March 31, 2022, we had an average of four full-time employees, only one of whom is an executive. This decrease in headcount and a shift in business operations resulted in the decrease of personnel related costs by approximately $7.1 million year over year, which was offset by a $0.1 million increase in consulting costs year over year, as we utilized part-time consultants for officer positions in the Company as well as various other consultants for operations. Lastly, we had an increase in corporate costs of $1.0 million year over year, which was a result of a shift in business operations. Our corporate costs during the year ended March 31, 2022 were approximately $5.5 million. Of these corporate costs, approximately $0.5 million are legal costs directly related to IPR proceedings and $1.4 million are legal costs directly related to litigation regarding patent enforcement. As of March 31, 2022, these legal matters were closed and no further costs are expected.

Other Income (Expense)

Other income was less than $0.1 million for the years ended March 31, 2022 and March 31, 2021. 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. For the year ended March 31, 2021, a loss of less than $0.1 million from the disposal of fixed assets was offset by interest income of less than $0.1 million.

Financial Condition, Liquidity and Capital Resources

We originally devoted our efforts to developing a platform technology to produce and study living tissues, with a focus on liver tissue, that emulate key aspects of human biology and disease, raising capital and building infrastructure. Following the decision to explore strategic alternatives, we took steps to manage our resources and extend our cash runway. These steps included reducing all commercial and research and development laboratory activities related to our liver tissues, except for sales of primary human cells out of inventory, negotiating an exit from our long-term facility lease, selling lab equipment and other inventory, and reducing our workforce. We have retained certain key management, employees and consultants, our core intellectual property, licenses, collaborations with research institutions and universities, and proprietary equipment. 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. In connection with our new strategy, we intend to rebuild our research and development functions to support our screening and drug development efforts.

As of March 31, 2022, we had cash and cash equivalents of approximately $28.7 million and an accumulated deficit of $307.7 million. As of March 31, 2021, we had cash and cash equivalents of $37.4 million and an accumulated deficit of $296.3 million. We had negative cash flows from operations of $8.5 million and $13.3 million for the years ended March 31, 2022 and 2021, respectively.

As of 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. At March 31, 2021, we had total current assets of approximately $38.4 million and current liabilities of approximately $0.7 million, resulting in working capital of $37.7 million.

The following table sets forth a summary of the primary sources and uses of cash for the years ended March 31, 2022 and 2021 (in thousands):

	Year Ended March 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (8,453)	$ (13,323)
Investing activities	(409)	(393)
Financing activities	205	23,835
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ (8,657)	$ 10,119

Operating activities

Net cash used in operating activities was approximately $8.5 million and $13.3 million for the years ended March 31, 2022 and 2021, respectively. The $4.8 million decrease in operating cash usage, for the year ended March 31, 2022, can be attributed primarily to our operational restructuring.

Investing activities

Net cash used in investing activities was $0.4 million for the years ended March 31, 2022 and 2021, respectively. The net cash used in investing activities for both the years ended March 31, 2022 and March 31, 2021 was related to the purchase of fixed assets.

Financing activities

Net cash provided by financing activities was approximately $0.2 million and $23.8 million for the years ended March 31, 2022 and 2021, respectively. The results in both years are primarily driven by at-the-market share offerings. Refer to “Operations funding requirements” below for further information regarding financing activities.

Operations funding requirements

During the year ended March 31, 2022, we raised net proceeds of approximately $0.3 million through the sale of 27,545 shares of our common stock through at-the-market (“ATM”) offerings.

Through March 31, 2022, 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, 2023 to be between $10.0 million and $12.0 million. Based on our current operating plan and available cash resources, we believe we have sufficient resources to fund our business for at least the next twelve months.

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 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 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 may offer and sell, from time to time through the Agents, shares of our common stock in ATM sales transactions having an aggregate offering price of up to $50.0 million. Any shares offered and sold will be issued pursuant to our 2021 Shelf. During the years ended March 31, 2022 and 2021, we sold 27,545 and 1,553,317 shares of common stock in ATM offerings, respectively, with net proceeds of approximately $0.3 million and $20.8 million under the Sales Agreement, respectively. As of March 31, 2022, we have sold an aggregate of 1,580,862 shares of common stock in ATM offerings under the Sales Agreement, with gross proceeds of approximately $21.7 million. As of March 31, 2022, there was approximately $100.0 million available in future offerings under the 2021 Shelf (excluding amounts available but not yet issued under the ATM Prospectus Supplement), and approximately $28.3 million available for future offerings through our ATM program.

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 ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

As of March 31, 2022, we had 8,710,627 total issued and outstanding shares of common stock.

Our 2008 Equity Incentive Plan (the "2008 Plan") provided for the issuance of up to 76,079 shares of common stock upon the exercise of outstanding stock options, of which 44,812 shares were issued. The 2008 Plan terminated on July 1, 2018. The 2012 Equity Incentive Plan (the "2012 Plan"), as amended, provides for the issuance of up to 2,327,699 shares of our common stock, of which 710,333 shares remain available for issuance as of March 31, 2022, to executive officers, directors, advisory board members, employees and consultants. Additionally, 75,000 shares of common stock have been reserved for issuance under the 2016 ESPP, of which 59,435 shares remain available for future issuance as of March 31, 2022. Finally, 750,000 shares of common stock have been reserved for issuances under our Inducement Plan, of which 700,000 remain available for issuance as of March 31, 2022. In aggregate, issued and outstanding common stock and shares issuable under outstanding equity awards or reserved for future issuance under the 2008 Plan, the 2012 Plan, the Inducement Plan, and the 2016 ESPP total 11,399,566 shares of common stock as of March 31, 2022.

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 12. 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.
Index to Consolidated Financial Statements

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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

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 audits 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
June 10, 2022

ORGANOVO HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands except for share and per share data)

	March 31, 2022	March 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 28,675	$ 37,364
Prepaid expenses and other current assets	858	1,034
Total current assets	29,533	38,398
Fixed assets, net	662	381
Restricted cash	143	111
Operating lease right-of-use assets	2,153	—
Prepaid expenses and other assets, net	805	1,027
Total assets	$ 33,296	$ 39,917
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 415	$ 281
Accrued expenses	489	440
Operating lease liability, current portion	479	—
Total current liabilities	1,383	721
Operating lease liability, net of current portion	1,704	—
Total liabilities	3,087	721
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 8,710,627 and 8,670,492 shares issued and outstanding at March 31, 2022 and 2021, respectively	9	9
Additional paid-in capital	337,940	335,479
Accumulated deficit	(307,739)	(296,291)
Treasury stock, 46 shares at cost	(1)	(1)
Total stockholders' equity	30,209	39,196
Total Liabilities and Stockholders' Equity	$ 33,296	$ 39,917

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, 2022	Year Ended March 31, 2021
Revenues		
Royalty Revenue	$ 1,500	$ —
Total Revenues	1,500	—
Research and development expenses	3,320	1,103
Selling, general, and administrative expenses	9,659	15,723
Total costs and expenses	12,979	16,826
Loss from Operations	(11,479)	(16,826)
Other Income		
Loss on fixed asset disposals	—	(19)
Interest income	8	15
Other income	25	6
Total Other Income	33	2
Income Tax Expense	(2)	(2)
Net Loss	$ (11,448)	$ (16,826)
Net loss per common share—basic and diluted	$ (1.32)	$ (2.44)
Weighted average shares used in computing net loss per common share—basic and diluted	8,703,596	6,902,000
Comprehensive Loss:		
Net Loss	$ (11,448)	$ (16,826)
Comprehensive Loss	$ (11,448)	$ (16,826)

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

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Common Stock		Additional Paid-in	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance at March 31, 2020	**6,528**	**$ 7**	**$ 306,089**	—	**$ —**	**$ (279,465)**	**$ 26,631**
Stock option exercises	8	—	42	—	—	—	42
Issuance of common stock under employee and director stock option, RSU and purchase plans	203	—	(4)	—	—	—	(4)
Stock-based compensation expense	—	—	5,556	—	—	—	5,556
Issuance of common stock from public offering, net	1,932	2	23,796	—	—	—	23,798
Purchase of treasury stock					(1)	—	(1)
Net loss	—	—	—	—	—	(16,826)	(16,826)
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**

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, 2022	Year Ended March 31, 2021
Cash Flows From Operating Activities		
Net loss	$ (11,448)	$ (16,826)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed assets	—	19
Depreciation and amortization	142	41
Stock-based compensation	2,256	5,556
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	—	111
Prepaid expenses and other assets	384	(1,135)
Accounts payable	134	(439)
Accrued expenses	49	(650)
Operating right-of-use asset and lease liability, net	30	—
Net cash used in operating activities	(8,453)	(13,323)
Cash Flows From Investing Activities		
Purchases of fixed assets	(409)	(405)
Proceeds from disposals of fixed assets	—	12
Net cash used in investing activities	(409)	(393)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock, net	251	23,798
Employee taxes paid related to net share settlement of equity awards	(46)	(4)
Proceeds from exercise of stock options	—	42
Purchase of treasury stock	—	(1)
Net cash provided by financing activities	205	23,835
Net Increase (Decrease) in Cash, Cash Equivalents, and Restricted Cash	(8,657)	10,119
Cash, cash equivalents, and restricted cash at beginning of period	37,475	27,356
Cash, cash equivalents, and restricted cash at end of period	$ 28,818	$ 37,475
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	$ 28,675	$ 37,364
Restricted cash	143	111
Total cash, cash equivalents and restricted cash	$ 28,818	$ 37,475
Supplemental Disclosure of Cash Flow Information:		
Income taxes paid	$ 2	$ 2
Operating lease liabilities arising from obtaining right-of-use assets	$ 2,301	$ —

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 an early-stage 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.

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.

COVID-19

Global health concerns relating to the COVID-19 pandemic continue to weigh on the macroeconomic environment, and the pandemic has significantly increased economic volatility and uncertainty.

The extent to which the coronavirus impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the rise of vaccine-resistant variants, the duration of the outbreak, and any travel bans and restrictions or other limitations that may be imposed in the future. In particular, the continued coronavirus pandemic could adversely impact various aspects of the Company's operations, including among others, the ability to raise additional capital, the timing and ability to pursue the Company's strategy, given the impact the pandemic may have on the manufacturing and supply chain, sales and marketing and clinical trial operations of potential strategic partners, and the ability to advance its research and development activities and pursue development of its pipeline products, each of which could have an adverse impact on the Company's business and financial results. Company employees and consultants have recently returned to working at the office and lab when necessary. The Company has developed guidelines and protocols to handle exposures and infections to keep disruptions to operations to a minimum.

Liquidity

As of March 31, 2022, the Company had cash and cash equivalents of approximately $28.7 million, restricted cash of approximately $0.1 million and an accumulated deficit of approximately $307.7 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 $8.5 million during the year ended March 31, 2022.

Through March 31, 2022, 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, 2022, the Company issued 27,545 shares of its common stock through its ATM facility and received net proceeds of approximately $0.3 million.

The Company believes its cash and cash equivalents on hand will be sufficient to meet its financial obligations for at least the next 12 months of operations. As the Company recommences 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. If required, the Company may 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, financial condition and ability to continue as a going concern.

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. Significant estimates used in preparing the consolidated financial statements include those assumed in revenue recognition and the valuation of stock-based compensation expense. On an ongoing basis, management reviews these estimates and assumptions. Though the impact of the COVID-19 pandemic to the Company's business and operating results presents additional uncertainty, the Company continues to use the best information available to inform its significant accounting estimates.

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 90 days or less to be cash equivalents.

Restricted cash

As of March 31, 2022 and 2021, 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, 2022 and 2021.

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.

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.

Licenses

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 4: 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). For the years ended March 31, 2022 and 2021, the comprehensive loss was equal to the net 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, 2022 and 2021 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 1.2 million shares and 1.0 million shares for the years ended March 31, 2022 and 2021, respectively.

Note 2. Fixed Assets

Fixed assets consisted of the following (in thousands):

	March 31, 2022	March 31, 2021
Laboratory equipment	$ 1,171	$ 978
Furniture and fixtures	38	—
Computer software and equipment	524	405
Fixed Assets, gross	1,733	1,383
Less accumulated depreciation	(1,071)	(1,002)
Fixed Assets, net	$ 662	$ 381

As of March 31, 2022 and 2021, all of the Company's fixed assets were active and in use. Depreciation expense for the years ended March 31, 2022 and 2021 was approximately $128,000 and $27,000, respectively.

Note 3. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2022	March 31, 2021
Accrued compensation	$ 434	$ 378
Accrued legal and professional fees	27	31
Other accrued expenses	28	31
	$ 489	$ 440

Note 4. 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, MatTek Incorporated and Visikol, Inc. (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. However, after analyzing all available information, the Company concluded that there are constraints on the estimates of variable consideration because there is a lack of complete and accurate information available. As the License Agreement was executed close to the end of the fiscal year, BICO Group AB was unable to timely deliver complete sales reports by product as stipulated in the License Agreement. Therefore, the Company concluded that there is a risk of significant reversal when the uncertainty associated with the variable consideration is resolved. For the year ended March 31, 2022, the Company recorded no royalty revenue based on sales-based royalties from the License Agreement.

Also as part of the License Agreement, certain patents involved in the agreement are sublicensed by the Company from the University of Missouri and 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 minimum annual royalties of $25,000 in January 2022 and January 2021 for their respective calendar years, 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, 2022 and 2021. The license agreement terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement, which is expected to expire after 2029.

The license agreement with the University of Missouri also includes an additional sales royalty of 3% of all revenue received from a sublicensee, when such sublicense is entered pursuant to settlement of litigation. Such revenue shall include, but not be limited to, all option fees, license issue fees (up-front payments), license maintenance fees, equity, and all royalty payments. Such revenue shall not include research funding provided to licensee by sublicensee. However, per the agreement, in the event that the Company defends the technology by litigation, it can offset any royalties due by legal expenses incurred. As of March 31, 2022, the Company's legal expenses exceeded royalties owed from the upfont payment related to the License Agreement. Therefore, no royalty expense to the University of Missouri was recorded for the year ended March 31, 2022. Additionally, as no royalty revenue for sales-based royalties was recorded for the year ended March 31, 2022, no corresponding royalty expense was recorded.

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, 2022 and 2021. 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, 2022, the Company's legal expenses exceeded royalties owed from the upfont payment related to the License Agreement. Therefore, no royalty expense to Clemson University was recorded for the year ended March 31, 2022. Additionally, as no royalty revenue for sales-based royalties was recorded for the year ended March 31, 2022, no corresponding royalty expense was recorded.

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

	March 31, 2022	March 31, 2021
License fees	$ 218	$ 218
Less accumulated amortization	(124)	(109)
License fees, net	$ 94	$ 109

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 $14,000 for each of the years ended March 31, 2022 and 2021. At March 31, 2022, the weighted average remaining amortization period for all licenses was approximately 8 years. The annual amortization expense of licenses for the next five years is estimated to be approximately $14,000 per year.

Note 5. Stockholders' Equity

Stock-based compensation expense and valuation information

Stock-based awards include stock options and RSUs under the Amended and Restated 2012 Equity Incentive Plan ("2012 Plan"), inducement awads, 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, 2022	Year Ended March 31, 2021
Research and development	$ 419	$ 105
General and administrative	1,837	5,451
Total	$ 2,256	$ 5,556

The total unrecognized compensation cost related to unvested stock option grants as of March 31, 2022 was approximately $4,299,000 and the weighted average period over which these grants are expected to vest is 2.34 years.

The total unrecognized stock-based compensation cost related to unvested RSUs (not including performance-based RSUs) as of March 31, 2022 was approximately $159,000, which will be recognized over a weighted average period of 2.84 years.

As of March 31, 2022, there are no participants enrolled into the ESPP for the current purchase period, beginning March 1, 2022.

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

	Year Ended March 31, 2022	Year Ended March 31, 2021
Dividend yield	—	—
Volatility	95.65%	107.88%
Risk-free interest rate	1.30%	0.61%
Expected life of options	5.75 years	5.81 years
Weighted average grant date fair value	$ 4.73	$ 6.97

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 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 Company's ESPP. Stock-based compensation expense is recognized over the purchase period using the straight-line method.

There were no participants in the ESPP for the purchase period September 1, 2021 – February 28, 2022 nor any participants in the ESPP for the current purchase period (beginning March 1, 2022).

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.

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 May of 2008, the Board approved the 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan authorized the issuance of up to 76,079 common shares for awards of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock award units, and stock appreciation rights. The 2008 Plan terminated on July 1, 2018. As of March 31, 2022, 44,812 shares under the 2008 Plan have been issued.

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. As of March 31, 2022, 710,333 shares remain available for issuance under the 2012 Plan.

On April 24, 2017, the Company filed a Registration Statement on Form S-8 with the Securities and Exchange Commission (the "SEC") authorizing the issuance of 114,852 shares of the Company's common stock, pursuant to the terms of an Inducement Award Stock Option Agreement and an Inducement Award Performance-Based Restricted Stock Unit Agreement (collectively, the "2017 Inducement Award Agreements").

On August 14, 2018, the Company filed a Registration Statement on Form S-8 with the SEC authorizing the issuance of 56,770 shares of the Company's common stock, pursuant to the terms of an Inducement Award Stock Option Agreement and an Inducement Award Restricted Stock Unit Agreement (collectively, the "2018 Inducement Award Agreements" and, together with the 2017 Inducement Award Agreements the "Inducement Award Agreements").

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. As of March 31, 2022, 700,000 shares remain available for issuance under the Inducement Plan.

The Company previously had an effective shelf registration statement on Form S-3 (File No. 333-222929) and the related prospectus supplement 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 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, pursuant to which the Company may offer and sell, from time to time through the Agents, shares of its common stock in at-the-market ("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 Company's 2021 Shelf. During the years ended March 31, 2022 and March 31, 2021, the Company issued 27,545 and 1,553,317 shares of common stock, respectively, for net proceeds of $0.3 million and $20.8 million in ATM offerings under the Sales Agreement, respectively. As of March 31, 2022, the Company has sold an aggregate of 1,580,862 shares of common stock in ATM offerings under the Sales Agreement, with gross proceeds of approximately $21.7 million. As of March 31, 2022, there was approximately $100.0 million available in future offerings under the 2021 Shelf (excluding amounts available but not yet issued under the ATM Prospectus Supplement), and approximately $28.3 million available for future offerings through the Company's ATM program.

During the years ended March 31, 2022 and 2021, the Company issued 0 and 7,800 shares of common stock, respectively, upon exercise of stock options.

Restricted stock units

The following table summarizes the Company's RSUs (not including performance-based RSUs) activity for the year ended March 31, 2022:

	Number of Shares		Weighted Average Price
Unvested at March 31, 2021	21,057	$	10.79
Granted	-	$	—
Vested	(5,557)	$	11.38
Cancelled / forfeited	—	$	—
Unvested at March 31, 2022	15,500	$	10.58

Performance-based restricted stock units

On July 2, 2019, the Company issued Performance-Based Restricted Stock Unit Awards (the "PBRSU Retention Awards") for an aggregate of 301,391 shares of common stock to its management team. The PBRSUs were issued pursuant to the 2012 Plan. The PBRSU Retention Awards were to vest in full upon the earlier of: (i) the Company's engagement in a pre-IND meeting with the FDA, (ii) twenty-four months from the grant date, or (iii) a change in control. As of March 31, 2022, 111,682 shares were forfeited due to terminations, vesting for 177,480 shares was accelerated due to a change in control that was triggered by changes to the Board in 2020, and the remaining 12,229 shares vested on July 1, 2021, twenty-four months from the grant date, as these particular shares required two of the conditions to be met in order to vest.

The following table summarizes the Company's performance-based restricted stock unit activity for the year ended March 31, 2022:

	Number of Shares		Weighted Average Price
Unvested at March 31, 2021	12,229	$	9.80
Granted	—	$	—
Vested	(12,229)	$	9.80
Canceled / forfeited	—	$	—
Unvested at March 31, 2022	—	$	—

Stock options

During the year ended March 31, 2022 under the 2012 Plan, 573,546 stock options were granted at various exercise prices.

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.

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, 2022, 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, 2022:

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2021	1,004,655	$ 20.03	$ 856,400
Options granted	573,546	$ 6.04	$ —
Options canceled	(374,530)	$ 39.31	$ —
Options exercised	—	$ —	$ —
Outstanding at March 31, 2022	1,203,671	$ 7.36	$ 71,650
Vested and Exercisable at March 31, 2022	240,493	$ 7.69	$ —

The weighted-average remaining contractual term of stock options exercisable and outstanding at March 31, 2022 was approximately 8.72 years.

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 or 500 shares per employee per six-month purchase period. Shares under the ESPP are purchased at 85 percent of the fair market value at the lower of (i) the closing price on the first trading day of the six-month purchase period or (ii) the closing price on the last trading day of the six-month purchase period. The initial offering period commenced in September 2016. During the year ended March 31, 2022, no shares were issued under the ESPP. At March 31, 2022, there were 59,435 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, 2022:

Common stock issuable pursuant to options outstanding and reserved under the 2012 Plan	1,153,671
Common stock reserved under the 2012 Plan	710,333
Common stock reserved under the ESPP	59,435
Common stock reserved under the 2021 Inducement Equity Plan	700,000
Common stock issuable pursuant to restricted stock units outstanding under the 2012 Plan	15,500
Common stock issuable pursuant to options outstanding and reserved under the Inducement Plan	50,000
Total at March 31, 2022	2,688,939

Note 6. 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, 2022 (in thousands):

	March 31, 2022
ASSETS	
Operating lease right-of-use assets	$ 2,153
Total lease right-of-use assets	$ 2,153
LIABILITIES	
Current	
Operating lease liability	$ 479
Noncurrent	
Operating lease liability, net of current portion	$ 1,704
Total lease liabilities	$ 2,183
Weighted average remaining lease term:	4.83 years
Weighted average discount rate:	6%

The Company recorded rent expense of approximately $18,000 and $50,000 for the years ended March 31, 2022 and 2021, respectively. Variable lease expense was approximately $59,000 and $13,000 for the years ended March 31, 2022 and 2021, respectively. Short term lease expense was approximately $117,000 and $54,000 for the years ended March 31, 2022 and 2021, respectively. Lastly, operating lease expense was approximately $172,000 and $0 for the years ended March 31, 2022 and 2021, respectively.

Cash outflows associated with the Company's operating lease for the year ended March 31, 2022 was $183,000.

Future lease payments relating to the Company's operating lease liabilities as of March, 31, 2022 are as follows (in thousands):

Fiscal year ending March 31, 2023	$ 495
Fiscal year ending March 31, 2024	509
Fiscal year ending March 31, 2025	524
Fiscal year ending March 31, 2026	540
Fiscal year ending March 31, 2027	461
Thereafter	—
Total future lease payments	2,529
Less: Imputed Interest	(346)
Total lease obligations	2,183
Less: Current obligations	(479)
Noncurrent lease obligations	$ 1,704

Note 7. Commitments and Contingencies

Legal matters

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

The Company previously disclosed the following actions (collectively, the "Actions"):

- In June 2021, the Company's U.S. Patent Nos. 9,855,369 and 9,149,952, which relate to its bioprinter technology, became the subject of IPR proceedings filed by Cellink AB and its subsidiaries, MatTek Incorporated and Visikol, Inc. (collectively, "BICO Group AB"). The Company filed a preliminary response to BICO Group AB's IPR petition in September 2021, and the Patent Trial and Appeal Board ("PTAB") denied institution of the proceedings in December 2021.

- Also in June 2021, U.S. Patent Nos. 9,149,952, 9,855,369, 8,931,880, 9,227,339 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent Nos. 7,051,654 and 9,752,116 (licensed exclusively to Organovo) were subject to a declaratory judgment complaint against the Company brought by BICO Group AB to obtain a declaration from the court that they do not infringe any claims of the noted patents (the "Action").

- Further, on July 28, 2021, the Company filed a complaint for patent infringement against BICO Group AB in the United States District Court for the Western District of Texas (the "Patent Complaint"). The Patent Complaint alleged that BICO Group AB has infringed U.S. Patent Nos. 9,149,952, 9,855,369 and 9,315,043 (all assigned to Organovo, Inc.) and U.S. Patent No. 9,752,116 (licensed exclusively to Organovo). The Company sought an injunction against continuing infringement of the foregoing patents by BICO Group AB and monetary damages. The Company later amended the complaint to add U.S. Patent No. 8,852,932. The case was transferred to the District of Delaware in December 2021 to be consolidated with BICO Group AB's declaratory judgment action.

- In addition, in September 2021, BICO Group AB filed two additional IPR proceedings against the Company's U.S. Patent Nos. 9,315,043 and 9,752,116 (exclusively licensed by the Company from the MUSC Foundation for Research and Development), which relate to its bioprinter technology. The Company filed preliminary responses to those proceedings in December 2021 and January 2022.

On February 22, 2022, the Company and BICO Group AB entered into a Settlement and Patent License Agreement fully and finally settling all matters between the parties regarding BICO Group AB's alleged infringement of the Company's patents. Concurrent with this settlement, the Delaware District Court action was dismissed and the remaining IPR proceeding was also dismissed.

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 of these legal matters were resolved against the Company in a reporting period, the Company's consolidated financial statements for that reporting period could be materially adversely affected.

Note 8. Income Taxes

A reconciliation of the statutory federal rate and the effective rate, for operations, is as follows for the years ended March 31, 2022 and 2021 (in thousands, except percentages):

	March 31, 2022		March 31, 2021	
Tax computed at federal statutory rate	$ (2,404)	21%	$ (3,533)	18.9%
State income tax, net of federal benefit	(6)	0%	(823)	4.4%
Executive compensation	—	0%	509	0.0%
Stock-based compensation	1,857	-16.2%	2,662	-14.2%
Research credits	(249)	2.1%	(35)	0.2%
Change in tax rate	454	-4.0%	(282)	1.5%
Removal of net operating losses and research development credits	2,269	-19.8%	3,269	-17.5%
Other	20	-0.1%	(215)	1.1%
Valuation allowance	(1,941)	16.9%	(1,552)	8.3%
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, 2022 and 2021 (in thousands, except percentages):

	March 31, 2022	March 31, 2021
Deferred tax assets:		
Net operating loss carry forwards	$ —	$ —
Research and development credits	—	9
Accrued expenses and reserves	110	86
Operating lease liability	611	—
Stock-based compensation	554	2,433
Other, net	3	3
Total deferred tax assets	1,278	2,531
Valuation allowance	(583)	(2,524)
Net deferred tax assets	$ 695	$ 7
Deferred tax liabilities:		
Operating lease right-of-use assets	(603)	—
Depreciation and amortization	(92)	(7)
Total deferred tax liabilities	$ (695)	$ (7)
	$ —	$ —

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, 2022. 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, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. The valuation allowance decreased by approximately $1,941,000 and approximately $1,552,000 for the years ended March 31, 2022 and 2021, respectively.

The Company had federal and state net operating loss carryforwards of approximately $203.9 million and $40.5 million, respectively, as of March 31, 2022. Federal net operating loss carryforwards of approximately $60.3 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 $4.4 million and $4.1 million at March 31, 2022, 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, 2022.

The Company did not accrue either interest or penalties from inception through March 31, 2022.

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, 2022, 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 9. Concentrations

Credit risk and significant customers

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments. The Company maintains cash balances at various financial institutions located within the United States. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. Balances may exceed federally insured limits. The Company has not experienced losses in such accounts, and management believes that the Company is not exposed to any significant credit risk with respect to its cash and cash equivalents.

The Company is also potentially subject to concentrations of credit risk in its revenues and accounts receivable. Because it is in the early commercial stage, the Company's revenues to date have been derived from a relatively small number of customers and collaborators. However, the Company has not historically experienced any accounts receivable write-downs and management does not believe significant credit risk exists as of March 31, 2022.

Note 10. Related Parties

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

Viscient 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, 2022 and 2021, the Company incurred approximately $47,000 and $38,000 in consulting expenses from Viscient, respectively. Additionally, for the years ended March 31, 2022 and 2021, the Company provided approximately $48,000 and $0 of histology services to Viscient, respectively.

Note 11. 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, 2022 and 2021 were approximately $25,000 and $39,000, respectively.

Note 12. Recent Accounting Pronouncements

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

Note 13. Restructuring

In September 2020, shareholders approved a change to the Company's operations and executive team, which triggered a "Change of Control" under the Company's severance plan. As a result, the Company terminated the employment of its executive officers and recorded a restructuring charge of approximately $2.8 million, related to employee severance and benefits costs, of which approximately $2.6 million was paid out during the second quarter of fiscal 2021. The Company paid approximately $30,000 each quarter through the end of fiscal 2022 as part of the severance and benefit obligations.

Restructuring charges were recorded in selling, general and administrative expenses and were comprised of the following (in thousands):

	Year Ended March 31, 2022	Year Ended March 31, 2021
Severance for Involuntary Employee Terminations	$ —	$ 2,808
Total Restructuring Expense	$ —	$ 2,808

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

	Severance for Involuntary Employee Terminations
Balance at March 31, 2021	$ 135
Increase to reserve	$ —
Utilization of reserve:	
Payments	$ (135)
Balance at March 31, 2022	$ —

As of March 31, 2022, the restructuring accrual was fully utilized and there is no remaining balance.

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, 2021. 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, 2022.

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, 2022 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.

None.

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 2022 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 2022 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, 2022:

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)	1,169,171 (2)	$ 7.56	769,768 (3)
Equity compensation plans not approved by security holders (4)	50,000 (5)	$ 2.75	700,000 (6)

(1) Includes the 2008 Plan, the 2012 Plan, and the ESPP.
(2) Includes stock options to purchase 1,153,671 shares of common stock with a per share weighted-average exercise price of $7.56. Also includes 15,500 restricted stock units with no exercise price.
(3) Includes 59,435 shares of common stock available for purchase under the ESPP as of March 31, 2022.
(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 700,000 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 2022 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 2022 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 2022 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, 2022 and 2021 and have therefore been omitted.

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

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

EXHIBIT INDEX

Exhibit No.	Description
2.1	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).
2.2	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).
3.1	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.2	Certificate of Amendment of Certificate of Incorporation of Organovo Holdings, Inc. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on July 27, 2018).
3.3	Certificate of Second Amendment of Certificate of Incorporation of Organovo Holdings, Inc. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the SEC on August 17, 2020).
3.4	Bylaws of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.2 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012).
3.5	Amendment to Bylaws of Organovo Holdings, Inc., dated October 10, 2019 (incorporated by reference from Exhibit 99.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 11, 2019).
3.6	Amendment to Bylaws of Organovo Holdings, Inc., dated September 29, 2021 (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 1, 2021).
4.1*	Description of Securities.
10.1+	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).
10.2+	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).
10.3+	Form of Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.16 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).
10.4+	Form of Indemnification Agreement (incorporated by reference from Exhibit 10.17 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012).
10.5†	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).
10.6†	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).
10.7†	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).
10.8+	Form of Non-Employee Director Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 9, 2015).
10.9+	Form of Executive Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K, as filed with the SEC on June 9, 2015).
10.10+	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).
10.11+	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).
10.12+	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).

Exhibit No.	Description
10.13+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement (Retention Form) under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).
10.14+	Form of Employee Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).
10.15+	Form of Non-Employee Director Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on August 4, 2016).
10.16+	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).
10.17+	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).
10.18+	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).
10.19+	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).
10.20+	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).
10.21+	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).
10.22+	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).
10.23+	Amendment #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).
10.24+	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).
10.25+	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).
10.26	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).
10.27	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).
10.28#	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).

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.
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:June 10, 2022

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)	June 10, 2022
/s/ Thomas Hess Thomas Hess	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	June 10, 2022
/s/ Adam Stern Adam Stern	Director	June 10, 2022
/s/ Douglas Cohen Douglas Cohen	Director	June 10, 2022
/s/ David Gobel David Gobel	Director	June 10, 2022
/s/ Vaidehi Joshi Vaidehi Joshi	Director	June 10, 2022
/s/ Alison Milhous Alison Milhous	Director	June 10, 2022

Exhibit 4.1

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, 2021.

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, 2021, 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 one Class I director, 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 2021. The directors designated as Class II directors have a term expiring at our annual meeting of stockholders in 2022, 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.

Exhibit 10.34

SETTLEMENT AND PATENT LICENSE AGREEMENT

This SETTLEMENT AND PATENT LICENSE AGREEMENT (the "**Agreement**") is entered into as of the Effective Date between **Organovo, Inc.**, a Delaware corporation ("**Organovo**" or "**Licensor**"**),** and **BICO Group AB**, a publicly listed stock company duly incorporated under the laws of Sweden ("**BICO**" or "**Licensee**"). Organovo and BICO may individually be referred to herein as a "**Party**" and collectively as the "**Parties**"**.**

A. **WHEREAS**, Organovo and BICO are engaged in a lawsuit filed on June 7, 2021 in the United States District Court for the District of Delaware (the "**Court**") regarding U.S. Patent Nos. 9,149,952; 9,855,369; 8,931,880; 9,227,339; 7,051,654; 9,752,116; and 9,315,043 (the "**Delaware Asserted Patents**"), in Civil Action No. 21-832-MN (the "**Delaware Civil Action**"). Organovo and BICO further engaged in a lawsuit filed on July 27, 2021 in the United States District Court for the Western District of Texas regarding the alleged infringement of U.S. Patent Nos. 9,149,952; 9,855,369; 9,752,116; 8,852,932; and 9,315,043 (the "**Texas Asserted Patents,**" collectively with the Delaware Asserted Patents, the "**Asserted Patents**") in Civil Action No. 6:21-cv-769-ADA, which was transferred to Delaware and became Civil Action No. 21-1724-MN (the two complaints shall be referred to collectively as the "**Civil Action**");

B. **WHEREAS**, BICO denies that it has infringed any claim of the Asserted Patents and does not admit validity of the Asserted Patents, and Organovo has asserted various defenses and counterclaims, including, without limitation, defenses and counterclaims for infringement and validity, in the Civil Action;

C. **WHEREAS**, BICO is a petitioner in two *inter partes* review ("**IPR**") proceedings pending before the Patent Trial and Appeal Board ("**PTAB**") of the United States Patent and Trademark Office ("**USPTO**") under case numbers IPR2021-01543 and IPR2021-01544 (collectively, the "**IPR Proceedings**"), in which BICO has challenged the patentability of various claims of two of the Asserted Patents;

D. **WHEREAS**, Organovo denies that any claim of the Asserted Patents is unpatentable and has opposed the bases for unpatentability proffered by BICO; and

E. **WHEREAS**, Organovo and BICO, in contemplation of the uncertainties associated with both the expense of pursuing, and the outcomes of, the Civil Action and the IPR Proceedings (collectively, the "**Litigations**"), desire to compromise, resolve, and settle all aspects of their disputes related to the Litigations without expending the further time, expense, and other resources that they anticipate otherwise would be required of each of them to fully pursue their respective claims, defenses, and other positions in the Litigations.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which, is hereby acknowledged, Organovo and BICO agree as follows:

1. **DEFINITIONS**. As used herein:

1.1 " **Affiliate**" with respect to a Party, means any Person that, directly or indirectly, or through one or more intermediaries, controls, is controlled by, or is under common control with the Party, including a Person that becomes an Affiliate after the Effective Date, provided that a Person is an Affiliate only during the time period that the foregoing control relationship exists.

1.2 "**Claims**" means any and all claims, counterclaims, third-party claims, contribution claims, indemnity claims, demands, actions, causes of action, and all other claims of every kind and nature in law or equity, whether arising under state, federal, international or other law, that were asserted in or that arise from the same transactions, circumstances, or occurrences as those claims and/or counterclaims asserted by any Party in any of the Litigations, whether such claims are absolute or contingent, direct or indirect, known or unknown.

1.3 "**Effective Date**" means the earliest date upon which all Parties have signed this Agreement or identical counterparts thereof.

1.4 "**Bioprinting Technology**" means and includes any form or type of bioprinters and related instrumentation, components and parts based on the Licensed Patents, including but not limited to the Bio X, Bio X6, and Bio MDX bioprinters.

1.5 "**Bioinks**" means bioink products sold with or without living cells by BICO, that are intended for use in a method that involve all steps of claim 1 or claim 4 of patent 9,855,369; including the bioink products LAMININK series, HEP-X series, GelMA-based, GelXG series, Coll1-based and ColMA series.

1.6 "**Licensed Patents**" means (i) the patents listed in Exhibit A; (ii) any reissue, reexamination, *inter partes* review certificate, post-grant review certificate, registration, extension, continuation application (including continuations, divisionals, and continuations- in-part only for claims fully supported by the disclosures of the patents listed in exhibit A) of any of the foregoing patents or patent application; and (iii) any patent or patent application that claims priority to or through any of the foregoing patents or patent application or from which any of the foregoing patents or patent application claim priority and only for claims fully supported by the disclosures of the patents listed in exhibit A, including any and all foreign counterpart patents and applications related to any of the foregoing.

1.7 "**Licensed Products**" means any product or method used, made, distributed, leased, imported, exported, licensed or offered to license, sold or offered for sale, or otherwise transferred by, for, or on behalf of Licensee or any Affiliate of Licensee, and any combination thereof that, after the Effective Date, would directly or indirectly infringe at least one Valid Claim of at least one Licensed Patent in the absence of a license thereto.

1.8 **"Settlement Payment**" means the Upfront Payment and all Royalty Payments.

1.9 "**Person**" means any individual or firm, association, organization, joint venture, trust, partnership, corporation, limited liability company, association, unincorporated organization, or other collective organization or entity.

1.10 "**Third Party**" means a Person other than the Parties to this Agreement and Licensee's Affiliates.

1.11 "**Valid Claim**" means a claim (including a process, use, or composition of matter claim) of (a) an issued and unexpired Licensed Patent that has not (i) irretrievably lapsed or been revoked, dedicated to the public or disclaimed or (ii) been held invalid, unenforceable or not patentable by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, which holding, finding or decision is final and unappealable or unappealed within the time allowed for appeal, or (b) a pending application in the Licensed Patents, which claim was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application, *provided*, *however*, that if a particular claim has not issued within four (4)

years of its filing date, it will not be considered a Valid Claim for purposes of this Agreement unless and until such claim is included in an issued or granted Patent, notwithstanding the foregoing definition.

1.12 "**Net Sales**" means the net sales revenues received by Licensee or its Affiliates from independent Third Parties for the sale of Licensed Products, after deduction (if not already deducted in the amount invoiced) of the following items paid by Licensee or its Affiliates with respect to sales of Licensed Products, provided and to the extent that such items are incurred or allowed and do not exceed reasonable and customary amounts in the market in which such sales occurred: (i) trade, quantity and/or cash discounts, allowances or rebates actually taken and allowed, including promotional or similar discounts or rebates and discounts or rebates to governmental or managed care organizations and wholesalers; (ii) credits or allowances given or made or amounts repaid with respect to Licensed Products by reason of rejection, defects, recalls, returns, rebates, retroactive price reductions or uncollectible amounts; (iii) any Taxes (including any sales, value added, excise or similar tax or customs duties, tariffs and other government charge, but excluding any income tax) levied on the sale, transportation or delivery of Licensed Products and borne by the seller thereof without reimbursement from any Third Party; and (iv) any charges for freight, postage, shipping or transportation, or for insurance, in each case to the extent borne by the seller, in all cases as determined in accordance with generally accepted accounting principles in the United States GAAP.

1.13 "**Cumulative Net Sales**" means the total, cumulative Net Sales from the Effective Date and continuing until the expiration of the last surviving Licensed Patents.

2. **LICENSE**. Subject to Licensee's payment of the Settlement Payment in accordance with the terms of this Agreement, Licensor hereby grants Licensee and each Affiliate of Licensee a worldwide, non- exclusive, non-sub-licensable, non-transferable (except as permitted under Section 7.1), perpetual, irrevocable, license under the Licensed Patents to make, have made, use, design, produce, manufacture, lease, support offer to sell, sell and otherwise distribute, import and export Licensed Products in all fields of use under any BICO brand, OEM customer's private label or in association.

3. **LICENSING TERMS**.

3.1 **Amount and Timing of Upfront Payment**. In consideration of the license, and release granted by Licensor under this Agreement and full and final settlement of all Claims, Licensee shall pay to Licensor an upfront payment of one million and five hundred thousand United States dollars ($1,500,000.00 USD) (the **"Upfront Payment"**) in one installment within thirty (30) business days after the Effective Date.

3.2 **Amount and Timing of Royalty Payment**. In further consideration of the license and release granted by Licensor under this Agreement and full and final settlement of all Claims, Licensee shall pay to Licensor ongoing royalties (the **"Royalty Payment"**) as follows:

Licensed Products	**Royalty Rate**	**Cumulative Net Sales (USD) (Worldwide)**
Bioprinting technology	8.0%	$0 - $22,000,000
	6.0%	$22,000,001 - $100,000,000
	5.0%	$100,000,001 and above
Bioinks	1.5%	All sales

Royalty Payment shall be due in arrears on a quarterly basis within forty five (45) days after the end of each calendar quarter.

3.3 **Method of Payment**. All payments shall be made by wire transfer in United States dollars and in immediately available funds. The wire transfer payment shall be sent to the following bank:

Organovo, Inc.
Wire Routing Transit No. (RTN/ABA): 121000248
Wells Fargo Bank, N.A.
420 Montgomery Street
San Francisco, CA 94104
Account No: 4123509788
SWIFT BIC: WFBIUS6S (International Transfers)
CHIPS Participants: UID ABA 0407

3.4 **Taxes**. All taxes shall be the financial responsibility of the Party obligated to pay such taxes as determined by applicable law, and neither Party is or shall be liable at any time for any of the other Party's taxes incurred in connection with or related to any amount paid under this Agreement, including without limitation the Settlement Payment.

3.5 **Reports.** Along with each Royalty Payment, Licensee will provide a statement showing Cumulative Net Sales (broken down by product), the Net Sales during the preceding quarter (broken down by product), and a calculation of and Royalty Payment accrued during such quarter. Licensor will treat the statement as confidential information of Licensee, will protect it from unauthorized use, access or disclosure in the same manner as Licensor protects its own confidential or proprietary information of similar nature and with no less than reasonable care, and will disclose it only to the employees or agents of Licensor who have a need to know such information for purpose of this Agreement and who are under a duty of confidentiality no less restrictive than Licensor's duties hereunder.

3.6 **Audit Rights.** Licensee shall maintain the usual records showing its actions under this Agreement, and sufficient to determine Licensee's compliance with its obligations under this Agreement. Licensor will have the right to request an audit of the books and records of Licensee directly relating to the royalty payments owed during the last twelve (12) months for the sole purpose of verifying the amounts due and payable under this Agreement, not more than once per calendar year upon providing at least four (4) weeks prior written notice to Licensee. Licensor further reserves the right to request additional inspections of Licensee's books and records at Licensor's expense upon providing at least four (4) weeks prior written notice to Licensee.

3.7 All such audits will be conducted during reasonable business hours of Licensee, in a manner that does not unreasonably interfere with Licensee's normal business activities and will be conducted by a certified public accountant or equivalent agreed upon by Licensor (the **"Auditor"**) and reasonably acceptable to Licensee. Except for the statement of royalty payments due, the Auditor will not disclose any information learned during the audit to Licensor, and all such information shall be considered the Confidential Information of Licensee and Licensee will protect it in accordance with the terms of Section 3.5. In the event the Auditor correctly determines that Licensee has underpaid Licensor, Licensee will pay Licensor the amount of such underpayment within sixty (60) days of the completion of the audit. In the event the Auditor correctly determines Licensee has overpaid Licensor, Licensor will, at Licensee's option, either (i) credit the amount of such overpayment against future amounts owed by Licensee to Licensor, or (ii) promptly refund to Licensee such overpayment. The audit will be conducted at Licensor's expense, except if the audit shows that amount of royalty payments due to Licensor is greater than five

percent (5%) of the total royalty paid to Licensor for the immediately preceding calendar year then Licensee will pay for the reasonable costs and expenses of such audit.

4. **RELEASES AND DISMISSAL**.

4.1 **Licensor Releases to Licensee**. Except with respect to the obligations created by or arising out of this Agreement, Licensor does hereby for itself, its Affiliates, and its legal successors, heirs and assigns, irrevocably and unconditionally release and absolutely discharge Licensee, Licensee's Affiliates, and each of their respective current and former customers, suppliers, manufacturers, distributors, employees, representatives, agents, officers, directors, parents, subsidiaries, past and present, of and from any and all claims, demands, damages, debts, liabilities, accounts, reckonings, obligations, costs, expenses, liens, attorney fees, actions, and causes of action of every kind and nature whatsoever, (a) arising out of or in connection with the Litigations or Licensed Patents prior to the Effective Date, including without limitation all Claims, or (b) based in whole or in part on acts of Licensee or an Affiliate of Licensee prior to the Effective Date of this Agreement that would have been licensed under this Agreement if performed by Licensee or an Affiliate of Licensee after the Effective Date of this Agreement.

4.2 **Licensee Releases to Licensor**. Except with respect to the obligations created by or arising out of this Agreement, Licensee does hereby for itself, its Affiliates, and its legal successors, heirs and assigns, irrevocably and unconditionally release and absolutely discharge Licensor, Licensor's Affiliates, and each of their respective current and former employees, representatives, agents, officers, directors, parents, subsidiaries, past and present, of and from any and all claims, demands, damages, debts, liabilities, accounts, reckonings, obligations, costs, expenses, liens, attorney fees, actions, and causes of action of every kind and nature whatsoever, arising out of or in connection with the prosecution of the Litigations, including, without limitation, all Claims.

4.3 **Unknown Claims**. Licensor and Licensee expressly acknowledge and agree that this Agreement fully and finally releases and forever resolves the Litigations, including those Claims involving the Licensed Products, that are unknown, unanticipated or unsuspected or that may hereafter arise as a result of the discovery of new and/or additional facts. The Parties acknowledge and understand the significance and potential consequences of its release of unknown claims. The Parties intend that the claims released under this Agreement be construed as broadly as possible and agree to waive and relinquish all rights and benefits each may have under Section 1542 of the Civil Code of the State of California, or any similar statute or law of any other jurisdiction. Section 1542 states as follows:

A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party.

4.4 **Denial of Liability**. The Parties acknowledge that (a) they are entering into this Agreement to resolve disputed claims, (b) nothing herein shall be construed to be an admission of liability by either Party, and (c) Licensor on the one hand, and Licensee on the other hand, expressly deny any liability to the other Party. Each Party shall bear its own costs and attorney fees incurred in the Litigations.

4.5 **Dismissal of the Litigations**.

(a) **The Civil Action**. Within five (5) business days after the Licensee has sent a confirmation receipt of the wire transfer of the Upfront Payment, the Parties shall jointly file a mutually acceptable stipulation of dismissal requesting that the Court dismiss with prejudice all claims and

counterclaims between the Parties in the Civil Action, each Party to bear its own costs. The Parties shall cooperate to draft and submit to the Court the aforementioned stipulation of dismissal, as well as appropriate motions, stipulations, and/or proposed orders for extensions of time for all upcoming due dates in the Civil Action, if any, so that neither Party is required to incur unnecessary expenses in the Civil Action between the Effective Date and the date on which the Civil Action is dismissed. The Parties shall promptly proceed with any and all additional procedures needed to effect the above dismissal. If for any reason (except for Licensee's failure to make the Upfront Payment), Licensor or its counsel refuses to take any such actions needed to effect the above dismissal, Licensee shall have the right to demand that Licensor immediately refund in full the Upfront Payment to Licensee, in addition to any other rights and remedies available to Licensee or its Affiliates (including the right to demand specific performance of this Agreement).

(b) **The IPR Proceedings**.

(i) Within five (5) business days of the date on which the Parties jointly file a stipulation of dismissal as set forth in Section 4.5(a), BICO shall notify the PTAB by e-mail (1) that BICO and Organovo have resolved all matters relating to the Asserted Patents, and (2) of BICO's and Organovo's intention to jointly file, and mutual consent to filing, in each of the IPR Proceedings, a motion to terminate the IPR Proceedings on the basis that the Parties have reached a settlement ("**Motion to Terminate**") and a request to treat their settlement agreement (i.e., this Agreement) as business confidential information ("**BCI Request**"). The notification email shall expressly request that the PTAB grant permission for BICO and Organovo to jointly file a Motion to Terminate and a BCI Request in each of the IPR Proceedings.

(ii) Within five (5) business days of the date on which the PTAB approves the filing of a Motion to Terminate and a BCI Request in each of the IPR Proceedings, BICO and Organovo shall jointly file in each of the IPR Proceedings a mutually acceptable Motion to Terminate and a mutually acceptable BCI Request.

(iii) The Parties shall cooperate to draft and submit to the PTAB the aforementioned Motions to Terminate and BCI Requests, as well as appropriate motions, stipulations, and/or proposed orders for extensions of time for all upcoming due dates in the IPR Proceedings, if any, so that neither Party is required to incur unnecessary expenses in the IPR Proceedings between the Effective Date and the date on which the IPR Proceedings are dismissed.

4.6 **Compromise offers and negotiations**. The Parties acknowledge and agree that this Agreement, the terms in this Agreement, and the discussions and negotiations leading up to this Agreement are subject to Rule 408 of the Federal Rules of Evidence and were made in an effort to amicably resolve the Litigations.

4.7 **Settlement Only**. The Parties acknowledge and agree that (a) this Agreement and the Settlement Payment effect a litigation settlement in compromise of disputed claims and defenses, (b) this Agreement has not been negotiated under the "Hypothetical Negotiation" standard, (c) no representation is made by any Party or Party Affiliate that the Settlement Payment represents a reasonable royalty for infringement of any patent, including, without limitation, any one or more of the Licensed Patents, and (d) this Agreement, the Settlement Payment, and all other terms of this Agreement relate solely to settling the Litigations and do not relate in any way to, and, except with respect to a legal action or other legal proceeding related to the enforcement of any provision of this Agreement, shall not be used by either Party in, or in connection with, any other current or future dispute of any form or nature between the Parties. Licensee acknowledges that the Licensing Terms reflect a discount to Licensee for being an early licensee.

5. **TERM AND TERMINATION OF LICENSE**.

5.1 **Term**. This Agreement is effective as of the Effective Date and continues until the expiration of the last surviving Licensed Patent, provided that following such expiration the licenses and releases granted herein shall survive in perpetuity.

5.2 **Termination**. Each Party will have the right to terminate this Agreement upon written notice to the other Party if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within thirty (30) days from the date of such notice. Such notice shall (a) expressly reference this Section 5.2, (b) reasonably describe the alleged breach which is the basis of such termination, and (c) clearly state the non-breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the applicable cure period. The Agreement shall terminate effective at the end of the notice period unless the breaching Party cures such breach during such notice period. If either Party disputes (i) whether such material breach has occurred, or (ii) whether the defaulting Party has cured such material breach, the Parties agree to promptly resolve the dispute. It is understood and acknowledged that, during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

5.3 **Effects of Termination**. If this Agreement is terminated pursuant to Section 5.2, all licenses granted to Licensee will terminate commencing on the termination date. Notwithstanding anything to the contrary herein, the Parties reserve all rights and remedies, including damages and equitable relief, for breach of this Agreement by the other Party and nothing herein releases any Party from its respective obligations under this Agreement or prevents any Party from enforcing the terms and conditions of this Agreement against the other.

6. **CONTESTING NON-INFRINGEMENT OR VALIDITY**.

6.1 During the term of this Agreement, Licensee, for itself and all Affiliates of Licensee, agrees not to challenge, or assist others in challenging, the validity or enforceability of the Licensed Patents except that Licensee and all Affiliates of Licensee may respond to properly issued subpoenas or other discovery in any judicial actions or administrative proceedings. Licensee, for itself and all Affiliates of Licensee, agrees not to file or bring, directly or indirectly, or assist any third party to file or bring, any action alleging that any products or service of Licensee do not infringe any Licensed Patents or seeking a judgement that such products or services do not infringe any such Licensed Patents without first complying with Section 8.2.

6.2 **Liquidated Damages on Challenge**. If Licensee (or any entity or person acting on its behalf) initiates any proceeding or otherwise asserts any claim or files any action or seeks any judgment, in any case prohibited by Section 6.1 ("Challenge"), Licensee shall pay the following:

(a) all royalties accruing or due during the Challenge, in the manner and at times provided for in this Agreement; and

(b) all costs and expenses incurred by Licensor in connection with defending the Challenge, including actual legal fees and disbursements ("Liquidated Damages") during the course of the Challenge in recognition of damages to Licensor caused by the Challenge, including but not limited to lost commercial opportunity and goodwill, for which a sum certain will be difficult to determine; Licensor may bill Licensee quarterly concerning those costs and expenses, and Licensee shall make payment no later than thirty (30) days after receiving an invoice from Licensor.

Licensee acknowledges that this Section 6.2 reasonably reflects the value derived from the Agreement by Licensee in the event of a Challenge. Licensee acknowledges that any payments made under this Section 6.2 are non-refundable and non-recoverable for any reason whatsoever. Notwithstanding any of the preceding, under no circumstances will Licensee be subject to this Section 6.2 in the event that Licensee (or any entity or person acting on its behalf) Challenges any Licensed Patent as a result of an action brought by Licensor against Licensee.

7. **ASSIGNMENT OF RIGHTS AND OBLIGATIONS**.

7.1 Licensee cannot assign this Agreement to a Third Party without Licensor';s consent, except that Licensee may assign (i) to any of Licensee's Affiliates; and (ii) to a Third Party in connection with a merger, change in control, acquisition, or sale of all or substantially all of the assets or business of Licensee pertaining to this Agreement to such Third Party. Licensor may assign this Agreement, in whole or in part, to any Third Party with Licensee' consent.

8. **GENERAL PROVISIONS**.

8.1 **Confidentiality**. Subject to Section 4.5, each Party will hold the terms of this Agreement in confidence and shall not publicize or disclose it in any manner whatsoever. Notwithstanding the foregoing, (a) the Parties may disclose this Agreement or its terms as required by applicable laws, regulations, or discovery requests, in confidence to a court (or otherwise as directed by law), to the Parties' respective attorneys, accountants, auditors, tax preparers, financial advisors, and other agents who have a need to know the content of this Agreement and who are subject to confidentiality, and in connection with actual or potential financing or sale of its business and assets related to this Agreement pursuant to a nondisclosure agreement; (b) Licensee or any Affiliate of Licensee may disclose the scope of the licenses granted in Section 2 and the releases granted in Section 4.1 to a Third Party to the extent that Licensee or any Affiliate of Licensee reasonably believes necessary to respond to an inquiry from such Third Party as to whether products are licensed and/or released and therefore not subject to a claim of infringement; and (c) either Party may, at its option, disclose the dismissal of the Litigations and signing of this Agreement, but not its terms, in the form of a press release or other form of public notice.

8.2 **Protection of the Licensed Patents.** Licensor has the sole discretion and right (but not the obligation), at its expense, to prepare, file, prosecute, maintain, defend and enforce the Licensed Patents. Licensee shall immediately inform the Licensor when made aware of any unlicensed activities that are carried out by any third party which could constitute an infringement of the Licensed Patents. At Licensor's request, Licensee may, at its sole discretion, assist Licensor with finding third parties conducting unlicensed activities of the Licensed Patents. In those cases where Licensor has requested Licensee's assistance and Licensee so materially assists the Licensor, the Licensee has a right to receive equally beneficial licensing terms, should such third party be similarly situated to Licensee and such third party's terms as a whole be more favorable than the Licensing Terms in this Agreement (taking into account, without limitation, all financial and contractual terms, the nature and extent of infringement and the volumes of licensed products, and all other relevant factors). Should Licensor be sued by a potential third party infringer or sue a potential third party infringer without material assistance from Licensee, this clause shall not apply with respect to licensing terms agreed to by such potential third party infringer.

8.3 **Mediation.** In the event that there shall be any dispute arising out of or in any way relating to this Agreement, the Parties agree to first use their reasonable good faith efforts to resolve such dispute among themselves. If the Parties are unable to resolve such dispute among themselves, before commencing any other legal proceeding such dispute shall be submitted to non-binding mediation by a mutually agreeable neutral. Either Party may cause a mediation proceeding to commence by giving the

other Party notice in writing of such mediation. The Parties covenant and agree to act as expeditiously as practicable in order to resolve all disputes by mediation.

8.4 **Governing Law, Jurisdiction and Venue**. This Agreement shall be governed by, interpreted, and construed in accordance with the laws of Delaware, without reference to conflicts of laws principles. Any legal action or other legal proceeding relating to this Agreement or the enforcement of any provision of this Agreement must be brought or otherwise commenced in the Court or a state court in Delaware. Each Party expressly and irrevocably consents and submits to the jurisdiction of such state and federal courts in connection with any such legal proceeding.

8.5 **Authority to Enter Into Agreement**. Each Party and each person signing this Agreement on behalf of a Party represents and warrants to the other that it has the full right and power to enter into this Agreement, and the person executing this Agreement has the full right and authority to enter into this Agreement on behalf of such Party and the full right and authority to bind such Party to the terms and obligations of this Agreement. Each of the Parties represents and warrants that it has not assigned any rights or interests in any actions, causes of action, damages, judgments, executions, claims, demands, debts, rights, obligations, attorney's fees, costs or liabilities of any nature arising under, out of, and/or related to the Released Matters to any Third Party. Licensor represents and warrants that as of the Effective Date (a) Licensor is the sole owner of the entire right, title and interest in and to the Licensed Patents in the same families as U.S. Patent Nos. 8,931,880, 9,149,952, 9,227,339, 9,315,043, and 9,855,369, including any and all rights to enforce and sue for past damages; and (b) Licensor has the exclusive right and authority to grant the rights, licenses, covenants, and releases hereunder.

8.6 **Comprehension**. Each Party acknowledges to the other Party that it has been represented by independent legal counsel of its own choice throughout all of the negotiations that preceded the execution of this Agreement and that it has executed this Agreement with the consent and on the advice of such independent legal counsel. Each Party further acknowledges that it and its counsel have had adequate opportunity to make whatever investigation or inquiry they may deem necessary or desirable in connection with the subject matter of this Agreement prior to the execution hereof. Each Party has authorized and directed its respective attorneys to execute and deliver such other and further documents as may be required to carry out the terms and conditions of this Agreement.

8.7 **Interpretation**. The language of this Agreement has been approved by counsel for the Parties. The language of this Agreement shall be construed as a whole according to its fair meaning and none of the Parties (or the Parties' respective attorneys) shall be deemed to be the draftsman of this Agreement in any action that may hereafter arise between the Parties.

8.8 **Entire Agreement**. This is an enforceable Agreement. This Agreement, including the attached Exhibit(s) that are incorporated by reference herein, constitutes the entire agreement between the Parties and supersedes all previous communications, representations, agreements, or understandings, either oral or written, between the Parties with respect to the subject matter hereof. This Agreement may be amended, supplemented, or modified only by a written instrument duly executed by or on behalf of each Party hereto that specifically refers to this Agreement.

8.9 **Waiver**. No waiver of any breach of any provision of this Agreement shall constitute a waiver of any prior, concurrent, or subsequent breach of the same or any provisions hereof, and no waiver shall be effective unless made in writing and signed by an authorized representative of the waiving Party

8.10 **Miscellaneous**.

(a) This Agreement does not create a relationship of agency, partnership, or joint venture between the Parties.

(b) The parties shall negotiate a press release announcing the settlement.

(c) The parties acknowledge that Clemson University Research Foundation (CURF) is an intended third-party beneficiary of this agreement to the full extent of its rights in the U.S. Patent No. 7,051,654 and subject to the license agreement between Licensor and CURF, certain provisions of which are in Appendix I.

(d) Licensee acknowledges that Licensed Products are in commercial use.

(e) Each Party acknowledges and agrees that it shall comply with all reasonable requests of the other Party relative to patent markings required to comply with or obtain the benefit of statutory notice or other provisions.

8.11 **Notices**. All notices required or permitted to be given in this Agreement shall be in writing and may be delivered by hand or sent prepaid overnight via a reputable courier utilizing a tracking capability, addressed as follows:

To Licensor:

Organovo, Inc.

Office of General Counsel

Attn: Tom Jurgensen

11555 Sorrento Valley Road, Suite 100

San Diego, CA 92121, USA

Email: tjurgensen@organovo.com

With a copy to:

Paul Hastings LLP

Attn: Elizabeth L. Brann

4747 Executive Dr., 12th Floor

San Diego, CA 92121

E-mail: elizabethbrann@paulhastings.com

To Licensee:

BICO Group AB CRN 559050-5052

Attn: Lotta Bus

Arvid Wallgrens Backe 20

413 46 Gothenburg, Sweden

Email: LB@bico.com

With a copy to:

legal-notice@bico.com

Such notices shall be deemed to have been served when delivered in person or three (3) business days after delivered by courier or express delivery service. Courtesy copies of such notices may be sent to the pertinent e-mail addresses set forth above, but no notice required or permitted under this Section 8.9 shall be considered properly served by e-mail alone.

Either Party may give written notice of a change of address and, after notice of such change has been received by the addressee, any notice or request shall thereafter be given to the notifying Party as above provided at the notifying Party's new address.

8.12 **Severability**. If any provision of this Agreement shall be determined to be invalid, illegal or unenforceable under any controlling body of law, that provision shall be reformed, construed and enforced to the maximum extent permissible; and the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

8.13 **Section Headings**. The section headings used in this Agreement and the attached Exhibit(s) shall be intended for convenience only and shall not be deemed to supersede or modify any provisions.

8.14 **Counterparts**. This Agreement and any amendments hereto may be signed in one or more counterparts, each of which, when signed and delivered, shall be deemed to be an original. All such

counterparts together shall constitute one and the same valid and binding agreement, even if all of the Parties have not signed the same counterpart. Notwithstanding anything to the contrary in Section 8.9, signatures to this Agreement may be delivered by e-mail, as one or more attachments thereto in PDF format, in which case the PDF copy of an original signature shall be deemed to be an original signature.

8.15 **Duty to Effectuate**. The Parties agree to perform any lawful additional acts, including the execution of additional agreements, as are reasonably necessary to effectuate the purpose of this Agreement.

8.16 **Incorporation of Recitals**. For the avoidance of doubt, the recitals, defined terms, and other text set forth above in Section 1 of this Agreement is hereby incorporated into, and made a part of, this Agreement.

IN WITNESS WHEREOF, the Parties hereby execute this Agreement through their respective duly authorized officials as follows:

Organovo, Inc.		BICO Group, AB	
By:	/s/ Keith Murphy	By:	/s/ Erik Gatenholm
Name:	Keith Murphy	Name:	Erik Gatenholm
Title:	President & Executive Chairman	Title:	CEO
Date:	2022-02-22	Date:	2022-02-22

EXHIBIT A: LICENSED PATENTS

NUMBER	TITLE
9,149,952	Devices, systems, and methods for the fabrication of tissue
9,855,369	Method of printing a three-dimensional structure
8,931,880	Devices, systems, and methods for the fabrication of tissue
9,227,339	Devices, systems, and methods for the fabrication of tissue
9,315,043	Automated devices, systems, and methods for the fabrication of tissue
7,051,654	Ink-jet printing of viable cells
9,752,116	Self-assembling cell aggregates and methods of making engineered tissue using the same
8,852,932	Self-assembling cell aggregates and methods of making engineered tissue using the same

APPENDIX I –

LICENSE AGREEMENT BETWEEN CLEMSON UNIVERSITY RESEARCH FOUNDATION (CURF) AND ORGANOVO, INC.

LICENSE AGREEMENT BETWEEN

CLEMSON UNIVERSITY

RESEARCH FOUNDATION
AND

Organovo, Inc.

CURF #01-025

Patent# 7,051,654

Entitled "Ink-Jet Printing of Viable Cells"

ARTICLE 2 - GRANT

2.1 CURF hereby grants to LICENSEE, subject to the terms and conditions of this Agreement, the exclusive right and license for the FIELD OF USE in the TERRITORY to use TECHNOLOGY, to practice under PATENT RIGHTS, and to make, have made, use, lease, sell, provide and/or import LICENSED PRODUCTS until the end of the term for which PATENT RIGHTS are granted, all to the extent not prohibited by other patents, unless terminated earlier hereunder.

2.2 The grant in Section 2.1 shall be subject to, restricted by and non-exclusive with respect to:

(a) The reserved rights of CURF, for itself and for UNIVERSITY, to practice the licensed PATENT RIGHTS and use TECHNOLOGY for any NON-COMMERCIAL RESEARCH PURPOSES, including sponsored research and collaborations, and the right to extend these reserved rights to INVENTOR(S), any non-profit academic or research institution or organization, and any successor(s) of CURF or UNIVERSITY. LICENSEE agrees that, notwithstanding any other provisions of this Agreement, it has no right to enforce the licensed PATENT RIGHTS against CURF, UNIVERSITY, or any institution or INVENTOR(S) that are granted rights m accordance with this Section 2.2.

(b) Any non-exclusive license of TECHNOLOGY that CURF is required by law or regulation to grant to the GOVERNMENT or to a foreign country pursuant to an existing or future treaty with the United States of America.

(c) Any rights of GOVERNMENT or any restrictions or obligations that may be imposed for any TECHNOLOGY or PATENT RIGHTS developed with the support of GOVERNMENT as provided in United States laws and regulations and in its contract(s) with CURF, UNIVERSITY and/or any of the INVENTOR(S).

2.3 The provisions of this Agreement shall not be construed in such a manner as to restrict the ability of CURF or that of its licensees or assigns to use TECHNOLOGY or to practice under PATENT RIGHTS outside of the FIELD OF USE or in the FIELD OF USE outside TERRITORY for any commercial or non-commercial purposes.

2.4 LICENSEE agrees that the right of publication of TECHNOLOGY shall reside with UNIVERSITY. CURF shall use its best efforts to provide a copy of each proposed publication to LICENSEE for pre-publication review at least thirty (30) days before submission to a publisher. If LICENSEE identifies potentially patentable subject matter in any such publication, and so notifies CURF, then CURF shall notify INVENTOR(S) and shall use its best efforts to delay submission and publication for up to a combined maximum of ninety (90) days or until a patent application has been filed for such subject matter, whichever occurs first. Such review will in no way be construed as a right to restrict such publication.

2.5 This Agreement, unless terminated earlier pursuant to Article 13, shall terminate on the expiration of the last to expire patent under PATENT RIGHTS, whereupon the exclusive licenses granted hereunder shall be fully paid and LICENSEE and SUBLICENSEES shall be free to develop, make, have made, use, sell, have sold, practice or provide LICENSED PRODUCTS without further duties or responsibilities to CURF.

2.6 LICENSEE shall have the right to enter into sublicensing agreements for the rights, privileges and license granted hereunder with respect to the use of TECHNOLOGY and the practice of

PATENT RIGHTS within TERRITORY and in the FIELD OF USE provided that LICENSEE is not in default of its obligations hereunder. Upon any termination of this Agreement, SUBLICENSEE's rights shall also terminate, subject to Section 13.8 hereof. No sublicense shall relieve LICENSEE of any of its obligations under this Agreement. LICENSEE has no obligation to enter into any such sublicensing agreement.

2.7 LICENSEE agrees that any and all sublicenses granted by it shall be subject to this Agreement in all respects and each such sublicense shall:

(a) Include a requirement that the SUBLICENSEE use its best efforts to bringthe subject matter of the sublicense into commercial use as quickly as is reasonably possible;

(b) Include copies of Articles 2, 5, 7, 8, 9, 10, 11, 12, 13 and 15 of this Agreement and shall provide that the obligations of LICENSEE to CURF contained in such Articles shall be binding upon the SUBLICENSEE as if it were a party to this Agreement;

(c) Prohibit further sublicensing by the SUBLICENSEE; and

(d) Contain a provision stating that CURF shall be an intended third-party beneficiary of such sublicense agreement.

2.8 LICENSEE agrees to forward to CURF a copy of any and all sublicenses (including, without limitation, all amendments and addenda) granted hereunder within thirty (30) days of execution by the parties thereto.

2.9 LICENSEE shall not receive from SUBLICENSEES anything of value in lieu of cash payments as consideration for any sublicense under this Agreement without the express prior written permission of CURF, such permission shall not beunreasonably withheld.

2.10 LICENSEE's failure to perform in accordance with any and all of these Sections relating to sublicenses with regard to a particular sublicense shall render such attempted sublicense void, shall constitute a material breach of this Agreement and shall be grounds for CURF to terminate this Agreement pursuant to Section 13.5herein.

2.11 CURF shall have no obligation to provide LICENSEE with technical information concerning TECHNOLOGY or PATENT RIGHTS or to provide technical assistance in the development or commercialization of TECHNOLOGY or PATENT RIGHTS. In the event that LICENSEE requires technical assistance with respect to the activities conducted by LICENSEE pursuant to this Agreement , obtaining such technical assistance (whether from the INVENTOR(S) or otherwise) shall be the responsibility of LICENSEE and at the expense of LICENSEE.

2.12 The license granted hereunder shall not be construed to confer any rights upon LICENSEE by implication, estoppel or otherwise as to any technology not specifically set forth in Appendix A.

ARTICLE 5 - REPORTS AND RECORDS

5.1 LICENSEE shall submit a Licensee Information Form attached hereto as Appendix B within ten (10) days of the Effective Date of this Agreement and shall verify and update the information annually within 30 days of notice fromCURF.

5.2 No later than sixty (60) days after December 31 of each calendar year, LICENSEE shall provide to CURF a written annual progress report describing progress by LICENSEE and any SUBLICENSEES on research and development, regulatory approvals, manufacturing, sublicensing, marketing, and sales during the preceding twelve (12) month period ending December 31 and plans for the forthcoming year. If multiple technologies are covered by the license granted hereunder, the progress report shall provide the information set forth above for each technology. LICENSEE also shall provide any additional data CURF reasonably requires to evaluate LICENSEE's performance and compliance with the terms of this Agreement.

5.3 LICENSEE, within sixty (60) days after June 30 and December 31 of each year, shall submit to CURF a Royalty Report attached hereto as Appendix C. The first such Royalty Report shall be due within sixty (60) days after December 31st, 2011 and shall include all information since the Effective Date of this Agreement. With each Royalty Report submitted, LICENSEE shall pay to CURF the royalties due and payable under this Agreement. If no royalties shall be due, LICENSEE shall soreport.

5.4 LICENSEE, within ninety (90) days following the close of its fiscal year, shall provide to CURF LICENSEE's financial statements for the preceding fiscal year including, at a minimum, a balance sheet and income statement.

5.5 LICENSEE shall keep full, true and accurate books of account containing all particulars that may be necessary for the purpose of showing the amount payable to CURF hereunder. The books of account shall be kept at LICENSEE' s principal place of business or the principal place of business of the appropriate division of LICENSEE to which this Agreement relates. The books and the supporting data shall be open at all reasonable times for five (5) years following the end of the calendar year to which they pertain to the inspection of CURF or its agents for the purpose of verifying LICENSEE's royalty statement or compliance in other respects with this Agreement. Should such inspection lead to the discovery of a shortage equal to or greater than five percent (5%) of the total amount due in the period under audit, LICENSEE shall promptly reimburse CURF for the full cost of such inspection, the shortage and an interest of five percent (5%) on any shortage due.

ARTICLE 7 - INFRINGEMENT

7.1 Each PARTY shall inform the other PARTY promptly in writing of any alleged infringement of PATENT RIGHTS by a third party and any available evidence thereof.

7.2 During the term of this Agreement, LICENSEE shall have the first right, but shall not be obligated to prosecute at its own expense, all infringements or misappropriations of TECHNOLOGY. LICENSEE may, for such purposes, include CURF as party plaintiff, if necessary, without expense to CURF. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of CU RF, which consent shall not unreasonably be withheld. The total cost of any such infringement or misappropriation action commenced or defended solely by LICENSEE shall be borne by LICENSEE, and LICENSEE shall keep any recovery or damages for past infringement or misappropriation derived therefrom subject to the payment of a percentage on any recoveries net of costs and expenses as an "other payment" in accordance with Section 4.l (e). LICENSEE shall indemnify CURF against any order for costs that may be made against CURF in such proceedings.

7.3 If within three (3) months after having been notified of any alleged infringement, LICENSEE is unsuccessful in persuading the alleged infringer to desist and has not brought or is not

diligently pursuing an infringement action or if LICENSEE notifies CURF at any time prior thereto of its intention not to bring suit against any alleged infringer, then, and in those events only, CURF shall have the right, but shall not be obligated, to prosecute at its own expense all infringements or misappropnat10ns of TECHNOLOGY and CURF may, for such purposes, include LICENSEE as a party plaintiff in any such suit, without expense to LICENSEE. The total cost of such infringement action commenced or defended solely by CURF shall be borne by CURF and CURF shall keep any recovery or damages for past infringement derived therefrom.

7.4 In the event that LICENSEE shall undertake the enforcement and/or defense of the TECHNOLOGY by litigation, LICENSEE may withhold up to fifty percent (50%) of the payments otherwise due CURF under Article 4 hereunder and apply the same toward payment of up to half of LICENSEE's expenses, including reasonable attorney ' s fees, in connection therewith. LICENSEE shall modify the Royalty Report form to reflect any withholdings. Any recovery of damages by LICENSEE for each such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of LICENSEE relating to such suit, and next toward reimbursement of CURF for any payments under Article 4 past due or withheld and applied pursuant to this Section 7.4. LICENSEE shall keep the balance remaining from any such recovery subject to the payment of a percentage as an "other payment" in accordance with Section 4.l (e).

7.5 In any infringement or misappropriation suit that either PARTY may institute to enforce the PATENT RIGHTS pursuant to this Agreement, the other PARTY hereto shall, at the request and expense of the PARTY initiating such suit, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens and the like.

7.6 LICENSEE, during the exclusive period of this Agreement, shall have the sole right in accordance with the terms and conditions herein to sublicense any alleged infringer for the FIELD OF USE for future use of the PATENT RIGHTS. Any upfront fees as pai1 of such a sublicense shall be treated pursuant to Article 4.

ARTICLE 8 - LIABILITY AND INDEMNIFICATION

8.1 LICENSEE shall at all times during the term of this Agreement and thereafter , indemnify, defend and hold INVENTOR(S) and CURF, UNIVERSITY, and their trustees , directors, officers , employees and affiliates harmless against all claims, proceedings, demands and liabilities of any kind whatsoever , including legal expenses and reasonable attorney's fees related to third party claims, arising out of injury , including death, to any person or persons or out of any damage to property, resulting from the production, manufacture , sale , use, lease, consumption, provision or advertisement of the LICENSED PRODUCTS or arising from any obligation of LICENSEE hereunder , excepting only claims that PATENT RIGHTS infringe third party intellectual property.

8.2 LICENSEE shall obtain and carry in full force and effect commercial, general liability insurance that shall protect LICENSEE, CURF, INVENTOR(S) and UNIVERSITY with respect to events covered in Section 8.1. Such insurance shall be written by a reputable insurance company authorized to do business in the state of South Carolina, shall list CURF, INVENTOR(S) and UNIVERSITY as additional named insureds thereunder, shall be endorsed to include product liability coverage and shall require thirty (30) days written notice to be given

to CURF prior to any cancellation or material change thereof. The limits of such insurance shall not be less than one million U.S. dollars ($1,000,000.00) per occurrence with an aggregate of two million U.S. dollars ($2,000,000.00) for personal injury or death and not be less than one million U.S. dollars ($1,000,000.00) per occurrence with an aggregate of two million U.S. dollars ($2,000,000.00) for property damage. LICENSEE shall provide CURF with Certificates of Insurance evidencing the same within thirty (30) days of the EFFECTIVE DATE of this Agreement.

8.3 Except as otherwise expressly set forth in this Agreement, INVENTOR(S) and CURF, UNIVERSITY, and their trustees, directors, officers, employees and affiliates make no representations and extend no warranties of any kind, either express or implied, including but not limited to warranties of merchantability, fitness for a particular purpose, validity of PATENT RIGHTS claims, issued or pending, and the absence of latent or other defects, whether or not discoverable. Nothing in this Agreement shall be construed as a representation made or warranty given by CURF that the practice by LICENSEE of the license granted hereunder shall not infringe the patent, copyright, trademark or other intellectual property rights of any third party. In no event shall INVENTOR(S) and CURF, UNIVERSITY, and their trustees, directors, officers, employees, and affiliates be liable for incidental or consequential damage of any kind, including economic damage or injury to property and lost profits, regardless of whether INVENTOR(S), CURF or UNIVERSITY shall be advised, shall have other reason to know or in fact shall know of the possibility.

8.4 In no event shall LICENSEE, its directors, officers, employees, or affiliates be liable for incidental or consequential damages arising out of any of the te1ms or conditions of this Agreement, or with respect to their performance or lack thereof.

8.5 CURF shall have no liability to LICENSEE for any use of TECHNOLOGY or PATENT RIGHTS by a third party (including but not limited to UNIVERSITY and its employees) that is not specifically authorized in writing by CURF, and such use shall not constitute a breach of this Agreement.

ARTICLE 9 - EXPORT CONTROLS

9.1 It is understood that CURF is subject to United States laws and regulations controlling the export of technical data , computer software, laboratory prototypes and other commodities (including the Arms Export Control Act, as amended and the Export Administration Act of 1979), and that its obligations hereunder are contingent on compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of GOVERNMENT and/or written assurances by LIC ENSEE that LICENSEE shall not export data or commodities to certain foreign countries without prior approval of such agency. CURF neither represents that a license shall not be required nor that, if required, it shall be issued.

ARTICLE 10 - CONFIDENTIALITY AND NON-USE OF NAMES

10.1 LICENSEE and its employees, agents and contractors shall maintain in confidence all CONFIDENTIAL INFORMATION furnished to LICENSEE or its employees, agents or contractors by any of the INVENTOR(S), CURF or UNIVERSITY or by persons, offices or facilities of CURF or UNIVERSITY in connection with this Agreement. Neither LICENSEE nor any of its respective employees, agents or contractors shall use CONFIDENTIAL

INFORMATION for any purpose except in connection with the exercise of the license granted hereunder. Only those employees, agents and contractors of LICENSEE who are subject t0 a preexisting, written obligation of confidentiality shall be assigned to perform duties that involve the use of or require access to such CONFIDENTIAL INFORMATION. LICENSEE shall inform (and shall require its SUBLICENSEES to inform) all of its employees, agents and contractors who are assigned to perform duties involving the use or exploitation of any CONFIDENTIAL INFORMATION of the confidentiality obligations created by this Agreement and shall assure their agreement to be bound by such confidentiality obligations prior to disclosing to such employees, agents and contractors any CONFIDENTIAL INFORMATION.

10.2 Notwithstanding any provision contained in this Agreement, LICENSEE shall not be required to maintain in confidence any of the following information:

(a) Information which, at the time of disclosure to LICENSEE, 1s m the public knowledge;

(b) Information which, after disclosure to LICENSEE, becomes part of the public knowledge by publication or otherwise , except by breach of this Agreement;

(c) Information which was lawfully in LICENSEE's possession (as reflected in its written records) at the time of disclosure by the disclosing party, and which was not acquired, directly or indirectly , from INVENTOR(S), CURF or the UNIVERSITY;

(d) Information which the LICENSEE can demonstrate by written documents is the result of its own research and development independent of disclosures hereunder;

(e) Information which the LICENSEE receives from third parties, provided such information was not obtained by such third parties from INVENTOR(S), CURF or the UNIVERSITY on a confidential basis and that LICENSEE has no notice of that such information is confidential; and

(f) Information, which LICENSEE is required to disclose by law or pursuant to the order of a court or other tribunal of competent jurisdiction, provided LICENSEE gives CURF written notice of such order prior to the disclosure thereof and gives CURF an opportunity to seek a protective order from such court or tribunal.

10.3 LICENSEE shall not use the names, trademarks, or service marks of CURF or the UNIVERSITY, nor any adaptation thereof, nor the names of any of their employees or any INVENTOR(S), in any advertising, promotional or sales literature without prior written consent obtained from CURF except that LICENSEE may state that it is licensed by CURF under one or more of the patents and/or applications comprising the PATENT RIGHTS. Any use of the names of CURF, UNIVERSITY, their employees or any INVENTOR(S) shall be limited to statements of fact and shall not imply endorsement of LICENSEE's products or services.

10.4 CURF shall not use the names, trademarks, or service marks of LICENSEE, nor any adaptation thereof, nor the names of any of its employees, in any advertising, promotional or sales literature without prior written consent obtained from LICENSEE. Any use of the names of LICENSEE or its employees shall be limited to statements of fact.

10.5 CURF shall maintain confidentially of information contained in reports received by the LICENSEE, which is clearly marked as confidential, to the extent permitted by state and federal law.

ARTICLE 11 - ASSIGNMENT

11.1 Neither this Agreement nor any obligation or right hereunder is assignable by LICENSEE except with written approval by CURF; provided however that LICENSEE, upon written notice to CURF, may assign this Agreement to a successor in ownership of all or substantially all of its business assets, provided such successor expressly agrees to assume LICENSEE'S obligations under this Agreement.

ARTICLE 12 - DISPUTE RESOLUTION

12.1 All disputes arising out of or related to this Agreement or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed , interpreted and applied in accordance with the laws of the United States of America and of the State of South Carolina. The South Carolina State Courts of Pickens County, South Carolina (or, if there is exclusive federal jurisdiction, the United States District Court for South Carolina) shall have exclusive jurisdiction and venue over any dispute arising out of this Agreement, and LICENSEE consents to the jurisdiction of such courts, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted.

12.2 Notwithstanding the foregoing, nothing in this Article 12 shall be construed to waive rights or timely performance of any obligations existing under this Agreement.

ARTICLE 13 -TERMINATION

13.1 Upon any termination of this Agreement, excluding termination due to expiration of patents pursuant to Section 2.5, all rights, privileges and license granted hereunder shall terminate and all rights to TECHNOLOGY and PATENT RIGHTS shall revert to CURF and/or UNIVERSITY.

13.2 If LICENSEE shall cease to carry on its business, this Agreement shall terminate upon notice by CURF.

13.3 Should LICENSEE fail to make any payment whatsoever due and payable to CURF hereunder, CURF shall have the right to terminate this Agreement by providing notice of intent to terminate to LICENSEE. The Agreement shall terminate forty-five (45) days from notice unless LICENSEE shall make all such payments to CURF within the forty• five (45) day period or CURF shall provide LICENSEE with a written extension thereto. Upon the expiration of the forty-five (45) day period or granted extension, if LICENSEE shall not have made all such payments to CURF, this Agreement shall automatically terminate.

13.4 If LICENSEE shall at any time become insolvent or make a general assignment for the benefit of creditors or if a petition of bankruptcy or any reorganization shall be commenced by, against or in respect of LICENSEE and shall remain un-dismissed for more than ninety (90) days, this Agreement shall automatically terminate.

13.5 Upon any material breach or default of this Agreement by LICENSEE, other than those occurrences set out in Sections 13.2, 13.3, and 13.4 herein above, which shall always take precedence in that

order over any material breach or default referred to in this Section 13.5, CURF shall have the right to terminate this Agreement effective on forty-five (45) days from receipt of notice to LICENSEE or CURF shall provide LICENSEE with a written extension thereto. Such termination shall be automatically effective unless LICENSEE shall have cured any such material breach or default prior to the expiration of the forty-five (45) day period.

13.6 LICENSEE shall have the right to terminate this Agreement at any time on six (6) months' notice to CURF and upon payment of a termination fee equal to the amount of the next Annual Minimum Royalty and all amounts due CURF through the effective date of termination.

13.7 Upon termination of this Agreement for any reason, nothing herein shall be construed to release either PARTY from any obligation that matured prior to the effective date of such termination; and Articles 1, 8, 9, 10, 13.7, 13.8, and 15, excluding 15.1, shall survive any such termination. Notwithstanding the foregoing, the license rights granted to CURF and UNIVERSITY pursuant to section 15.1, shall survive termination if such improvements or modifications are being used as part of an active research project at time of termination. Such license rights will continue through the end of the project. LICENSEE and any SUBLICENSEES thereof, may, however, after the effective date of such termination, complete and sell all LICENSED PRODUCTS in the process of manufacture at the time of such termination, provided that LICENSEE shall make the payments to CURF as required by Article 4 of this Agreement and shall submit the reports required by Article 5 hereof.

13.8 Upon termination of this Agreement for any reason, any SUBLICENSEE not then in default shall have the right to seek a license from CURF. CURF agrees to negotiate such licenses in good faith under reasonable, and substantially similar terms and conditions.

ARTICLE 15 - MISCELLANEOUS PROVISIONS

15.1 During the term of this Agreement, LICENSEE shall fully disclose to CURF all improvements and modifications to TECHNOLOGY and LICENSED PRODUCTS which are developed wholly or partly by LICENSEE or its SUBLICENSEES and their employees, contractors, agents and subsidiaries. The UNIVERSITY and CURF shall have a non-exclusive non -transferable royal ty-free license to utilize such improvements and modifications for NON-COMMERCIAL RESEARCH PURPOSES. LICENSEE hereby acknowledges that the provisions of this paragraph shall not in any way inhibit or detract from the rights of ownership CURF or UNIVERSITY may enjoy in any improvements or modifications to the TECHNOLOGY and LICENSED PRODUCTS developed in whole or in part by INVENTOR(S) or other employees of CURF or the UNIVERSITY.

15.2 Each PARTY expressly acknowledges that the relationship between the PARTIES to this Agreement is that of independent contractors, and not agents, employees or representatives of the other. This Agreement shall not be deemed to create a partnership, joint venture or principal-and-agent relationship between CURF and LICENSEE or UNIVERSITY and LICENSEE. Except as expressly permitted in this Agreement, neither PARTY shall have the authority to bind the other to any agreement or obligation whatsoever, nor shall either PARTY represent that it has any such right or authority to any third party.

15.3 This Agreement constitutes the entire and only agreement between the PARTIES as to the subject matter hereof and all other prior negotiations, representations, agreements and warranties are superseded in totality by this Agreement. No agreements altering or

supplementing the terms hereof shall be made except by a written document signed by both PARTIES. To become effective, this Agreement must be signed by LICENSEE within twenty (20) calendar days of signature by CURF.

15.4 If any part of this Agreement is for any reason found to be invalid or unenforceable, all other parts nevertheless remain enforceable.

15.5 LICENSEE and its SUBLICENSEES shall mark all products covered by PATENT RIGHTS with patent numbers in accordance with the statutory requirements in the country(ies) of manufacture, use and sale, and pending the issue of any patents, LICENSEE and its SUBLICENSEES shall mark the products, "Patent Pending," or the foreign equivalent as appropriate.

15.6 The failure of either PARTY to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a subsequent and/or similar failure to perform any such term or condition by the other PARTY.

15.7 Upon the request of the other PARTY, each PARTY shall execute and deliver such additional documents and perform such other acts as the other PARTY may reasonably request and as may be necessary to affect the purposes and intent of this Agreement.

15.8 All titles and article headings contained in this Agreement are inserted only as a matter of convenience and reference and do not define, limit, extend or describe the scope of this Agreement or the intent of any of its provisions.

Exhibit 21.1

Subsidiaries of Organovo Holdings, Inc.

I. Organovo, Inc., a Delaware corporation

II. Opal Merger Sub, Inc., a Delaware corporation

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in Registration Statement Nos. 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 Statement No. 333-252224 on Form S-3, of our report dated June 10, 2022, relating to the consolidated financial statements of Organovo Holdings, Inc. as of March 31, 2022 and 2021, and for each of the two years in the period ended March 31, 2022, included in this Annual Report on Form 10-K for the year ended March 31, 2022.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
June 10, 2022

Exhibit 31.1

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: June 10, 2022

/s/ Keith Murphy
Keith Murphy
Executive Chairman

Exhibit 31.2

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: June 10, 2022

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Organovo Holdings, Inc. (the "Company") for the year ended March 31, 2022, 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: June 10, 2022

/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.