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, 2019

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.)*
6275 Nancy Ridge Drive, Suite 110 **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 Stock Market (Nasdaq Global 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 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 Global Market on September 30, 2018, the last trading day of the registrant's second fiscal quarter, was $131,933,864. 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, 2019 was 130,227,053.

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 2019 annual meeting of the registrant's stockholders, expected to be filed within 120 days of the end of the registrant's fiscal year.

Organovo Holdings, Inc.

Annual Report on Form 10-K

For the Year Ended March 31, 2019

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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 our technology, our product and service development opportunities and timelines, our business strategies, customer acceptance and the market potential of our technology, products and services, our future capital requirements, our future financial performance and other matters. This includes, in particular, Item 1. "Business" and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report, as well as other portions of this Annual Report. The words "believe," "expect," "anticipate," "project," "could," "would," and similar expressions, among others, generally identify "forward-looking statements," which speak only as of the date the statements were made. The matters discussed in these forward-looking statements are subject to risks, uncertainties and other factors that could cause our actual results to differ materially from those projected, anticipated or implied in the forward-looking statements. As a result, you should not place undue reliance on any forward-looking statements. The most significant of these risks, uncertainties and other factors are described in Item 1A. "Risk Factors" of this Annual Report. Except to the limited extent required by applicable law, we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business.

Overview

Organovo Holdings, Inc. (“Organovo Holdings,” “we,” “us,” “our,” “the Company” and “our Company”) is a biotechnology company pioneering the development of bioprinted human tissues that emulate human biology and disease. Initially, we are developing our *in vivo* liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. Our objective is to serve as a ‘bridge-to-transplant’ for these patients, with an ultimate goal of delaying or reducing the overall need for transplant. The Company’s program focused on an orphan disease known as Alpha-1-antitrypsin deficiency (“A1AT”), received the U.S. Food and Drug Administration’s (“FDA”) orphan drug designation in December 2017. We are also utilizing our foundational ability to isolate highly specialized human cells to build robust, functional human tissues by creating a range of novel preclinical *in vitro* disease modeling platforms, including a broad set of non-alcoholic fatty liver disease (“NAFLD”) and non-alcoholic steatohepatitis (“NASH”) conditions. Our clients can access these diseased tissue platforms through collaborative, revenue-generating agreements.

In May 2019, we announced our plans to conduct additional preclinical studies and to optimize our manufacturing processes and complete additional preclinical studies that generate consistent scientific data regarding the prolonged functionality and therapeutic benefits of our *in vivo* liver tissues. We also announced that these efforts would extend our preclinical development efforts into calendar 2020. Our decision to complete additional studies and to optimize our manufacturing processes resulted from data generated from a larger group of animal studies that differed from our earlier pilot studies. These studies continued to show statistically meaningful reductions in toxic globules in the A1AT animal models over a three-month period. However, in these and other animal models, we observed shorter tissue duration than we observed in our pilot studies, as measured by human protein output and the quantity of hepatocytes.

As we focus our efforts on our *in vivo* tissue development efforts, we intend to be increasingly selective about pursuing and entering into collaborative and revenue-generating agreements for our *in vitro* disease models. Our *in vitro* and *in vivo* tissues are both built upon the same proprietary 3D bioprinting technology and our highly specialized cells. As a result, we intend to enter into collaborative, revenue-generating agreements where the scientific outcomes are complementary to our key regulatory goals for our *in vivo* tissues.

Over the long-term, we intend to focus on achieving the following key milestones:

- One or more successful IND submissions, leading to the initiation of Phase I clinical studies involving implantation and functional evaluation of our liver therapeutic tissue patch in target disease patients;
- Achieving key FDA designations associated with tissue-based approaches that address serious unmet medical needs in rare disease indications, which can include Regenerative Medicine Advanced Therapy (“RMAT”), Orphan Drug, Fast Track and Breakthrough designations;
- Deploying of proof-of-concept disease modeling capabilities in NASH to enable high content drug profiling collaborations with current and prospective clients;
- Developing our Samsara Sciences, Inc. (“Samsara”) division’s cell-based product revenue opportunities, as well as continuing to generate revenue from grant and licensing agreements;
- Achieving operational breakeven profitability for our commercial business by securing selected revenue-generating fee-based service agreements and collaborations and creating business opportunities which may lead to valuable spin-out and/or partnering opportunities; and
- Continuing academic, partner and internal research programs to generate additional, high value tissue applications and therapeutics pipeline opportunities in other organ and disease areas.

Our Platform Technology

Our 3D human tissue platform is enabled by our proprietary NovoGen Bioprinters® and related technologies for preparing bio-inks and bioprinting multicellular tissues with complex architecture. We believe the tissue-like configuration of our 3D human tissues make them ideally suited as implantable tissue patches for augmentation or replacement of organ function and for the assessment of drug safety and efficacy. Our foundational proprietary technology, grounded in over a decade of peer-reviewed scientific publications, derives from research led by Dr. Gabor Forgacs, the former George H. Vineyard Professor of Biological Physics at the University of Missouri-Columbia. We have a broad portfolio of intellectual property rights covering the principles, enabling instrumentation,

applications, and methods of cell-based printing, including exclusive licenses to certain patented and patent pending technologies from the University of Missouri-Columbia and Clemson University. We have continued to develop our technology and grow our intellectual property portfolio. In addition to our in-licensed patents, we own more than 100 additional patents and pending applications worldwide covering specific tissue designs, uses, and methods of manufacture. We believe that our broad and exclusive commercial rights to patented and patent-pending 3D tissues and related bioprinting technology provide us with a strong and defensible market position for the successful commercialization of 3D bioprinted human tissues to address a broad array of unmet preclinical and clinical needs.

The key distinguishing features of our bioprinted 3D human tissues are their dense cellularity and the controlled patterning of specific cell types relative to each other, both of which are enabled by our proprietary bio-inks and bioprinters. Unlike the majority of engineered tissue strategies, where biomaterials such as fixed scaffolds are the major component of the tissue and cells are present in relatively low proportions, our platform builds tissues that are comprised primarily of human cells. We primarily focus on the use of human cells as inputs, yielding functional models of human tissue that can be used *in vitro* for drug discovery and development. In addition, complex bioprinted human tissues may also address unmet clinical needs by serving as tissue grafts for the augmentation or replacement of functional mass in tissues and organs that are damaged by trauma or disease

Our Market Opportunity

We believe that our proprietary 3D bioprinting platform can enable us to deliver functional human tissues to multiple clinical markets for direct therapeutic purposes and to the drug discovery and development market for the creation and optimization of novel therapeutic treatments:

1) **Implantable 3D Tissues for Therapeutic Use:** We have identified several target diseases where there are significant unmet needs that can potentially be addressed by our tissue platform. The FDA is currently providing significant development and financial incentives to pursue diseases involving serious, unmet orphan conditions and/or involving breakthrough regenerative medicine treatment strategies, which are strongly aligned with our technology platform. Our ultimate goal is to construct surgically implantable tissues that restore significant function to a damaged tissue or organ after delivery. It is our belief that, in most cases, whole organ replacement may not be required to achieve meaningful clinical outcomes and address unmet medical needs. We believe 3D tissues with well-defined architecture and composition can create a new product category within cell and tissue therapies. Our future tissue products may include bioprinted tissues (patches, tubes, etc.) or hybrids comprised of bioprinted tissues and device component(s). We are currently self-funding the development of our *in vivo* liver tissue. In the future, we may develop specific tissue targets with partners through technology licenses and royalty-bearing deals.

   During the past several years, we have implanted our 3D bioprinted human liver tissue patches onto the livers of diseased mice, and through serum and histopathologic evaluation of the implanted therapeutic tissue, showed engraftment, retention and the potential for disease modification in two different disease models. Our results have demonstrated the important presence of key human liver proteins such as albumin and A1AT in the animal bloodstream. In addition, our pathologic evaluation of diseased animals receiving our implanted bioprinted liver tissues in an earlier A1AT study suggested an approximately 75 percent reduction in the pathologic hallmarks of the disease in the livers of treated animals versus non-treated animals in the region of implant. During more recent studies, while continuing to see this significant reduction in the pathologic hallmark of the disease, our tissues have also shown a shorter duration and functionality than what was reflected in our earlier pilot studies. This will require us to further optimize the manufacturing process and complete additional preclinical studies that generate consistent confirmatory data on the sustained functionality and therapeutic benefits of our liver tissue patch necessary to move forward with development.

2) **3D Tissue Models for Drug Discovery and Development:** Our NovoGen® bioprinting platform can produce highly specialized human tissues that model human biology and disease. We have used our bioprinting platform to create a wide array of proof-of-concept studies developing human tissue constructs, including blood vessels, liver tissues, skin tissues, kidney tissues, lung tissues, intestinal tissues and tissues with tumors. Our 3D bioprinted tissues possess unique features, including cell type-specific compartments, prevalent intercellular tight junctions and microvascular structures. These features facilitate the development of complex, multicellular disease models for use in the development of targeted therapeutics for bowel disease, lung disease, liver disease, kidney disease and oncology. We have demonstrated that our ExVive™ Human Liver Tissue is capable of modeling the pathogenesis of non-alcoholic steatohepatitis (“NASH”), whereby immune competent bioprinted tissues containing Kupffer cells were exposed to steatogenic cues via a nutrient overload approach of simple sugars and fatty acids, followed by inflammatory stimulation using prototypical inducers. Key features of NASH such as steatosis, increased inflammatory cytokine release, hepatic stellate cell activation, and subsequent fibrogenesis, which are often lacking in other commercially available liver disease models, are attainable in our ExVive™ Liver Tissue via a nutrient overload approach, analogous to diets high in fat and sugar and inflammatory stimuli. The longevity of our ExVive™ Liver Tissue, which is typically several weeks, allows for the testing of several

induction strategies such as various dosing and durations of insults (nutrients, inflammatory inducers, xenobiotics), and also has the potential to enable the study of multiple, modulatory approaches to profile prophylactic and treatment-oriented drug strategies. Together, these features suggest that our ExVive™ Human Liver Tissue holds promise for the study of complex, chronic conditions such as NASH, which may enable a better understanding of disease processes, lead to the discovery of novel therapeutics, facilitate target identification and validation, facilitate the identification of potential biomarkers, and allow for the safety assessment of drugs in a disease-relevant background.

3) **Procurement of Specialized Human Cells for Use in Customer's Research Programs:** In January 2016, we formed our wholly-owned subsidiary, Samsara Sciences, Inc. ("Samsara"). Samsara is an important source for the provision and delivery of a broad range of primary human liver cells to facilitate customer research studies. Samsara also supports our own R&D mission by providing high-quality cell-based products that form the building blocks of our therapeutic tissues and custom disease models. In November 2018, we partnered with the International Institute for the Advancement of Medicine ("IIAM") for receiving donated organs designated for research and clinical use.

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 currently collaborate with several academic institutions by providing them with access to our NovoGen Bioprinters® for research purposes, including: Yale School of Medicine, University of California, San Francisco ("UCSF"), Knight Cancer Institute at Oregon Health & Science University ("OHSU"), the National Eye Institute ("NEI"), the University of Virginia ("UVA"), and Murdoch Children's Research Institute ("MCRI"), the Royal Children's Hospital, Melbourne, Australia and Ton Rabelink at Universiteit Leiden, Netherlands. We believe that the use of our bioprinting platform by major research institutions will help to advance the capabilities of the platform and generate new applications for bioprinted tissues including proof-of-concept exploration of kidney, eye, and vasculature tissue constructs, ultimately creating future opportunities for our commercial products and intellectual property licensing. In some instances, an academic institution or other third party has provided funding to support the academic collaborator's access to our technology platform. This funding is typically reflected as collaboration revenues in our financial statements. Our research collaborations typically involve both us and the academic partner contributing resources directly to projects, but also may involve sponsored research agreements where we fund specific research programs. We may also contribute a bioprinter and technical support or a bioprinter and research headcount, depending on the project scope.

Samsara Sciences, Inc. ("Samsara")

In January 2016, we announced that Samsara commenced commercial operations. We formed Samsara to serve as a key source of certain of the primary human cells we utilize in our products and services and in the development of our therapeutic products. We believe Samsara can help us optimize our supply chain and reduce operating expenses related to cell sourcing and procurement and ensure that the cellular raw materials we use are of the highest quality and are derived from tissues that are ethically sourced in full compliance with state and federal guidelines. Samsara provides us with qualified liver cells for use in our liver tissue manufacturing, and certain other human cells for use in our preclinical research and development programs. In addition to serving as one of our key suppliers, Samsara offers human cells for use by life science customers, both directly and through distribution partners.

Competition

We are subject to competition from pharmaceutical and biotechnology companies; academic and research institutions; and government or other publicly-funded agencies that are pursuing the development of tissue models and therapeutic products targeted to our potential customers and market opportunities. We believe our future success will depend, in large part, on our ability to maintain a first mover advantage and competitive lead in our industry.

Set forth below is a discussion of the competitive factors for each of the markets in which we intend to utilize our technology:

1) **Implantable 3D Tissues for Clinical Use:** This aspect of our business involves application of our 3D bioprinting technology to generate human tissues suitable for implantation *in vivo* to augment or replace damaged or degenerating tissues. Our platform has the ability to generate and optimize unique or hybrid tissue prototypes. We may undertake these efforts alone, or as partnered projects with leading therapeutic companies seeking to develop a tissue product for a specific application. Primarily, our clinical competition may come from other biotech companies targeting small and large molecule strategies, gene therapies, gene editing approaches and other cellular therapy approaches for treating one or more of the same diseases we elect to target. For instance, we may face future competition from companies such as Arrowhead Therapeutics, Promethera, Mereo Biopharma, AGTC, Grifols SA, and Kamada. These companies uniquely represent potential competition for us while also being partner candidates.

2) **Models for Drug Discovery and Development:** This aspect of our business is driven by leveraging our technology as a high-end partnered service that designs and delivers highly complex, custom tissue models of normal or diseased tissue for use in drug discovery and development. Each model is designed to enable a customer to discover or optimally formulate a pharmacologic product that delivers a specific therapeutic effect or avoids a particular side effect. Competition in this area arises mainly from two sources, traditional cell-based *in vitro* culture approaches and traditional *in vivo* animal models and testing. We may also face future competition from companies like Cyfuse Biomedical (including service companies using their instrument platform), Emulate, Hesperos, HemoShear, Mimetas, Ascendance/Hepatopac, InSphero, and CN Bio Innovations. We believe that an important factor distinguishing our approach from that of our competitors is our ability to build models that are composed primarily of human cells and have a 3D tissue-like configuration (i.e., able to generate results that are not subject to inherent limitations of 2D monolayer culture). We acknowledge, however, that there are some areas of research for which the existing methods (2D cell culture and/or animal studies) are adequate and 3D *in vitro* human tissues are not sufficiently advantageous.

Research and Development

We continuously engage in research and development to enhance our platform technology to pursue our therapeutic initiatives. Our research and development efforts include internal initiatives as well as collaborative development opportunities with third parties. As noted above, we currently intend to focus our efforts on examining and optimizing our manufacturing processes, with the goal of improving the durability and functionality of our in vivo liver tissues. In the future, we plan to focus our research and development activities in areas where we have technological expertise and where we believe a significant market opportunity exists for our technology and the pipeline products we develop.

Intellectual Property

Our success depends in large part on our ability to establish and protect our proprietary bioprinting technologies and our engineered tissue products and services. 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 the University of Missouri-Columbia (“MU”) and the Medical University of South Carolina. We have subsequently expanded our intellectual property portfolio by filing patent and trademark applications worldwide and negotiating additional licenses and purchases.

We solely own or hold exclusive licenses to 21 issued U.S. patents and more than 40 issued international patent applications. We solely or jointly own or hold exclusive licenses to 19 pending U.S. patent applications and more than 80 pending international applications. These patent families relate to our bioprinting technology and our engineered tissue products and services, including its various uses in areas of tissue creation, *in vitro* testing, utilization in drug discovery, and *in vivo* therapeutics.

In-Licensed IP

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 6 issued U.S. patents, 2 pending U.S. applications, 16 issued international patents and 1 pending international application. Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of Biophysics at MU, was one of the co-inventors of all of these works (collectively, the "**Forgacs Intellectual Property**"). The Forgacs Intellectual Property provides us with intellectual property rights relating to cellular aggregates, the use of cellular aggregates to create engineered tissues, and the use of cellular aggregates to create engineered tissue with no scaffold present. The intellectual property rights derived from the Forgacs Intellectual Property also enables us to utilize our NovoGen MMX Bioprinter® to create engineered tissues.

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

In 2015, we obtained world-wide exclusive licenses to intellectual property owned by The University of Queensland (collectively, "**UniQuest Intellectual Property**") relating to technologies for producing kidney cells and kidney organoids from induced pluripotent stem cells (iPSCs). At the time, Professor Melissa Little and her team at The University of Queensland developed a method of growing kidney tissue from iPSCs for potential use in drug screening, disease modeling and cell therapy. Professor Little's research was eventually published in 2015 in the prestigious scientific journal *Nature*. Currently, the UniQuest Intellectual Property includes 2 pending U.S. patent applications, 2 issued international patents and 15 pending international patent applications.

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 7. Licensing Agreements and Research Contracts" in the Notes to Consolidated Financial Statements included in this Annual Report.

Company Owned IP

In addition to the IP we have in-licensed, we have continued to innovate and grow our IP portfolio.

With respect to our bioprinting platform, we have 7 issued U.S. patents and 11 issued foreign patents directed to our NovoGen MMX Bioprinter® and methods of bioprinting: U.S. Patent Nos. 8,931,880; 9,149,952; 9,227,339; 9,499,779; 9,315,043; 9,855,369; and 10,174,276; Australia Patent Nos. 2011318437, 2015202836, 2016253591, and 2013249569; China Patent Nos. ZL201180050831.4 and ZL201480054148.1; Hong Kong Patent No. HK1187024; Israel Patent No. 225392; Japan Patent No. 6333231; Russia Patent No. 2,560,393; and Singapore Patent No. 11201600770R. We have additional U.S. continuation applications pending in these families as well foreign counterpart applications in multiple countries. We intend to continue pursuing patent protection as we continue to innovate the design, features, and functionality of our bioprinter platform and bioprinting methods.

We are also pursuing U.S. and foreign patents covering our 3D bioprinted tissues and methods of fabricating such tissues. Our ExVive™ Human Liver Tissue is protected by U.S. Patent Nos. 9,222,932 and 9,442,105; Singapore Patent No. 11201507202Y; Israel Patent No. 241055; Australia Patent No. 2014236780; Canada Patent No. 2,903,844; and Russia Patent No. 2625016. U.S. Application No. 15/166,006 and China Application No. 201480028365.3 have been allowed and will also grant as patents. Our ExVive™ Human Kidney Tissue is protected by U.S. Patent Nos. 9,481,868 and 10,094,821. 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 tissue types, their methods of fabrication, and specific applications. We intend to continue filing additional patent applications as we continue to innovate in this area.

Additionally, in 2013, we purchased the exclusive rights to "Perfusion Bioreactors for Culturing Cells" (U.S. Patent No. 7,767,446, Japan Patent No. 4,914,835, and Australia Patent No. 2,005,287,162) from Becton Dickinson and Company. This patent represents the acquisition of bioreactor technology for the support of our 3D tissues for use in drug discovery and development.

We believe that protection of the proprietary nature of our bioprinting technologies and products and services is essential to our business. Accordingly, we have adopted and will continue a vigorous program to secure and maintain protection of our intellectual property. Under this program, we intend to continue to file patent applications with respect to novel technology, and improvements thereof, that are important to our business. This program may also feature out-bound patent licensing of some or all of our IP portfolio. We also will continue to rely upon trade secret and confidential know-how protection of our methods and technology, including our proprietary in-house manufacturing methods and *in vitro* testing methods. As with other areas of biotechnology, this provides a critical adjunct to the protection offered by patents. As always, we continue to pursue our internal technological innovation and external

licensing opportunities to develop and maintain our competitive position. There can be no assurance, however, that others will not independently develop substantially equivalent proprietary technology or that we can meaningfully protect our proprietary position.

Regulatory Considerations

Therapeutic tissues and other regenerative medicine products are subject to an extensive, lengthy and uncertain regulatory approval process by the FDA and comparable agencies in other countries. The regulation of new products is extensive, and the required process of laboratory testing and human studies is lengthy and expensive. For example, as our therapeutic tissue constructs move into clinical and commercial settings, full compliance with the FDA's cGTP (current Good Tissue Practices), cGMP (current Good Manufacturing Practices), and cGCP (current Good Clinical Practices) guidelines will be required. Suitable design and documentation for clinical use of the bioprinter will be a part of future phases of our NovoGen Bioprinter® design programs.

The process required by the FDA under the drug provisions of the United States Food, Drug, and Cosmetic Act before our initial therapeutic tissue products may be marketed in the U.S. generally involves the following:

- Preclinical laboratory and animal tests;
- Submission of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin;
- Adequate and well-controlled human clinical trials to establish the safety and efficacy of the tissue candidate for its intended use;
- Submission to the FDA of a Biologic License Application ("BLA"); and
- FDA review and approval of a BLA.

The resource investment of time, staff and expense to satisfy these regulations will fall on us for the proprietary products we are developing on our own. We may not be able to obtain FDA approvals for those products in a timely manner, or at all. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses. Even if we obtain FDA regulatory approvals, the FDA extensively regulates manufacturing, labeling, distributing, marketing, promotion and advertising after product approval. Moreover, several of our product development areas may involve relatively new technology and have not been the subject of extensive product testing in humans. The regulatory requirements governing these products and related clinical procedures remain uncertain and the products themselves may be subject to substantial review by the FDA and/or foreign governmental regulatory authorities that could prevent or delay approval of these products and procedures. Regulatory requirements ultimately imposed on our products could limit our ability to test, manufacture and, ultimately, commercialize our products and thereby could adversely affect our financial condition and results of operations.

Raw Materials

We use live human cells to produce our 3D tissues. We source cells only from suppliers who have provided assurances that their cells come from tissues that were (1) collected in compliance with applicable laws, and (2) provided based on informed consent by the donors. We formed our wholly-owned subsidiary, Samsara, in 2016 to serve as a key source of the primary human cells we use in our products and services and in the development of therapeutic products. Samsara is currently supplying us with qualified human liver and kidney cells for use in manufacturing our ExVive™ Human Liver Tissue and ExVive™ Human Kidney Tissue, as well as certain specialized cells for research and development activities. We believe that Samsara can help us optimize our supply chain and reduce operating expenses and ensure that the human cells we use for our services, products and research and development programs are of the highest quality and are derived from tissues that are ethically sourced in full compliance with state and federal guidelines. In addition to Samsara, we also purchase human cells from selected third-party suppliers based on quality assurance, cost effectiveness and regulatory requirements.

Employees

As of June 1, 2019, we had approximately 61 employees, all of which were full-time. We also engage consultants and temporary employees from time to time to provide services that relate to our bioprinting business and technology as well as for general administrative services.

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 Global

Market under the symbol “ONVO” since August 8, 2016. 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 wholly-owned subsidiary, Samsara Sciences, Inc., was incorporated in Delaware in December 2014. In September 2015, we established another wholly-owned subsidiary in the United Kingdom, Organovo UK Ltd, for the primary purpose of establishing a sales presence in Europe.

Our principal executive offices are located at 6275 Nancy Ridge Dr., San Diego, California 92121 and our phone number is (858) 224-1000. Our Internet website can be found at http://www.organovo.com. The information found on our Internet website is not part of this Annual Report.

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 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 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.

Risks Related to our Development of *In Vivo* Therapeutic Tissue Candidates

We may not be successful in improving or demonstrating the durability and functionality of our in vivo liver tissue candidate.

Our *in vivo* liver tissue is our lead therapeutic candidate. In May 2019, we announced our need to conduct additional preclinical studies and to optimize our manufacturing processes to generate decisive scientific data regarding the prolonged functionality and therapeutic benefits of our liver tissue candidate. The requirement to complete additional studies and to optimize our manufacturing processes resulted from data generated from a larger group of animal studies that differed from our earlier pilot studies. These studies continued to show statistically meaningful reductions in toxic globules in the A1AT animal models over a three-month period. However, in these and other animal models, we observed shorter tissue duration than we observed in our pilot studies, as measured by human protein output and the quantity of hepatocytes. In the near-term, we intend to focus our efforts on examining and optimizing our manufacturing processes, with the goal of improving the durability and functionality of our liver tissue candidate. We also plan to focus on conducting the confirmatory animal studies and scientific validations required to support moving forward with our clinical development efforts for our liver tissue candidate. There is no assurance that we will be successful in improving the durability or functionality of our liver tissue candidate or completing the necessary studies and scientific validations on a timely basis, or at all. If we fail to do so, we may not be able to generate the scientific and preclinical data necessary to support an investigational new drug (IND) submission with the FDA, and may be required to cease pursuing the development of our current liver tissue candidate. We may not have sufficient capital resources on-hand to engage in a lengthy redesign or redevelop our manufacturing processes or our liver tissue candidate or to complete the preclinical studies necessary to submit an IND for another tissue candidate. As a result, if we are not successful in improving and demonstrating the durability and functionality of our liver tissue candidate, our business, financial condition and liquidity may be harmed.

The development of new biopharmaceutical products involves a lengthy and complex process and we may be unable to obtain regulatory approval for any of the therapeutic products we are currently developing.

We are focusing the majority of our resources on the development of our liver tissue candidate. In addition to our liver tissue candidate, we have conducted initial research and development activities on several other tissue candidates. Each of our therapeutic tissue candidates are in the early stages of research and development and will require substantial financial resources, development, preclinical testing, clinical trials, manufacturing scale-up and regulatory approval prior to being ready for sale. This process can take

many years of effort without any assurance of ultimate success. Our product development efforts with respect to a tissue candidate could be delayed or could fail for many reasons, including:

- the failure of the tissue candidate in preclinical or clinical studies, including failing to demonstrate sufficient durability and functionality to support further development activities; the inability to satisfy the regulatory requirements to successfully submit an IND with the FDA;
- adverse patient reactions to the tissue candidate or indications of other safety concerns;
- insufficient clinical trial data to support the effectiveness or superiority of the tissue candidate;
- our inability to manufacture sufficient quantities of the tissue candidate for development, clinical, or commercialization activities in a timely and cost-efficient manner;
- our failure to obtain, or delays in obtaining, the required regulatory approvals for the tissue candidate, the facilities or the process used to manufacture the tissue candidate;
- changes in the regulatory environment, including pricing and reimbursement, that make development of a new product or of an existing product for a new indication no longer attractive;
- the failure to obtain or maintain satisfactory drug reimbursement rates by governmental or third-party payers; and
- the development of a competitive product or therapy.

We cannot provide any assurance that the preclinical or clinical studies we perform for our tissue candidates will support the submission of an IND, or that any of our tissue candidates will receive regulatory approval. Even if a tissue candidate did receive the required regulatory approval, there can no assurance that we could provide for the effective marketing and sale of such product, either by ourselves or in partnership with others. Accordingly, our prospects must be considered in light of the risks, expenses, and difficulties frequently encountered by companies in an early stage of drug development.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Before we can commence clinical trials for our therapeutic candidates, we must complete extensive preclinical studies that support an IND submission in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit an IND, or similar application for any of our preclinical tissue candidates on the timelines we expect, if at all, and we cannot be sure that submission of an IND or similar application will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Our 3D bioprinted tissue candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approval or commercialization of our tissue candidates.

Our future success is dependent on the successful development of 3D bioprinted tissue products in general and our liver candidate in particular. Because this program represents a new approach to treating liver disease, inborn errors of metabolism, and other diseases, developing and commercializing our liver tissue and other potential tissue candidates subject us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of 3D bioprinted human tissues;
- developing and deploying consistent and reliable processes for manufacturing 3D bioprinted tissues for implantation into patients;
- utilizing these tissue candidates in combination with other therapies, which may increase the risk of adverse side effects;
- developing processes for the safe administration of these tissues, including long-term follow-up for all patients who receive these tissue candidates;
- sourcing clinical and, if approved, commercial supplies for the materials used to manufacture and process these tissue candidates that are free from viruses and other pathogens that may increase the risk of adverse side effects;

- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment;
- qualifying, engaging, and training clinical trial investigators and institutions who will be able to implement the institutionally-approved protocols, recruit and treat patients, and generate data in accordance with targeted goals and timelines;
- establishing sales and marketing capabilities after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for types of diseases beyond those initially addressed by our current tissue candidates.

The regulatory approval process for novel tissue candidates such as ours can be more expensive and take longer than for other, better known or extensively studied product candidates. As we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is a heightened risk that the FDA, EMA, or comparable foreign regulatory bodies may not consider our proposed clinical trial endpoints to provide clinically meaningful results.

Further, we cannot be sure that the manufacturing processes used in connection with our 3D bioprinted tissue candidates will yield a sufficient supply of satisfactory products that are safe, effective, scalable, or profitable.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment options.

Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

We have not yet tested any bioprinted therapeutic tissue candidates in clinical trials. Success in early preclinical studies may not be indicative of results obtained in later preclinical studies. Similarly, results from early clinical trials may not be indicative of results obtained in later clinical trials.

Our tissue candidates involve novel technologies and have never been evaluated in clinical trials. It is unknown how translatable the preclinical animal models used in our preclinical studies are to humans. We will be required to demonstrate through adequate and well-controlled clinical trials that our tissue candidates are safe and effective, with a favorable risk-benefit profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Initial positive results we have observed for our tissue candidates in preclinical animal models may not be predictive of results from our later preclinical trial results, nor of results from future clinical trials in humans. For example, in May 2019, we announced that data generated from a larger group of animal studies differed from our earlier pilot studies and put into question the durability and functionality of our liver tissue candidate. Our products may also fail to show the desired safety and efficacy in later stages of development even if they successfully advance through initial clinical trials.

We rely on third parties to conduct certain aspects of our preclinical studies and to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with legal and regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential tissue candidates.

We depend upon third parties to conduct certain aspects of our preclinical studies and will depend on third parties to conduct our clinical trials, under agreements with universities, medical institutions, CROs, strategic partners and others. This requires us to negotiate budgets and contracts with such third parties, and if we are unsuccessful or if the negotiations take longer than anticipated, this could result in delays to our development timelines and increased costs.

We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we will be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for tissue candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data

generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with biologic product produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue conducting clinical trials for our tissue candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for tissue candidates that treat the same indications as our tissue candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' tissue candidates. Patient enrollment is affected by other factors including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the eligibility criteria for, and design of, the clinical trial in question, including factors such as frequency of required assessments, length of the study, and ongoing monitoring requirements;
- the perceived risks and benefits of the tissue candidate under study, including the potential advantages or disadvantages of the tissue candidate being studied in relation to other available therapies;
- competition in recruiting and enrolling patients in clinical trials;
- the patient referral practices of physicians;
- inability to obtain or maintain patient informed consents;
- risk that enrolled patients will drop out before completion;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Enrollment delays in our clinical trials may result in increased development costs for our tissue candidates, or the inability to complete development of our tissue candidates, which would cause the value of our company to decline, limit our ability to obtain additional financing, and materially impair our ability to generate revenues.

Our experience manufacturing NovoTissues is limited. Manufacturing issues, including technical or quality issues or issues, may arise that could cause delays in our development programs or increase costs. Furthermore, we may experience delays in regulatory approval of our tissue candidates if we do not satisfy applicable manufacturing regulatory requirements.

Before we may initiate a clinical trial or commercialize any of our tissue candidates, we must demonstrate to the FDA that the chemistry, manufacturing and controls for our tissue products meet applicable requirements. Because no bioprinted tissue product has been approved in the United States, there is no manufacturing facility that has demonstrated the ability to comply with FDA requirements, and therefore the timeframe and requirements for demonstrating compliance to the FDA's satisfaction is uncertain.

Bioprinted tissue manufacturing is a nascent industry. To our knowledge, there are no contract manufacturing organizations (CMO) with experience in manufacturing bioprinted tissue products under GMP conditions. We conduct all of our manufacturing internally.

We have been conducting all of our research to date in research facilities and are in the process of implementing applicable FDA manufacturing requirements. However, we have limited experience as a company in developing a manufacturing facility that meets all applicable GMP requirements, and we may never be successful in developing our own manufacturing facility.

Manufacturing our therapeutic tissue candidates may be complicated or present novel technical challenges. We may encounter problems achieving adequate quantities and quality of clinical-grade materials to conduct our clinical trials, or to meet FDA, EMA or other applicable standards or specifications with consistent and acceptable production yields and costs.

To date, we have not yet scaled up the manufacturing process for NovoTissues Liver beyond the scale used for research and nonclinical studies. The time and efforts required for us to develop and validate our manufacturing process to support clinical use may delay or impair our ability to develop this program in accordance with our expected timelines.

In order to manufacture and supply any of our tissue candidates on a commercial scale in the future, we will need to bolster our quality control and quality assurance capabilities, including by augmenting our manufacturing processes and adding personnel. We also may encounter problems hiring and retaining the experienced specialist scientific and manufacturing personnel needed to operate our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements. As we engage in scale-up manufacturing of any approved product, we may encounter unexpected issues relating to the manufacturing processes, donor variability, or the quality, purity or stability of the product, and we may be required to refine or alter our manufacturing processes to address these issues. Resolving these issues could result in significant delays and may result in significantly increased costs. If we underestimate the demand for an approved product, given the long lead times required to manufacture or obtain regulatory approvals for our products, we could potentially face commercial drug product supply shortages. If we experience significant delays or other obstacles in producing any approved product at commercial scale, our ability to market and sell any approved products may be adversely affected and our business could suffer.

We may in the future wish to engage contract manufacturers to conduct some or all of our clinical and/or commercial manufacturing. We believe that the high demand for and scarcity of potential contract manufacturers may cause long lead times for establishing contract manufacturing capabilities for our bioprinted tissue products.

It is often the case that early stage research is conducted with materials that are not manufactured using GMP starting materials, techniques or processes and which are not subject to the same level of analysis that would be required for clinical grade material. We may encounter difficulties in translating the manufacturing processes used to produce research grade materials to GMP compliant processes, and any changes in the manufacturing process may affect the safety and efficacy profile of our tissue candidates. In order to progress the development of our NovoTissues Liver candidate or any other engineered tissue candidate, we will need to devote significant time and financial resources to establishing manufacturing processes that are sufficient for IND-enabling preclinical toxicology studies as well as clinical supplies. In addition, because early stage, pilot manufacturing is often done on a small scale, we may face challenges scaling up any early stage manufacturing to the scale necessary to support supply for clinical trials. If we are not able to establish manufacturing or related processes in a manner required for further development of our tissue candidates, our development plans may be delayed or stalled, and our business may be materially harmed.

Any problems in our manufacturing process could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

Our tissue candidates are novel, complex, and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.

The manufacturing processes used to produce our tissue candidates are complex, novel, and have not been validated for commercial use. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error, or disruptions in the operations of our suppliers.

Our tissue candidates require processing and manufacturing steps that are more complex than those required for manufacturing most small molecule drugs. Unlike small molecules, the physical and chemical properties of our tissue candidates are challenging to fully characterize, and the products may be manufactured “just in time” to be implanted, which limits the timeframe for conducting release testing on the finished product. As a result, assays of the finished product may not be sufficient to ensure that the product is consistent from lot-to-lot or will perform in the intended manner. We are in the process of developing our in-process controls to assure that the manufacturing process works reproducibly. If we are unable to develop and validate these manufacturing controls, our development

plans may be delayed or stalled, and our business may be materially harmed. If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing and accomplishment of various scientific, clinical, regulatory, manufacturing, and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submissions of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly as compared with our estimates, in some cases for reasons beyond our control. If we do not meet milestones that we have publicly announced, the commercialization of our tissue candidates may be delayed, and as a result, our stock price may be negatively impacted.

Development of combination tissue candidates may present more or different challenges than development of a single-agent product candidate.

FDA may designate our liver tissue candidate a combination product, and development of combination product candidates may present more or different challenges than development of a single-agent product candidate. A combination therapy is a single therapeutic product that consists of two or more active ingredients, with each component making a contribution to the claimed effect of the drug. The development of combination drugs may be more complex than the development of single agent products. This requirement may make the design and conduct of clinical trials more complex, requiring more clinical trial subjects. We also may not be able to meet the FDA's approval standards required for combination products. Finally, the FDA's requirements concerning combination products may change in the future. Moreover, the applicable requirements for approval may differ from country to country.

We may never obtain FDA approval for any of our tissue candidates in the United States, and even if we do, we may never obtain approval for or commercialize any of our tissue candidates in any other jurisdictions, which would limit our ability to realize their full market potential.

In order to eventually market any of our tissue candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country many not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in additional costs and require additional preclinical studies or clinical trials. We do not have any therapeutic products approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to obtain regulatory approval in international markets, our target market would be limited and our ability to achieve the full market potential of our products will be unrealized.

We obtain our clinical grade livers from a single source, and we may be unable to obtain sufficient quantities of clinical grade livers to support our clinical trials and/or commercialization.

Our liver tissue candidate is manufactured using human primary liver cells from non-transplantable livers we receive from IIAM. We currently rely upon this single source to obtain the clinical grade non-transplantable livers that serve as the starting materials for manufacturing the liver cells we intend to use in our NovoTissues Liver product. The availability and quality of clinical grade livers may be sporadic and unpredictable. We have begun receiving clinical grade livers for use in our preclinical development program and intend to begin developing our inventory of cells for use in our preclinical and clinical trials. However, if we are unable to obtain sufficient quantities and qualities of clinical grade livers to supply our clinical program or meet commercial demand, our development plans may be delayed or stalled, and our business may be materially harmed.

Our liver tissue candidate includes primary cells from two donors. If the FDA does not authorize us to include cells from more than one donor, this may delay our development timeline.

Our NovoTissues Liver product is manufactured using cells from a liver donor and cells from an umbilical cord donor. Under 21 CFR §1271, cells from more than one donor cannot be combined in the manufacturing process absent a waiver from the FDA. We applied to FDA for a waiver authorizing us to include cells from two donors in manufacturing our NovoTissues Liver for clinical trials. If

FDA does not grant the waiver, we will be required to redesign our NovoTissues Liver product. This could result in additional development costs and a delay in our development timeline, in which case our business may be materially harmed.

Any contamination in our manufacturing facility, shortage of raw materials or reagents, or failure of any of our key suppliers to deliver necessary materials could result in delays in our clinical development.

Given the nature of manufacturing engineered tissue products, there is a risk of contamination. Any contamination could materially adversely affect our ability to produce our tissue candidates on schedule and could therefore harm our results of operations and cause reputational damage.

We may expend our limited resources to pursue a particular tissue candidate or indication and fail to capitalize on tissue candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we have focused our development program on our liver tissue candidate. As a result, we may forego, limit, or delay pursuit of opportunities relating to other tissue candidates or indications that may later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and tissue candidates for specific indications may not yield commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular tissue candidate, we may relinquish valuable rights to that product.

We may not enjoy the market exclusivity benefits of our orphan drug designation.

Although we may obtain orphan designations in the treatment of certain diseases our therapeutic products are intended to treat, the designation may not be applicable to any particular product we might get approved and that product may not be the first product to receive approval for that indication. Under the Orphan Drug Act, the first product with an orphan drug designation receives market exclusivity, which prohibits the FDA from approving the “same” drug for the same indication. The FDA has stated that drugs can be the “same” even when they are not identical but has not provided guidance with respect to how it will determine “sameness” in the context of 3D bioprinted tissues. It is possible that another bioprinted therapeutic tissue product could be approved for the treatment of a disease one of our orphan products is intended to treat before our product is approved, which means that we may not obtain orphan drug exclusivity and could also potentially be blocked from approval until the first product’s orphan drug exclusivity for a product expires or we demonstrate, if we can, that our product is superior. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved and granted orphan drug exclusivity, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care.

It is possible that a competitor may achieve regulatory approval before we do or develop therapies that are more advanced or effective than ours, which may harm our business and financial condition, and our ability to successfully market or commercialize our tissue candidates.

The biotechnology and pharmaceutical industries, including the fields of gene therapies, cellular therapies, and engineered tissue products, are characterized by rapid technological progress, competition, and a strong emphasis on intellectual property. We are aware of several companies focused on developing gene therapies and cellular therapies for use in treating end stage liver disease and/or inborn errors of metabolism. We may also face competition from large or specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies, and public and private research institutions.

Some of our potential competitors, alone or with their strategic partners, have greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in these industries may result in even greater concentration of resources among a smaller number of competitors. Competitors may obtain FDA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market, if ever. New or advanced technologies may render our current or future tissue candidates uneconomical or obsolete. Our competitors could develop products that are safer, more effective, have fewer or less side effects, or are more convenient or less expensive than any tissue candidates that we may develop.

Related to Our Financial Position

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 $27.3 million and $35.3 million for the years ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had incurred cumulative operating losses of $208.4 million and cumulative net losses totaling $260.8 million. We expect to incur substantial additional operating losses over the next several years as we continue our research and development efforts. To achieve profitability, we must either generate sufficient revenue through our *in vitro* tissues business to offset the costs of operating our business, or we must successfully develop and obtain regulatory approval for one or more of our therapeutic candidates and effectively market and sell any products we develop. Even if we are successful in commercializing a therapeutic product that receives regulatory approval, we may not be able to realize revenues at a level that would allow us to achieve or sustain profitability. We may therefore never generate significant revenue, and even if we do generate significant revenue, we may never achieve profitability.

We will require additional capital resources to develop and seek regulatory approval for our tissue candidates and to implement our business plan.

We are currently focusing our research and development efforts on examining and optimizing our manufacturing processes for our liver tissue candidate, with the goal of improving its durability and functionality. There is no assurance that we will be successful in improving the durability or functionality of our liver tissue candidate or completing the necessary studies and scientific validations on a timely basis, or at all. We may not have sufficient capital resources on-hand to engage in a lengthy redesign or redevelop our manufacturing processes or our liver tissue candidate or to complete the preclinical studies necessary to submit an IND for another tissue candidate. Further, even if we are successful in enhancing the durability and functionality of our liver tissue candidate, we will require additional capital resources in order to complete our planned and future preclinical and clinical development activities and to seek regulatory approval for our liver tissue candidate and any other tissue candidates we elect to pursue. We intend to cover our future operating expenses through cash on hand, the issuance of additional equity or debt securities, and from revenue derived from research service agreements, product sales, grants, and collaborative research agreements. 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. Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs, relinquish rights to our technology, or pursue a strategic transaction on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

We may not be able to correctly estimate our future capital requirements or revenues, which could lead to cash shortfalls, and require us to secure additional financing sooner than planned.

We expect that our spending levels will increase in connection with the preclinical and clinical trials required to support the development of our lead tissue candidate and any other therapeutic tissues we seek to advance toward commercialization. Our future operating expenses, however, will vary depending on many factors, including:

- the costs associated with the scope, progress and results of discovery, preclinical development, process development, and clinical trials for our therapeutic tissue candidates;
- the costs associated with the development of our internal manufacturing facility and processes, including transitioning to GTP and subsequently GMP manufacturing;
- the extent to which we are able to secure collaborations or partnerships with third parties in order to further support the development of our therapeutic tissue candidates;
- the costs and fees associated with the discovery, acquisition or in-license of tissue candidates or technologies; and
- the amount of revenues received from commercial sales of our *in vitro* products and services.

In addition, we may not correctly predict the amount or timing of future revenues. As a result, the timing and amount of our capital requirements may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- our expectations regarding revenues from sales of our products and services, and from collaborations with third parties;

- delays in our anticipated timing to complete preclinical and clinical studies and obtaining required regulatory approvals for the therapeutic tissue candidates we elect to pursue;
- the cost and time to pursue additional research and development programs as part of our long-term business plan;
- the cost and time required to create effective sales and marketing capabilities and commercialization strategies;
- the expenses we incur to maintain and improve our platform technology;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

In addition, our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our products and services, and from collaborations with third parties. However, we may not correctly predict the amount or timing of future revenues. In addition, we may not correctly estimate the costs and time required to develop, complete preclinical and clinical studies and obtain regulatory approval for our therapeutic tissue candidates. We may not be able to adjust our operations in a timely manner to compensate for any unexpected shortfall in our revenues or any increase in our expenses as part of implementing our long-term business plan. As a result, a significant shortfall in our planned revenues or a significant increase in our planned expenses could have an immediate and material adverse effect on our business and financial condition. In such case, we may be required to issue additional equity or debt securities or enter into other commercial arrangements, including relationships with corporate and other partners, sooner than anticipated to secure the additional financial resources to support our development efforts and future operations.

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:

- the results of our development and regulatory approval progress for our therapeutic tissue candidates;
- our reported revenues and financial results;
- the commencement, postponement, delay, progress, completion, or cancellation of client contracts or collaborations in the quarter;
- changes in the mix of our products and services;
- changes in the general global economy
- competitive pricing pressures;
- the extent of cost overruns or delays in our product development and regulatory approval plans;
- holiday buying patterns of our clients;
- budget cycles of our clients;

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.

Our business will be adversely impacted if we are unable to successfully attract, hire and integrate key additional employees or if we are unable to retain our executive officers and other key personnel.

Our future success depends in part on our ability to attract, hire, and integrate key medical, clinical, scientific, technical, and managerial personnel required to develop our business. Our success will also 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. As a result, the loss of any of our executive officers or other key personnel or our inability to timely attract and hire qualified personnel in the future (in particular skilled technical, managerial and sales and marketing personnel) will adversely impact our ability to meet our key commercial and technical goals and successfully implement our business plan.

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 the Company, its employees and its 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 harms, result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and/or cause reputational harm.

If our laboratory facilities become inoperable, we will lose access to our 3D bioprinters and tissues, and our ability to conduct our business and comply with our contractual obligations will be harmed.

We manufacture our NovoGen Bioprinters® and our 3D Human Liver Tissues at our laboratory facilities in San Diego, California. We also provide research services to our customers and collaboration partners and conduct our product research and development activities at our laboratory facilities in San Diego, California. We do not currently have redundant laboratory facilities. Our San Diego, California laboratory facilities are situated near active earthquake fault lines. Our facilities may be harmed or rendered inoperable by natural or manmade disasters, including earthquakes, flooding, fires, power outages and contamination, which may render it difficult or impossible for us to continue to provide our products and services and engage in our research and development activities for some period of time. Even if our facilities are inoperable for a short period of time, we may suffer the loss of our existing tissue and cell inventory, and the loss of any research services and activities currently in process. Accordingly, any disruption to operations at our laboratory facilities in San Diego, California would materially affect our business, prospects and results of operations.

We are subject to risks associated with doing business outside the United States.

We do business with customers outside the United States. We intend to continue to pursue customers and growth opportunities in international markets, and we expect that international revenues may account for a significant percentage of our revenues in the foreseeable future. There are a number of risks arising from our international business, including those related to:

- foreign currency exchange rate fluctuations, potentially reducing the United States dollars we receive for sales denominated in foreign currency;
- general economic and political conditions in the markets we operate in;
- potential increased costs associated with overlapping tax structures;
- potential trade restrictions and exchange controls;
- more limited protection for intellectual property rights in some countries;
- difficulties and costs associated with staffing and managing foreign operations;
- unexpected changes in regulatory requirements;
- the difficulties of compliance with a wide variety of foreign laws and regulations; and
- longer accounts receivable cycles in certain foreign countries, whether due to cultural differences, exchange rate fluctuation or other factors.

These risks, individually or in the aggregate, could have an adverse effect on our results of operations and financial condition. For example, we are subject to compliance with the United States Foreign Corrupt Practices Act and similar anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. While our employees are required to comply with these laws, we cannot be sure that our internal policies and procedures will always protect us from violations of these laws, despite our commitment to legal compliance and corporate ethics. The occurrence or allegation of these types of risks may adversely affect our business, performance, prospects, value, financial condition, and results of operations.

Risks Related to Our Common Stock and Liquidity Risks

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

The Nasdaq Stock Market 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.

As of the date of this filing, our common stock is trading below $1 per share. If the closing bid price of our common stock continues trading below $1 per share for an aggregate of 30 consecutive business days, we will receive a deficiency notice from Nasdaq. If, in such circumstance, we are not able to regain compliance with the minimum bid price requirement within 180 days, our common stock will be subject to a delisting action by Nasdaq. If we are unable to cure the deficiency or regain compliance, our common stock will be delisted from Nasdaq and begin trading on the OTC bulletin board.

A delisting from Nasdaq and commencement of trading on the OTC bulletin board would likely result in a reduction in some or all of the following, each of which could have a material adverse effect on stockholders:

- the liquidity of our common stock;
- the market price of shares 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.

We have a limited trading history and there is no assurance that an active market in our common stock will continue at present levels or increase in the future.

There is limited trading history in our common stock, and although our common stock is now traded on the Nasdaq Global Market, 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.

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. The costs of complying with the reporting requirements of the federal securities laws, including preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders, can be substantial.

If we fail to comply with the rules of Section 404 of the Sarbanes-Oxley Act of 2002 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 (the “Act”) requires that we evaluate and determine the effectiveness of our internal control over financial reporting and requires an attestation and report by our external auditing firm on our internal control over financial reporting. We believe our system and process evaluation and testing comply with the management certification and auditor attestation 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, especially as we grow our business. 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 or our independent registered public accounting firm identifies 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.

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:

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors, including new product and service offerings;
- results of our preclinical studies and regulatory actions regarding our therapeutic products;
- reduced government funding for research and development activities;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- 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, 2019, there were an aggregate of 153,092,560 shares of our common stock issued and outstanding on a fully diluted basis and no shares of preferred stock outstanding. That total for our common stock includes 27,743,413 shares of our common stock that may be issued upon the exercise of outstanding stock options or is available for issuance under our equity incentive plans, 1,188,718 shares of common stock that may be issued through our Employee Stock Purchase Plan ("ESPP"), and 145,000 shares of our common stock that may be issued upon the exercise of outstanding warrants.

In the future, we may issue additional authorized but previously unissued equity securities to raise funds to support our continued operations and to implement our business plan. We may also issue additional shares of our capital stock or other securities that are convertible into or exercisable for our capital stock in connection with hiring or retaining employees, future acquisitions, or for other business purposes. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders may result. In addition, the future issuance of any such additional shares of capital stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently traded on the Nasdaq Global 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 and 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 the 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;
- 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 *In Vitro* Tissues Business

Our In Vitro Tissues Business Depends on New and Unproven Technology and Approaches

Our *in vitro* products and services involve new and unproven models and approaches. We began offering our first commercial product (and related research services), our ExVive™ Human Liver Tissue, on a limited basis in April 2014 and more broadly in November 2014. We began offering our second product (and related research services), our ExVive™ Human Kidney Tissue, for predictive preclinical testing of drug compounds in September 2016. Our commercial products reflect a novel approach to preclinical testing of drug compounds and disease modeling, and there is no assurance that they will perform as expected or as required by our customers. Our success depends on the commercial acceptance of, and the success of our efforts to increase customer awareness and demand for, our drug discovery and biological research tools, products and services. Some of our customers may require unique features, cell sourcing, validation data, or greater degrees of reproducibility than we have been able to achieve to date, in order to utilize our commercial products in their drug discovery, biological research or development programs. Even if we or our customers are successful in our respective efforts, we or our customers may not be able to discover or develop commercially viable therapeutics or other products therefrom. If our drug discovery and biological research tools do not assist in the discovery and development of such therapeutic products or to model diseases, our current and potential customers may lose confidence in our *in vitro* products and services, and our ability to achieve or maintain commercial acceptance for those products and services may adversely affect our business, financial condition and results of operations.

Our ability to successfully commercialize our In Vitro products and services is subject to a variety of risks.

The commercialization of our *in vitro* products and services is subject to risks and uncertainties, including:

- failing to develop products or services that are effective, reproducible, and competitive;
- failing to demonstrate the commercial and technical viability of any products or services that we successfully develop, failing to meet customer expectations or requirements or otherwise failing to achieve market acceptance of such products or services;
- failing to be cost effective and timely;
- being unable to implement features or functionality required by customers;
- being difficult or impossible to manufacture on a large scale;
- being unable to establish and maintain supply and manufacturing relationships with reliable third parties;
- being unable to obtain a sufficient supply of human cells for our products, services and research and development activities on a timely basis and at acceptable quality levels and costs;

- failing to develop our products and services before the successful marketing of similar products and services by competitors;
- being unable to hire and retain qualified personnel; and
- infringing the proprietary rights of third parties or competing with superior products marketed by third parties.

If any of these or any other risks and uncertainties occur, our efforts to commercialize our *in vitro* products and services may be unsuccessful, which would harm our business and results of operations.

The near and long-term viability of our products and services will depend on our ability to successfully establish new strategic relationships.

The near and long-term viability of our products and services will depend in part on our ability to successfully establish new strategic collaborations with biotechnology companies, pharmaceutical companies, universities, hospitals, insurance companies and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our technology or product offerings or our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of new collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts. Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any product or service candidates for several reasons both within and outside of our control.

We face intense competition which could result in reduced acceptance and demand for our products and services.

The biotechnology industry is subject to intense competition and rapid and significant technological change. We have many potential competitors, 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 do:

- research and technology development;
- product identification and development;
- regulatory processes and approvals;
- production and manufacturing;
- securing government contracts and grants to support their research and development efforts;
- sales and marketing of products, services and technologies; and
- identifying and entering into agreements with potential collaborators.

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

In order to effectively compete, we will need to make substantial investments in our research and technology development, product identification and development, testing and regulatory approval, manufacturing, customer awareness activities, publications of our technology and results in scientific publications and sales and marketing activities. There is no assurance that we will be successful in commercializing and gaining significant market share for any products or services we offer in part through use of our technology. Our technologies, products and services also may be rendered obsolete or noncompetitive as a result of products and services introduced by our competitors.

We will require access to a constant, steady, reliable supply of human cells to successfully develop and commercialize our in vitro products and services.

We require a reliable supply of qualified human cells for our commercial products and services and for our research and product development activities. We purchase certain qualified human cells from selected third-party suppliers based on quality assurance, cost effectiveness, and regulatory requirements. We formed our wholly-owned subsidiary, Samsara, to eventually serve as a key source of the primary human cells we utilize in our business. We intend to utilize a combination of third-party suppliers and Samsara to meet our overall future demand for human cells for our *in vitro* business. We work closely with Samsara and our third-party suppliers to

assure adequate supply while maintaining high quality and reliability. If demand for our products and services grows significantly, we may need 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 will harm our business and our results of operations and could cause us to be unable to comply with the contractual obligations we owe to our customers and collaboration partners.

We may not be successful in establishing Samsara as a profitable commercial business.

In January 2016, we announced that our wholly-owned subsidiary, Samsara, commenced commercial operations. We formed Samsara to serve as a key source of certain of the primary human cells we utilize in our products and services and in the development of therapeutic products. In addition to supplying human cells for our business requirements, we believe there is an opportunity for Samsara to operate as a commercial business by selling human cells to other pharmaceutical, biotech and research organizations. Samsara has begun selling its human cell offerings to end users both directly and through distribution partners. Operating and developing Samsara's business is subject to a number of risks and uncertainties, including:

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

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

A significant portion of our sales will be dependent upon our customers' capital spending policies and research and development budgets, and government funding of research and development programs at universities and other organizations, which are each subject to significant and unexpected decrease.

Our prospective customers include pharmaceutical and biotechnology companies, academic institutions, government laboratories, and private research foundations. Fluctuations in the research and development budgets at these organizations could have a significant effect on the demand for our products and services. Research and development budgets fluctuate due to changes in available resources, patent expirations, mergers of pharmaceutical and biotechnology companies, spending priorities, general economic conditions, and institutional and governmental budgetary policies, including but not limited to reductions in grants for research by federal and state agencies as a result of the current budget crises and budget reduction measures. In addition, our business could be seriously damaged by any significant decrease in life sciences research and development expenditures by pharmaceutical and biotechnology companies, academic institutions, government laboratories, or private foundations.

The timing and amount of revenues from customers that rely on government funding of research may vary significantly due to factors that can be difficult to forecast. Research funding for life science research has increased more slowly during the past several years compared to the previous years and has declined in some countries, and some grants have been frozen for extended periods of time or otherwise become unavailable to various institutions, sometimes without advance notice. Government funding of research and development is subject to the political process, which is inherently fluid and unpredictable. Other programs, such as homeland security or defense, or general efforts to reduce the federal budget deficit could be viewed by the United States government as a higher priority. These budgetary pressures may result in reduced allocations to government agencies that fund research and development activities. National Institute of Health and other research and development allocations have been diminished in recent years by federal budget control efforts. The prolonged or increased shift away from the funding of life sciences research and development or delays surrounding the approval of government budget proposals may cause our customers to delay or forego purchases of our products or services, which could seriously damage our business.

Risks Related to Government Regulation

Violation of government regulations or quality programs could harm demand for our products or services, and the evolving nature of government regulations could have an adverse impact on our business.

To the extent that our collaborators or customers use our products in the manufacturing or testing processes for their drug and medical device products, such end-products or services may be regulated by the FDA under Quality System Regulations (QSR) or the Centers for Medicare & Medicaid Services (CMS) under Clinical Laboratory Improvement Amendments of 1988 (CLIA'88) regulations. The customer is ultimately responsible for QSR, CLIA'88 and other compliance requirements for their products. However, we may agree to comply with certain requirements, and, if we fail to do so, we could lose sales and our collaborators or customers and be exposed to regulatory delays or objections and potential product liability claims. In addition, our customers may require that our services be conducted pursuant to the requirements of Good Laboratory Practice (GLP) in order to provide suitable data for their INDs and other regulatory filings. No regulatory review of data from our platform technology has yet been conducted and there is no guarantee that our technology will be acceptable under GLP, or that we will be able to comply with GLP requirements on the timetable required by our customers. As a result, the violation of government regulations or failure to comply with quality requirements could harm demand for our products or services, and the evolving nature of government regulations could have an adverse impact on our business.

Any therapeutic tissues we develop will be subject to extensive, lengthy and uncertain regulatory requirements, which could adversely affect our ability to obtain regulatory approval in a timely manner, or at all.

Any therapeutic and other life science products we develop, including our therapeutic human liver tissue, will be subject to extensive, lengthy and uncertain regulatory approval process by the Food and Drug Administration (FDA) and comparable agencies in other countries. The regulation of new products is extensive, and the required process of laboratory testing and clinical studies is lengthy, expensive and uncertain. We may not be able to obtain FDA approvals for any therapeutic products we develop in a timely manner, or at all. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses. Even if we obtain FDA regulatory approvals, the FDA extensively regulates manufacturing, labeling, distributing, marketing, promotion and advertising after product approval. Moreover, several of our product development areas may involve relatively new technologies and have not been the subject of extensive laboratory testing and clinical studies. The regulatory requirements governing these products and related clinical procedures remain uncertain and the products themselves may be subject to substantial review by the FDA and other foreign governmental regulatory authorities that could prevent or delay approval in the United States and any other foreign country. Regulatory requirements ultimately imposed on our products could limit our ability to test, manufacture and, ultimately, commercialize our products and thereby could adversely affect our financial condition and results of operations.

As we continue to adapt and develop parts of our product line in the future, including tissue-based products in the field of regenerative medicine, the manufacture and marketing of our products will become subject to government regulation in the United States and other countries. In the United States and most foreign countries, we will be required to complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. The steps required by the FDA before our proposed products may be marketed in the United States include performance of preclinical (animal and laboratory) tests; submissions to the FDA of an IND, NDA (New Drug Application), or BLA (Biologic License Application) which must become effective before human clinical trials may commence; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product in the intended target population; and performance of a consistent and reproducible manufacturing process intended for commercial use.

The processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our products to the satisfaction of such regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which are outside of our control. Safety concerns may emerge that could lengthen the ongoing trials or require additional trials to be conducted. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical studies. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to our distribution. Expanded or additional indications for approved devices or drugs may not be approved, which could limit our revenues. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our tissue candidates, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our products are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

Even if a product gains regulatory approval, such approval is likely to limit the indicated uses for which it may be marketed, and the product and the manufacturer of the product will be subject to continuing regulatory review, including adverse event reporting requirements and the FDA's general prohibition against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with

any approved products, could adversely affect our ability to market products and generate revenues and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or our manufacturer are subsequently discovered, and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any treatment by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the treatment itself, and only if the specific event occurs with some regularity over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

If restrictions on reimbursements and health care reform limit our or our collaborators' actual or potential financial returns on therapeutic products that we or they develop based on our platform technology, we may not be able to recover our research and development costs and our collaborators may reduce or terminate their collaborations with us.

Our ability to recover our research and development costs and successfully commercialize any therapeutic products we develop and our collaborators' abilities to successfully commercialize the therapeutic and other life science products they develop through the research tools or services that we provide them may depend in part on the extent to which coverage and adequate payments for these products will be available from government payers, such as Medicare and Medicaid, private health insurers, including managed care organizations, and other third-party payers. These payers are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the reimbursement status of newly approved therapeutic and other life science products, and coverage and adequate payments may not be available for these products.

In recent years, officials have made numerous proposals to change the health care system in the U.S. These proposals included measures to limit or eliminate payments for some medical procedures and treatments or subject the pricing of pharmaceuticals and other medical products to government control. Government and other third-party payers increasingly attempt to contain health care costs by limiting both coverage and the level of payments of newly approved health care products. In some cases, they may also refuse to provide any coverage of uses of approved products for disease indications other than those for which the FDA has granted marketing approval. Governments may adopt future legislative proposals and federal, state or private payers for healthcare goods and services may take action to limit their payments for goods and services. Any of these events could reduce the demand for our products and services by our collaboration partners, reduce the proceeds we receive from our arrangements with our collaboration partners based on future sales of their therapeutic products or limit our ability to recover our research and development costs and successfully commercialize any therapeutic products we develop.

We use 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 involve 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 are 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 require that environmental permits and approvals be issued by applicable government agencies. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts. If we fail 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.

Risks Related to Our Intellectual Property

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

Our commercial 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.

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 so 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.

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 patent applications at risk of not issuing. Additionally, our licensors may 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 and substantial penalties. Moreover, patent disputes and related proceedings can distract management's attention and interfere with running the 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, and any such assertions 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 thus 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. 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.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and potential products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for these breaches. Alternatively, if a third party alleges that any of our employees or consultants has breached confidentiality obligations to our benefit, we may have to defend against allegations of trade secret misappropriation.

Enforcing or defending a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent that competitor from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We rely in part on trademarks to distinguish our products and services from those of other entities. Trademarks may be opposed or cancelled, and we may be involved in lawsuits or other proceedings to protect or enforce our trademarks.

We rely on trademarks, in the United States and in certain foreign jurisdictions, to distinguish our products and services in the minds of consumers and our business partners from those of other entities. Third parties may challenge our pending trademark applications through opposition proceedings in the U.S., or comparable proceedings in foreign jurisdictions, in which they seek to prevent registration of a mark. Our registered trademarks may be subject to cancellation proceedings in the U.S., or comparable proceedings in foreign jurisdictions, in which a third party seeks to cancel an existing registration. To enforce our trademark rights, we may be involved in lawsuits or other proceedings which could be expensive, time-consuming and uncertain.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Since July 2012, the Company has leased its main facilities at 6275 Nancy Ridge Drive, San Diego, California 92121. The lease, as amended in 2013, 2015, 2016, 2018 and 2019, consists of approximately 45,580 rentable square feet containing laboratory, clean room and office space. Monthly rental payments are currently approximately $120,000 per month with 3% annual escalators. The lease for 14,685 of rentable square footage was amended to accelerate the expiration date from December 15, 2018 to October 31, 2018. On November 30, 2018, the Company agreed to extend the term for the remainder of the total rentable square footage under the lease from August 31, 2021 to August 31, 2024 in exchange for $500,000 of landlord funded tenant improvements and a rescission of its option to terminate the lease on or after September 1, 2019 with 9 months prior written notice.

We believe our facilities are adequate for our current and intermediate-term needs, and that we will be able to locate additional facilities as needed.

Item 3. Legal Proceedings.

The Company is not involved in any material legal proceedings or legal matters at this time. See “Note 6. 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 has been quoted on the Nasdaq Global Market under the symbol "ONVO" since August 8, 2016. Prior to that time, we traded on the NYSE MKT and the OTC.

Holders of Record

As of March 31, 2019, there were 99 holders of record of the Company's 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.

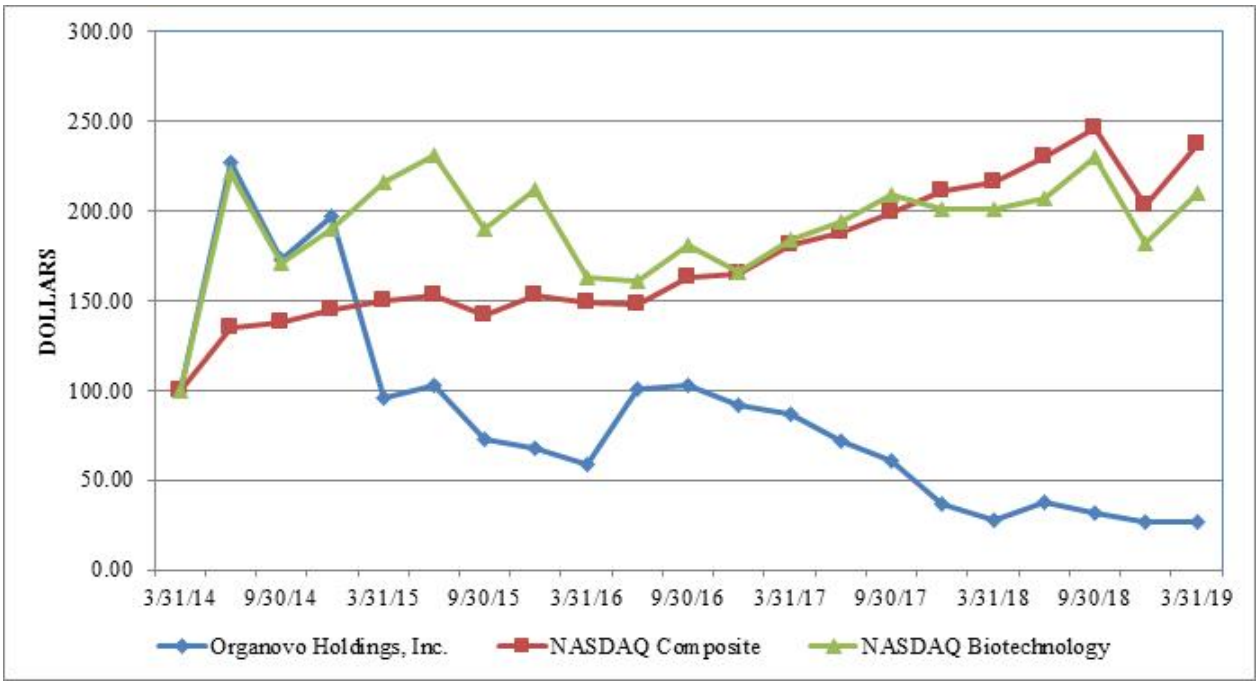
Performance Graph

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, 2019. This graph assumes the investment of $100 on March 31, 2014 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, 2014 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. Selected Financial Data (in thousands except per share data).

The following selected historical financial data reflects our consolidated statements of operations and consolidated balance sheets as of and for the years ended March 31, 2019, 2018, 2017, 2016, and 2015. The data below should be read in conjunction with, and is qualified by reference to, Item 7. “Management's Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and notes thereto contained elsewhere in this annual report. The following table is presented in thousands, except share and per share amounts.

	Year Ended March 31, 2019	Year Ended March 31, 2018	Year Ended March 31, 2017	Year Ended March 31, 2016	Year Ended March 31, 2015
Selected Consolidated Statement of Operations Data:					
Revenue	$ 3,091	$ 4,603	$ 4,230	$ 1,483	$ 571
Operating loss	$ (27,274)	$ (35,271)	$ (38,575)	$ (38,643)	$ (30,297)
Net loss	$ (26,635)	$ (34,803)	$ (38,447)	$ (38,575)	$ (30,082)
Loss per share, basic and diluted	$ (0.23)	$ (0.32)	$ (0.39)	$ (0.43)	$ (0.38)
Weighted average shares outstanding, basic and diluted	115,379,902	107,243,974	97,763,032	90,057,356	79,650,087

	March 31, 2019	March 31, 2018	March 31, 2017	March 31, 2016	March 31, 2015
Selected Consolidated Balance Sheet Data:					
Working capital (deficit)	$ 34,837	$ 42,102	$ 59,081	$ 59,162	$ 46,501
Total assets	$ 40,623	$ 49,827	$ 69,180	$ 67,576	$ 53,489
Long-term liabilities	$ 588	$ 583	$ 807	$ 905	$ 32
Stockholders’ equity (deficit)	$ 36,298	$ 44,586	$ 62,362	$ 62,181	$ 48,696

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

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

Overview

We are a biotechnology company pioneering the development of bioprinted human tissues that emulate human biology and disease. Internally, we are developing our *in vivo* liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. Our objective is to serve as a 'bridge-to-transplant' for these patients, with an ultimate goal of delaying or reducing the overall need for transplant. Our program focused on an orphan disease known as Alpha-1-anityprisin deficiency ("A1AT"), received the U.S. Food and Drug Administration's ("FDA") orphan drug designation in December 2017. We are also utilizing our foundational ability to isolate highly specialized human cells to build robust, functional human tissues by creating a range of novel preclinical *in vitro* disease modeling platforms, including a broad set of non-alcoholic fatty liver disease ("NAFLD") and non-alcoholic steatohepatitis ("NASH") conditions. Our clients can access these diseased tissue platforms through collaborative, revenue-generating agreements.

In May 2019, we announced our plans to conduct additional preclinical studies and to optimize our manufacturing processes and complete additional preclinical studies that generate consistent scientific data regarding the prolonged functionality and therapeutic benefits of our *in vivo* liver tissues. We also announced that these efforts would extend our preclinical development efforts into calendar 2020. The requirement to complete additional studies and to optimize our manufacturing processes resulted from data generated from a larger group of animal studies that differed from our earlier pilot studies. These studies continued to show statistically meaningful reductions in toxic globules in the A1AT animal models over a three-month period. However, in these and other animal models, we observed shorter tissue duration than we observed in our pilot studies, as measured by human protein output and the quantity of hepatocytes.

As we focus our efforts on our *in vivo* tissue development efforts, we intend to be increasingly selective about pursuing and entering into collaborative and revenue-generating agreements for our *in vitro* disease models. Our *in vitro* and *in vivo* tissues are both built upon the same proprietary 3D bioprinting technology and our highly specialized cells. As a result, we intend to enter into collaborative, revenue-generating agreements where the scientific outcomes are complementary to our key regulatory goals for our *in vivo* tissues.

Over the long-term, we intend to focus on achieving the following key milestones:

- One or more successful IND submissions, leading to the initiation of Phase I clinical studies involving implantation and functional evaluation of our liver therapeutic tissue patch in target disease patients;
- Achieving key FDA designations associated with tissue-based approaches that address serious unmet medical needs in rare disease indications, which can include Regenerative Medicine Advanced Therapy ("RMAT"), Orphan Drug, Fast Track and Breakthrough designations;
- Deploying of proof-of-concept disease modeling capabilities in NASH to enable high content drug profiling collaborations with current and prospective clients;
- Developing our Samsara Sciences, Inc. ("Samsara") division's cell-based product revenue opportunities, as well as continuing to generate revenue from grant and licensing agreements;
- Achieving operational breakeven profitability for our commercial business by securing selected revenue-generating fee-based service agreements and collaborations and creating business opportunities which may lead to valuable spin-out and/or partnering opportunities; and
- Continuing academic, partner and internal research programs to generate additional, high value tissue applications and therapeutics pipeline opportunities in other organ and disease areas.

Critical Accounting Policies, Estimates, and Judgments

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to revenue recognition, stock-based compensation expense, and the valuation allowance on deferred tax assets. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known. 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.

There have been no significant changes to our critical accounting policies since March 31, 2018, with the exception of changes made upon adoption of ASU No. 2014-09 and the related supplemental ASUs. 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. 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.

Revenue recognition

The Company generates revenues from payments received from research service agreements, product sales, collaborative agreements with partners including pharmaceutical and biotechnology companies and academic institutions, licenses, and grants from the National Institutes of Health (“NIH”) and private not-for-profit organizations.

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met. As of March 31, 2019 and 2018, the Company had approximately $525,000 and $687,000, respectively, in deferred revenue related to its research service agreements, collaborative agreements, and licenses within the scope of Topic 606. In the twelve months ended March 31, 2019 the Company recognized revenue on approximately $178,000 that had been recorded as deferred revenue at March 31, 2018.

Effective April 1, 2018, the Company adopted the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 606, *Revenue from Contracts with Customers* (“Topic 606”). Under Topic 606, the Company recognizes revenue when (or as) the promised services are transferred to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those services. To determine revenue recognition for arrangements the Company concludes are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the performance obligation(s) are satisfied. At contract inception, the Company assesses the goods or services promised within each contract, assesses whether each promised good or service is distinct and identifies those that are performance obligations. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Service revenues

The Company’s service-based business, Organovo, Inc., utilizes its NovoGen® bioprinting platform to provide customers access to its highly specialized tissues that model human biology and disease, and to *in vitro* testing services based on that technology. These contracts with customers contain multiple performance obligations including: (i) bioprinting tissues for the customer, (ii) reporting the results of tests performed on the printed tissues pursuant to the agreed upon work plan through exposure of the tissue to various factors (including the customer’s proprietary compound), and (iii) delivering specific byproduct study materials, which are satisfied, respectively, at each of the following points in time: (i) upon completion of manufacturing of the bioprinted tissue for the customer, (ii) upon delivery of the report on tests performed on the tissue, and (iii) upon making certain study materials generated from the aforementioned testing process available to the customer. The customer does not have access or control of any performance obligation prior to the point in time of full completion of the corresponding performance satisfying event as defined above. Furthermore, although the service can be customized for each customer, it is not so highly customized as to not have an alternative use either to other customers or to the Company without significant economic consequences or rework. Accordingly, the Company’s service-based business utilizes point-in-time recognition under Topic 606.

For service contracts, the Company allocates the transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations. The transaction price for service business contracts is a fixed consideration.

Product sales, net

The Company's product-based business, Samsara Sciences, Inc., produces cell-based products for use in Organovo's 3D tissue manufacturing and for use by life science customers. The Company recognizes product revenue when the performance obligation is satisfied, which is at the point in time the customer obtains control of the Company's product, typically upon delivery. Product revenues are recorded at the transaction price, net of any estimates for variable consideration under Topic 606. The Company's process for estimating variable consideration does not differ materially from its historical practices. Variable consideration is estimated using the expected value method which considers the sum of probability-weighted amounts in a range of possible amounts under the contract. Product revenue reflects the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the individual contracts. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary materially from the Company's estimates, the Company will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted.

The Company provides no right of return to its customers except in cases where a customer obtains authorization from the Company for the return. To date, there have been no product returns. The Company will continue to assess its estimates of variable consideration as it accumulates additional historical data and will adjust its estimates accordingly.

Collaborative research, development, and licenses

The Company enters into collaborative agreements with partners that typically include one or more of the following: (i) non-exclusive license fees; (ii) non-refundable up-front fees; (iii) payments for reimbursement of research costs; (iv) payments associated with achieving specific development milestones; and (v) royalties based on specified percentages of net product sales, if any. At the initiation of an agreement, the Company analyzes whether it results in a contract with a customer under Topic 606 or in an arrangement with a collaborator subject to guidance under ASC 808, *Collaborative Arrangements* ("Topic 808").

The Company considers a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company evaluates each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, non-exclusive license fees, non-refundable upfront fees, and funding of research activities are considered fixed, while milestone payments are identified as variable consideration which must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

The Company's collaborative agreements that were not completed at the implementation of Topic 606 on April 1, 2018, consisted of research collaboration and limited technology access licenses. These agreements provide the licensee with a non-exclusive, non-transferable, limited, royalty-free technology license, including access to Organovo's proprietary bioprinter platform, training, and continued support by means of consumables and consultation throughout the duration of the contract. The Company has determined the intellectual property license is not distinct from the continued support promised under the agreement and is therefore a single combined performance obligation. The Company recognizes revenue for these combined performance obligations over time for the duration of the license period, as the combined performance obligation will not be fully satisfied until the end of the contract.

For the twelve months ended March 31, 2019, all collaborations and licenses revenue was within the scope of Topic 606 and recognized accordingly.

In April 2015, the Company entered into a research collaboration agreement with a third party to develop custom tissue models for fixed fees. Based on the proportional performance achieved under this agreement for the years ended March 31, 2019 and 2018, the Company has recorded approximately $0 and $150,000, respectively, in collaboration revenue. The Company has completed its obligations under this agreement as of March 31, 2018.

In June 2016, the Company entered into a collaborative nonexclusive research affiliation with a university medical school and a non-profit medical charity, under which the Company received a one-time grant from the charity towards the placement of a NovoGen Bioprinter® at the university for the purpose of developing bioprinted tissues for skeletal disease research. The Company received an up-front payment in June 2016, which was initially recorded as deferred revenue. Revenues of $0 and $65,000 were recognized under this agreement during the years ended March 31, 2019 and 2018, respectively. The Company does not anticipate recording any further revenue under this agreement.

In December 2016, the Company signed another collaborative nonexclusive research affiliation with a university medical school and a non-profit medical charity, under which the Company received a one-time grant from the charity towards the placement of a NovoGen Bioprinter® at the university for the purpose of developing an architecturally correct kidney for potential therapeutic applications. The Company received up-front payments in January and March of 2017, which has been recorded as deferred revenue. Revenues of $39,000 and $39,000 have been recorded under this agreement during the years ended March 31, 2019 and 2018, respectively.

In April 2017, the Company signed a collaborative non-exclusive research affiliation with a university, under which the Company received a one-time nonrefundable payment toward the placement of a NovoGen Bioprinter® at the university for the purpose of specific research projects mutually agreed upon by the university and the Company in the field of volumetric muscle loss. The Company received an up-front payment in May 2017, which has been recorded as deferred revenue. Revenue of approximately $57,000 and $43,000 has been recorded during the years ended March 31, 2019 and 2018, respectively, beginning subsequent to the installation of the printer in July of 2017. In addition, during April 2017, the Company signed a non-exclusive patent license agreement with the university including an annual fee of $75,000 for each of two years for the license to Company patents for research use limited to the field of volumetric muscle loss. The Company received the first annual payment of $75,000 in April 2017, which was initially recorded as deferred revenue. Revenue of $75,000 has been recorded under this agreement during the year ended March 31, 2018. The Company received the second annual payment of $75,000 in May 2018. Revenue of $75,000 has been recorded under this agreement during the year ended March 31, 2019.

In September 2017, the Company entered into an agreement with a company, under which the Company received a one-time non-refundable payment of $50,000 for limited use of a Company patent in reference to four bioprinters developed and placed at research and academic facilities. The Company has recorded $0 and $50,000 in revenue during the years ended March 31, 2019 and 2018, respectively.

Grant revenue

In July 2017, the National Institutes of Health (“NIH”) awarded the Company a “Research and Development” grant totaling approximately $1,657,000 of funding over three years. The Company has concluded this government grant is not within the scope of Topic 606, as government entities do not meet the definition of a “customer” as defined by Topic 606, as there is not considered to be a transfer of control of goods or services to the government entity funding the grant. Additionally, the Company has concluded this government grant does meet the definition of a contribution and is a non-reciprocal transaction, however, Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as the Company is a business entity and the grant is with a governmental agency.

Revenues from this grant are based upon internal costs incurred that are specifically covered by the grant, plus an additional rate that provides funding for overhead expenses. Revenue is recognized as the Company incurs expenses that are related to the grant. The Company believes this policy is consistent with the overarching premise in Topic 606, to ensure that it recognizes revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services, even though there is no “exchange” as defined in the ASC. The Company believes the recognition of revenue as costs are incurred and amounts become earned/realizable is analogous to the concept of transfer of control of a service over time under ASC 606.

Revenue recognized under this grant was approximately $587,000 and $554,000 for the twelve months ended March 31, 2019 and 2018, respectively.

Cost of revenues

We reported approximately $0.5 million and $1.0 million in cost of revenues for the twelve months ended March 31, 2019 and 2018, respectively. Cost of revenues consists of our costs related to manufacturing and delivering our product and service revenue.

Stock-based compensation

For purposes of calculating stock-based compensation, we estimate the fair value of stock options and shares acquirable under our 2016 Employee Stock Purchase Plan (the “ESPP”) 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, due to our limited historical data, the expected volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available, in addition to our own. For shares acquirable under our ESPP, during the first full year of ESPP offering periods, beginning September 1, 2016, the expected volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available due to our limited historical data as an early-stage commercial business. As of September 1, 2017 and the beginning of the second year of ESPP offering periods, we are using 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. 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.

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, is 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 the Company. The expense for PBRSUs with pre-defined performance criteria is adjusted with the probability of achievement of such performance criteria at each period end.

Results of Operations

Comparison of the Years Ended March 31, 2019 and 2018

The following table summarizes our results of operations for the years ended March 31, 2019 and 2018 (in thousands):

	Year Ended March 31,		2018 to 2019	
	2019	2018	$	%
Revenues	$ 3,091	$ 4,603	$ (1,512)	(33%)
Cost of revenues	$ 482	$ 1,030	$ (548)	(53%)
Research and development	$ 14,752	$ 17,956	$ (3,204)	(18%)
Selling, general and administrative	$ 15,131	$ 20,888	$ (5,757)	(28%)
Other income	$ 642	$ 470	$ 172	37%

Revenues

Revenues of $3.1 million for the year ended March 31, 2019 decreased approximately $1.5 million, or approximately 33%, over revenues of $4.6 million for the year ended March 31, 2018. This change reflects decreases of $1.3 million and $0.2 million in product and service revenue and collaboration revenue, respectively, over the year ended March 31, 2018, due to a decrease in service revenues resulting from fewer contracts for liver tissue testing services and the completion of a couple of collaborations.

Costs and Expenses

Cost of Revenues

Cost of product and service revenues, which reflects expenses related to manufacturing our products and delivering services, was $0.5 million and $1.0 million for the years ended March 31, 2019 and 2018, respectively. The reduction in cost of revenues and resulting improvement in our product and service gross margin percentage is due to a reduction in revenues and an increased proportion of higher margin revenues from the sales of primary human cell-based products, respectively.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended March 31, 2019 and 2018 (in thousands):

	Year ended March 31,		2018 to 2019	
	2019	2018	$	%
Research and development	$ 13,290	$ 16,130	$ (2,840)	(18%)
Non-cash stock-based compensation	911	1,174	(263)	(22%)
Depreciation and amortization	551	652	(101)	(15%)
Total research and development expenses	$ 14,752	$ 17,956	$ (3,204)	(18%)

Research and development expenses decreased $3.2 million, or 18%, from approximately $18.0 million for the year ended March 31, 2018 to approximately $14.8 million for the year ended March 31, 2019 as we reduced investment in the development of disease modeling research services to focus on progressing our therapeutic development program. This resulted in a reduction in full-time research and development staffing from an average of seventy-one full-time employees during the year ended March 31, 2018 to an average of forty-seven full-time employees during the year ended March 31, 2019 and led to decreases of $2.2 million in staffing expense, $0.5 million in lab services and supply expenses, $0.4 million in facility costs, and $0.1 million in depreciation and amortization.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the years ended March 31, 2019 and 2018 (in thousands):

	Year ended March 31,		2018 to 2019	
	2019	2018	$	%
Selling, general and administrative	$ 10,420	$ 14,544	$ (4,124)	(28%)
Non-cash stock-based compensation	4,282	5,729	(1,447)	(25%)
Depreciation and amortization	429	615	(186)	(30%)
Total selling, general and administrative expenses	$ 15,131	$ 20,888	$ (5,757)	(28%)

Selling, general and administrative expenses decreased approximately $5.8 million, or 28%, from $20.9 million for the year ended March 31, 2018 to approximately $15.1 million for the year ended March 31, 2019. The decrease was primarily driven by a $4.3 million reduction in compensation costs, a $1.5 million reduction in consulting and outside services costs, a $0.3 million reduction in travel and entertainment costs, and a $0.2 million reduction in depreciation and amortization costs, which offset a $0.4 million increase in facilities costs and a $0.1 million increase in corporate costs. Selling, general and administrative headcount decreased from an average of thirty-three full-time employees during the year ended March 31, 2018 to an average of twenty-two full-time employees during the year ended March 31, 2019.

Other Income (Expense)

Other income was approximately $0.6 million for the year ended March 31, 2019, and consisted of $0.7 million of interest income, which was offset by a $0.1 million loss on the disposal of fixed assets related to a reduction in our facilities footprint. For the year ended March 31, 2018, other income of approximately $0.5 million consisted primarily of interest income. Interest income increased from fiscal 2018 to fiscal 2019 due to higher average yields on our cash portfolio.

Financial Condition, Liquidity and Capital Resources

We have primarily devoted our efforts to developing a platform technology to produce and study living tissues that emulate key aspects of human biology and disease, raising capital and building infrastructure.

As of March 31, 2019, we had cash and cash equivalents of $36.5 million and an accumulated deficit of $260.8 million. As of March 31, 2018, we had cash and cash equivalents of $43.7 million and an accumulated deficit of $234.1 million. We also had negative cash flows from operations of $20.4 million and $28.9 million for the years ended March 31, 2019 and 2018, respectively.

At March 31, 2019, we had total current assets of $38.6 million and current liabilities of $3.8 million, resulting in working capital of $34.8 million. At March 31, 2018, we had total current assets of $46.8 million and current liabilities of $4.7 million, resulting in working capital of $42.1 million.

The following table sets forth a summary of the primary sources and uses of cash for the years ended March 31, 2019 and 2018 (in thousands):

	Year ended March 31,	
	2019	2018
Net cash (used in) provided by:		
Operating activities	$ (20,375)	$ (28,857)
Investing activities	(76)	(292)
Financing activities	13,154	10,113
Effect of currency exchange rate	—	11
Net decrease in cash, cash equivalents, and restricted cash	$ (7,297)	$ (19,025)

Operating activities

Net cash used by operating activities was approximately $20.4 million and $28.9 million for the years ended March 31, 2019 and 2018, respectively. This $8.5 million decrease, for the year ended March 31, 2019, is a result of the improvement in our net loss resulting from a streamlining of research and administrative activities combined with a reduction in working capital requirements.

Investing activities

Net cash used in investing activities was less than $0.1 million and approximately $0.3 million for the years ended March 31, 2019 and 2018, respectively. The majority of net cash used in investing activities to date has been for capital purchases, including laboratory equipment purchases and the expansion and buildout of our facilities related to our expanded research capabilities and the commercialization of our products.

Financing activities

Net cash provided by financing activities was approximately $13.2 million and $10.1 million for the years ended March 31, 2019 and 2018, respectively.

Operations funding requirements

During the year ended March 31, 2019, we raised net proceeds of approximately $13.2 million through the sale of 11,631,803 shares of our common stock through “at-the-market” offerings, $0.1 million through the sale of shares through the ESPP, and less than $0.1 million through stock option exercises, which were offset by $0.2 million of payroll taxes paid by the Company related to the vesting of restricted stock units where vested shares were withheld by us to satisfy employee withholding tax obligations.

During the year ended March 31, 2018, we raised net proceeds of approximately $9.2 million through the sale of 5,307,105 shares of our common stock in “at-the-market” offerings and approximately $0.8 million through stock option exercises and $0.2 million through the sale of shares through the ESPP, which were offset by $0.1 million of payroll taxes paid by the Company related to the vesting of restricted stock units where vested shares were withheld by us to satisfy employee withholding tax obligations.

Through March 31, 2019, we have financed our operations primarily through the sale of common stock in public offerings, the private placement of equity securities, from revenue derived from products and research-based services, grants, and collaborative research agreements, and from the sale of convertible notes. Based on our current operating plan and available cash resources, we have sufficient resources to fund our business for at least the next twelve months.

We will need substantial additional capital to further fund the development of our therapeutic tissues. We intend to cover our future operating expenses through cash on hand, the issuance of additional equity or debt securities, and from revenue derived from research service agreements, product sales, grants, and collaborative research agreements. 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 have an effective shelf registration statement on Form S-3 (File No. 333-222929), or the 2018 Shelf, that expires on February 22, 2021. As of March 31, 2018, we are authorized to offer and sell under the 2018 Shelf, in one or more offerings, common stock, preferred stock, warrants to purchase common stock, preferred stock, or any combination of the foregoing, either individually or as units compromised one or more of the other securities, in the aggregate amount of $100.0 million. On March 16, 2018, we filed a prospectus supplement to the 2018 Shelf to register the sale of up to $50.0 million of shares of our common stock that may be issued

in at-the-market offerings pursuant to an equity offering sales agreement we entered into with two investment banking firms as of the same date. During the twelve months ended March 31, 2019, we sold 11,631,803 shares of common stock in at-the-market offerings, with net proceeds of approximately $13.2 million under the 2018 Shelf.

Based on our use of the 2018 Shelf through March 31, 2019, we cannot raise more than an aggregate of $86.4 million in future offerings under the 2018 Shelf, including through our at-the-market program.

Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs or relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

As of March 31, 2019, we had 124,015,429 total issued and outstanding shares of common stock and 145,000 warrants with remaining terms of less than one year and exercise prices of $6.84 and $7.62 per share.

In addition, our 2008 Equity Incentive Plan provided for the issuance of up to 1,521,584 shares of common stock upon the exercise of outstanding stock options, of which 896,256 shares were issued. The 2008 Equity Incentive Plan terminated on July 1, 2018. The 2012 Equity Incentive Plan, as amended, provides for the issuance of up to 28,553,986 shares of our common stock, of which 13,464,720 shares remain available for issuance as of March 31, 2019, to executive officers, directors, advisory board members, employees and consultants. Additionally, 1,500,000 shares of common stock have been reserved for issuance under the 2016 ESPP, of which 1,188,718 shares remain available for future issuance as of March 31, 2019. Lastly, 3,382,326 shares of common stock have been reserved for issuances under Inducement Award Agreements. In aggregate, issued and outstanding common stock, shares underlying outstanding warrants, and shares issuable under outstanding equity awards or reserved for future issuance under the 2008 and 2012 Equity Incentive Plans, the Inducement Award Agreements, and the 2016 ESPP total 153,092,560 shares of common stock as of March 31, 2019.

Off-Balance Sheet Arrangements

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

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.

Contractual Obligations

In the normal course of business, we enter into contracts and commitments that obligate us to make payments in the future. The table below sets forth our significant contractual obligations and related scheduled payments as of March 31, 2019 (in thousands):

	Total	2020	2021 to 2022	2023 to 2024	2025 and thereafter
Operating lease obligations (A)	$ 6,273	$ 1,084	$ 2,274	$ 2,401	$ 514
Total	$ 6,273	$ 1,084	$ 2,274	$ 2,401	$ 514

(A) Operating lease obligations include the remaining payments due under our facility leases.

Recent Accounting Pronouncements

For information regarding recently adopted and issued accounting pronouncements, see “Note 12. Recent Accounting Pronouncements” in the Notes to Consolidated Financial Statements.

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

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.** (the "Company") as of March 31, 2019 and 2018, and the related consolidated statements of operations and other comprehensive loss, stockholders' equity, and cash flows for each of the years in the two year period ended March 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of March 31, 2019, based on criteria established in the *2013 Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated June 3, 2019, expressed an unqualified opinion.

Adoption of New Accounting Standard

As discussed in Note 1 to the financial statements, the Company has changed its method of accounting in the year ended March 31, 2019, due to the adoption of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers*, effective April 1, 2018, under the modified retrospective method.

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. 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.

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2011.
San Diego, California
June 3, 2019

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited **Organovo Holdings, Inc.'s** ("Company") internal control over financial reporting as of March 31, 2019, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO criteria). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of March 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the years in the two year period ended March 31, 2019, and our report dated June 3, 2019, expressed an unqualified opinion on those financial statements and included explanatory paragraphs regarding the Company's change in method of accounting for revenue from contracts with customers as a result of the adoption of Accounting Codification Topic 606, *Revenue from Contracts with Customers,* effective April 1, 2018.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying **Management's Report on Internal Control over Financial Reporting**. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's 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 for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
June 3, 2019

ORGANOVO HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands except for share and per share data)

	March 31, 2019	March 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	$ 36,477	$ 43,726
Accounts receivable	503	883
Grant receivable	55	145
Inventory, net	490	842
Prepaid expenses and other current assets	1,049	1,164
Total current assets	38,574	46,760
Fixed assets, net	1,832	2,788
Restricted cash	79	127
Other assets, net	138	152
Total assets	$ 40,623	$ 49,827
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 628	$ 464
Accrued expenses	2,549	3,341
Deferred revenue	525	668
Deferred rent	35	185
Total current liabilities	3,737	4,658
Deferred revenue, net of current portion	—	19
Deferred rent, net of current portion	588	564
Total liabilities	4,325	5,241
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 200,000,000 shares authorized, 124,015,429 and 111,032,957 shares issued and outstanding at March 31, 2019 and March 31, 2018, respectively	124	111
Additional paid-in capital	296,929	278,595
Accumulated deficit	(260,755)	(234,120)
Total stockholders' equity	36,298	44,586
Total Liabilities and Stockholders' Equity	$ 40,623	$ 49,827

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, 2019	Year Ended March 31, 2018
Revenues		
Products and services	$ 2,333	$ 3,627
Collaborations and licenses	171	422
Grants	587	554
Total Revenues	3,091	4,603
Cost of revenues	482	1,030
Research and development expenses	14,752	17,956
Selling, general, and administrative expense	15,131	20,888
Total costs and expenses	30,365	39,874
Loss from Operations	(27,274)	(35,271)
Other Income (Expense)		
Gain (loss) on fixed asset disposals	(63)	4
Interest income	705	478
Other income (expense)	—	(12)
Total Other Income (Expense)	642	470
Income Tax Expense	(3)	(2)
Net Loss	$ (26,635)	$ (34,803)
Net loss per common share—basic and diluted	$ (0.23)	$ (0.32)
Weighted average shares used in computing net loss per common share—basic and diluted	115,379,902	107,243,974
Comprehensive Loss:		
Net Loss	$ (26,635)	$ (34,803)
Currency Translation Adjustment	—	11
Comprehensive Loss	$ (26,635)	$ (34,792)

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 Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
Balance at March 31, 2017	**104,551**	**$ 104**	**$ 261,586**	**$ (199,317)**	**$ (11)**	**$ 62,362**
Stock option exercises	500	1	825	—	—	826
Issuance of common stock under employee and director stock option, RSU and purchase plans	675	1	113	—	—	114
Stock-based compensation expense	—	—	6,903	—	—	6,903
Issuance of common stock from public offering, net	5,307	5	9,168	—	—	9,173
Net loss	—	—	—	(34,803)	—	(34,803)
Currency translation adjustment	—	—	—	—	11	11
Balance at March 31, 2018	**111,033**	**$ 111**	**$ 278,595**	**$ (234,120)**	**$ —**	**$ 44,586**
Stock option exercises	622	1	49	—	—	50
Issuance of common stock under employee and director stock option, RSU and purchase plans	728	1	(140)	—	—	(139)
Stock-based compensation expense	—	—	5,193	—	—	5,193
Issuance of common stock from public offering, net	11,632	11	13,232	—	—	13,243
Net loss	—	—	—	(26,635)	—	(26,635)
Balance at March 31, 2019	**124,015**	**$ 124**	**$ 296,929**	**$ (260,755)**	**$ —**	**$ 36,298**

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, 2019	Year Ended March 31, 2018
Cash Flows From Operating Activities		
Net loss	$ (26,635)	$ (34,803)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on disposal of fixed assets	63	(4)
Depreciation and amortization	980	1,267
Stock-based compensation	5,193	6,903
Donation of fixed assets	—	25
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	380	(236)
Grants receivable	90	(145)
Inventory	352	(292)
Prepaid expenses and other assets	118	5
Accounts payable	164	(707)
Accrued expenses	(792)	(760)
Deferred revenue	(162)	(157)
Deferred rent	(126)	47
Net cash used in operating activities	(20,375)	(28,857)
Cash Flows From Investing Activities		
Purchases of fixed assets	(79)	(226)
Proceeds from disposals of fixed assets	3	4
Purchases of intangible assets	—	(70)
Net cash used in investing activities	(76)	(292)
Cash Flows From Financing Activities		
Proceeds from issuance of common stock	13,327	9,381
Employee taxes paid related to net share settlement of equity awards	(223)	(94)
Proceeds from exercise of stock options	50	826
Net cash provided by financing activities	13,154	10,113
Effect of currency exchange rate changes on cash and cash equivalents	—	11
Net Decrease in Cash and Cash Equivalents	(7,297)	(19,025)
Cash, cash equivalents, and restricted cash at beginning of period	43,853	62,878
Cash, cash equivalents, and restricted cash at end of period	$ 36,556	$ 43,853
Reconciliation of cash, cash equivalents, and restricted cash to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 36,477	$ 43,726
Restricted cash	79	127
Total cash, cash equivalent and restricted cash	$ 36,556	$ 43,853
Supplemental Disclosure of Cash Flow Information:		
Income Taxes	$ 3	$ 2

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

Organovo Holdings, Inc.

Notes to Consolidated Financial Statements

1. Description of Business and Summary of Significant Accounting Policies

Nature of operations and basis of presentation

Organovo Holdings, Inc. ("Organovo Holdings," "we," "us," "our," "the Company" and "our Company") is a biotechnology company pioneering the development of bioprinted human tissues that emulate human biology and disease. Initially, we are developing our *in vivo* liver tissues to treat end-stage liver disease and a select group of life-threatening, orphan diseases, for which there are limited treatment options other than organ transplantation. Our objective is to serve as a 'bridge-to-transplant' for these patients, with an ultimate goal of delaying or reducing the overall need for transplant. The Company's program focused on an orphan disease known as Alpha-1-antitrypsin deficiency ("A1AT"), received the U.S. Food and Drug Administration's ("FDA") orphan drug designation in December 2017. We are also utilizing our foundational ability to isolate highly specialized human cells to build robust, functional human tissues by creating a range of novel preclinical *in vitro* disease modeling platforms, including a broad set of non-alcoholic fatty liver disease ("NAFLD") and non-alcoholic steatohepatitis ("NASH") conditions. Our clients can access these diseased tissue platforms through collaborative, revenue-generating agreements.

Except where specifically noted or the context otherwise requires, references to "Organovo Holdings," "the Company," "we," "our," and "us" in these notes to the condensed consolidated financial statements refers to Organovo Holdings, Inc. and its wholly owned subsidiaries, Organovo, Inc., Samsara Sciences, Inc., and Organovo UK Ltd in March 2018, the U.K. operations were combined with Organovo, Inc.'s operations.

The Company's activities are subject to significant risks and uncertainties including failing to successfully develop products and services based on its technology, failing to achieve regulatory approvals for its therapeutic candidates, and failing to achieve the market acceptance necessary to generate sufficient revenues to achieve and sustain profitability.

Reclassification of prior year presentation

As a result of the adoption of the new accounting standard associated with clarifying presentation and classification in the statement of cash flows, certain reclassifications have been made to the prior period financial statements to conform with the current period presentation. These reclassifications did not have any effect on previously reported cash flows, net loss, or financial position.

Nasdaq listing

On August 8, 2016, the Company moved its stock exchange listing to the Nasdaq Global Market, under the "ONVO" ticker symbol. From July 11, 2013 through August 5, 2016, the Company listed its shares on the NYSE MKT. Prior to July 11, 2013, the Company's shares were quoted on the OTC QX.

Liquidity

As of March 31, 2019, the Company had cash and cash equivalents of approximately $36.5 million and restricted cash of less than $0.1 million. The restricted cash was pledged as collateral for two letters of credit the Company is required to maintain as security deposits under the terms of the leases of its facilities. The Company had an accumulated deficit of approximately $260.8 million. The Company also had negative cash flows from operations of approximately $20.4 million during the year ended March 31, 2019.

Through March 31, 2019, the Company has financed its operations primarily through the sale of convertible notes, the private placement of equity securities, the sale of common stock through public and at-the-market ("ATM") offerings, and through revenue derived from product and research service-based agreements, collaborative agreements, grants, and licenses. During the year ended March 31, 2019, the Company issued 11,631,803 shares of its common stock through its ATM facility and received net proceeds of approximately $13.2 million.

Based on its current operating plan and available cash resources, the Company believes it has sufficient resources to fund its business for at least the next twelve months.

The Company will need additional capital to further fund the development of its proprietary platform to produce and study living tissues focusing on critical unmet medical needs in the liver disease space. The Company intends to cover its future operating expenses through cash on hand, through revenue derived from research service agreements, product sales, collaborative agreements, grants and license payments, and through the issuance of additional equity or debt securities. 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.

Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs or relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could eventually adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to our existing stockholders would likely result. If we raise additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

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, the valuation of stock-based compensation expense, and the valuation allowance on deferred tax assets. On an ongoing basis, management reviews these estimates and assumptions.

Financial instruments

For certain of the Company's financial instruments, including cash and cash equivalents, inventory, prepaid expenses and other assets, accounts payable, accrued expenses, deferred revenue, and capital lease obligations, 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.

Foreign Currency

The functional currency of our U.K. operations was the pound sterling. Accordingly, all assets and liabilities of this subsidiary were translated to US dollars based on the applicable exchange rate on the balance sheet date. Revenue and expense components were translated to US dollars at the exchange rates in effect during the period. Gains and losses resulting from foreign currency translation are reported as a separate component of accumulated other comprehensive income or loss in the equity section of our consolidated balance sheets.

Foreign currency transaction gains and losses, which are primarily the result of remeasuring United States dollar-denominated receivables and payables, are recorded in our Consolidated Statements of Operations and Other Comprehensive Loss. For the years ended March 31, 2019 and 2018, we recognized foreign currency translation losses of approximately $0 and $1,000, respectively.

As of March 31, 2019 and 2018, we realized $0 and $11,000 of cumulative foreign currency translation losses as Other Expense on the Consolidated Statement of Operations and Other Comprehensive Loss for the years ending March 31, 2019 and 2018, respectively. No further foreign currency translation losses will be recorded as the U.K. operations have been combined with Organovo, Inc.'s operations as of March 31, 2018.

Restricted cash

As of March 31, 2019 and 2018, the Company had approximately $79,000 and $127,000 of restricted cash, respectively, deposited with a financial institution. The entire amount is held in certificates of deposit to support a letter of credit agreement related to the Company's facility lease.

Inventory

Inventories are stated at the lower of the cost or net realizable value (first-in, first-out). Inventory at March 31, 2019 consists of approximately $361,000 in raw materials, approximately $0 in work-in-process inventory, and approximately $129,000 in finished goods net of reserve. Inventory at March 31, 2018 consisted of approximately $578,000 in raw materials, approximately $26,000 in work-in progress inventory, and approximately $238,000 in finished goods net of reserve.

Fixed assets and depreciation

Property and equipment 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 property and equipment 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, 2019.

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.

Revenue recognition

The Company generates revenues from payments received from research service agreements, product sales, collaborative agreements with partners including pharmaceutical and biotechnology companies and academic institutions, licenses, and grants from the National Institutes of Health (“NIH”) and private not-for-profit organizations.

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met. As of March 31, 2019 and 2018, the Company had approximately $525,000 and $687,000, respectively, in deferred revenue related to its research service agreements, collaborative agreements, and licenses within the scope of Topic 606. In the twelve months ended March 31, 2019 the Company recognized revenue on approximately $178,000 that had been recorded as deferred revenue at March 31, 2018.

Effective April 1, 2018, the Company adopted the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), Topic 606, *Revenue from Contracts with Customers* (“Topic 606”). Under Topic 606, the Company recognizes revenue when (or as) the promised services are transferred to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those services. To determine revenue recognition for arrangements the Company concludes are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the performance obligation(s) are satisfied. At contract inception, the Company assesses the goods or services promised within each contract, assesses whether each promised good or service is distinct and identifies those that are performance obligations. The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Service revenues

The Company’s service-based business, Organovo, Inc., utilizes its NovoGen® bioprinting platform to provide customers access to its highly specialized tissues that model human biology and disease, and to *in vitro* testing services based on that technology. These contracts with customers contain multiple performance obligations including: (i) bioprinting tissues for the customer, (ii) reporting the results of tests performed on the printed tissues pursuant to the agreed upon work plan through exposure of the tissue to various factors (including the customer’s proprietary compound), and (iii) delivering specific byproduct study materials, which are satisfied, respectively, at each of the following points in time: (i) upon completion of manufacturing of the bioprinted tissue for the customer,

(ii) upon delivery of the report on tests performed on the tissue, and (iii) upon making certain study materials generated from the aforementioned testing process available to the customer. The customer does not have access or control of any performance obligation prior to the point in time of full completion of the corresponding performance satisfying event as defined above. Furthermore, although the service can be customized for each customer, it is not so highly customized as to not have an alternative use either to other customers or to the Company without significant economic consequences or rework. Accordingly, the Company's service-based business utilizes point-in-time recognition under Topic 606.

For service contracts, the Company allocates the transaction price to each performance obligation based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations. The transaction price for service business contracts is a fixed consideration.

Product sales, net

The Company's product-based business, Samsara Sciences, Inc., produces cell-based products for use in Organovo's 3D tissue manufacturing and for use by life science customers. The Company recognizes product revenue when the performance obligation is satisfied, which is at the point in time the customer obtains control of the Company's product, typically upon delivery. Product revenues are recorded at the transaction price, net of any estimates for variable consideration under Topic 606. The Company's process for estimating variable consideration does not differ materially from its historical practices. Variable consideration is estimated using the expected value method which considers the sum of probability-weighted amounts in a range of possible amounts under the contract. Product revenue reflects the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the individual contracts. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary materially from the Company's estimates, the Company will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted.

The Company provides no right of return to its customers except in cases where a customer obtains authorization from the Company for the return. To date, there have been no product returns. The Company will continue to assess its estimates of variable consideration as it accumulates additional historical data and will adjust its estimates accordingly.

Collaborative research, development, and licenses

The Company enters into collaborative agreements with partners that typically include one or more of the following: (i) non-exclusive license fees; (ii) non-refundable up-front fees; (iii) payments for reimbursement of research costs; (iv) payments associated with achieving specific development milestones; and (v) royalties based on specified percentages of net product sales, if any. At the initiation of an agreement, the Company analyzes whether it results in a contract with a customer under Topic 606 or in an arrangement with a collaborator subject to guidance under ASC 808, *Collaborative Arrangements* ("Topic 808").

The Company considers a variety of factors in determining the appropriate estimates and assumptions under these arrangements, such as whether the elements are distinct performance obligations, whether there are determinable stand-alone prices, and whether any licenses are functional or symbolic. The Company evaluates each performance obligation to determine if it can be satisfied and recognized as revenue at a point in time or over time. Typically, non-exclusive license fees, non-refundable upfront fees, and funding of research activities are considered fixed, while milestone payments are identified as variable consideration which must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

The Company's collaborative agreements that were not completed at the implementation of Topic 606 on April 1, 2018, consisted of research collaboration and limited technology access licenses. These agreements provide the licensee with a non-exclusive, non-transferable, limited, royalty-free technology license, including access to Organovo's proprietary bioprinter platform, training, and continued support by means of consumables and consultation throughout the duration of the contract. The Company has determined the intellectual property license is not distinct from the continued support promised under the agreement and is therefore a single combined performance obligation. The Company recognizes revenue for these combined performance obligations over time for the duration of the license period, as the combined performance obligation will not be fully satisfied until the end of the contract.

For the year ended March 31, 2019, all collaborations and licenses revenue was within the scope of Topic 606 and recognized accordingly. See "Note 4. Collaborative Research, Development, and License Agreements" for more information on the Company's collaborative agreements.

Grant revenues

In July 2017, the NIH awarded the Company a “Research and Development” grant totaling approximately $1,657,000 of funding over three years. The Company has concluded this government grant is not within the scope of Topic 606, as government entities do not meet the definition of a “customer” as defined by Topic 606, as there is not considered to be a transfer of control of goods or services to the government entity funding the grant. Additionally, the Company has concluded this government grant does not meet the definition of a contribution and is a non-reciprocal transaction, however, Subtopic 958-605, *Not-for-Profit-Entities-Revenue Recognition* does not apply, as the Company is a business entity and the grant is with a governmental agency.

Revenues from the grant are based upon internal costs incurred that are specifically covered by the grant, plus an additional rate that provides funding for overhead expenses. Revenue is recognized when the Company incurs expenses that are related to the grant. The Company believes this policy is consistent with the overarching premise in Topic 606, to ensure that it recognizes revenues to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which it expects to be entitled in exchange for those goods or services, even though there is no “exchange” as defined in the ASC. The Company believes the recognition of revenue as costs are incurred and amounts become earned/realizable is analogous to the concept of transfer of control of a service over time under ASC 606.

Revenue recognized under this grant was approximately $587,000 and $554,000 during the years ended March 31, 2019 and 2018, respectively.

Cost of revenue

The Company reported $0.5 million and $1.0 million in cost of revenue for the years ended March 31, 2019 and 2018, respectively. Cost of revenues consists of our costs related to manufacturing and delivering our product and service revenue.

Stock-based compensation

The Company accounts for stock-based compensation in accordance with the Financial Accounting Standards Board’s ASC Topic 718, *Compensation — Stock Compensation,* which establishes accounting for equity instruments exchanged for employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, 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).

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity-based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at its estimated fair value as it vests.

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, 2019 and 2018, the comprehensive loss was materially equal to the net loss and consisted of net loss and foreign currency translation. As of March 31, 2019, unrealized foreign currency translation previously recorded in other comprehensive loss was realized and recorded to other expense.

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, and shares subject to repurchase as the effect would be anti-dilutive. No dilutive effect was calculated for the years ended March 31, 2019 and 2018 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 14.4 million and 12.6 million for the years ended March 31, 2019 and 2018, respectively.

2. Fixed Assets

Fixed assets consisted of the following (in thousands):

	March 31, 2019	March 31, 2018
Construction in Progress	$ 47	$ —
Laboratory equipment	$ 3,690	$ 3,695
Leasehold improvements	1,809	2,177
Computer software and equipment	645	656
Furniture and fixtures	213	319
Vehicles	9	9
Fixed Assets, gross	6,413	6,856
Less accumulated depreciation	(4,581)	(4,068)
Fixed Assets, net	$ 1,832	$ 2,788

Depreciation expense for the years ended March 31, 2019 and 2018 was approximately $969,000 and $1,253,000, respectively.

3. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2019	March 31, 2018
Accrued compensation	$ 2,160	$ 2,735
Accrued legal and professional fees	152	99
Other accrued expenses	237	507
	$ 2,549	$ 3,341

4. Collaborative Research, Development, and License Agreements

In April 2015, the Company entered into a research collaboration agreement with a third party to develop custom tissue models for fixed fees. Based on the proportional performance achieved under this agreement for the years ended March 31, 2019 and 2018, the Company has recorded approximately $0 and $150,000, respectively, in collaboration revenue. The Company has completed its obligations under this agreement as of March 31, 2018.

In June 2016, the Company entered into a collaborative nonexclusive research affiliation with a university medical school and a non-profit medical charity, under which the Company received a one-time grant from the charity towards the placement of a NovoGen Bioprinter® at the university for the purpose of developing bioprinted tissues for skeletal disease research. The Company received an up-front payment in June 2016, which has initially been recorded as deferred revenue. Revenues of $0 and $65,000 were recognized under this agreement during the years ended March 31, 2019 and 2018, respectively. The Company does not anticipate recording any further revenue under this agreement.

In December 2016, the Company signed another collaborative nonexclusive research affiliation with a university medical school and a non-profit medical charity, under which the Company received a one-time grant from the charity towards the placement of a NovoGen Bioprinter® at the university for the purpose of developing an architecturally correct kidney for potential therapeutic applications. The Company received up-front payments in January and March of 2017, which has been recorded as deferred revenue. Revenue of $39,000 has been recorded under this agreement during each of the years ended March 31, 2019 and 2018.

In April 2017, the Company signed a collaborative non-exclusive research affiliation with a university, under which the Company received a one-time nonrefundable payment toward the placement of a NovoGen Bioprinter® at the university for the purpose of specific research projects mutually agreed upon by the university and the Company in the field of volumetric muscle loss. The Company received an up-front payment in May 2017, which was recorded as deferred revenue. Revenue of approximately $57,000 and $43,000 has been recorded during the year ended March 31, 2019 and 2018, respectively, beginning subsequent to the installation of the printer in July of 2017. In addition, during April 2017, the Company signed a non-exclusive patent license agreement with the university including an annual fee of $75,000 for each of two years for the license to Company patents for research use limited to the field of volumetric muscle loss. The Company received the first annual payment of $75,000 in April 2017, which was initially

recorded as deferred revenue. The Company received the second annual payment of $75,000 in May 2018. Revenue of $75,000 has been recorded under this agreement during each of the years ended March 31, 2019 and 2018.

In September 2017, the Company entered into an agreement with a company, under which the Company received a one-time non-refundable payment of $50,000 for limited use of a Company patent in reference to four bioprinters developed and placed at research and academic facilities. The Company has recorded $0 and $50,000 in revenue during the year ended March 31, 2019 and 2018, respectively.

5. Stockholders' Equity

Stock-based compensation expense and valuation information

Stock-based awards include stock options and restricted stock units under the 2012 Equity Incentive Plan, as amended ("2012 Plan") and Inducement Awards, performance-based restricted stock units under an Incentive Award Performance-Based Restricted Stock Unit Agreement, and rights to purchase stock under the 2016 Employee Stock Purchase Plan ("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 awards consists of the following (in thousands):

	Year Ended March 31, 2019	Year Ended March 31, 2018
Research and development	$ 911	$ 1,174
General and administrative	$ 4,282	$ 5,729
Total	$ 5,193	$ 6,903

The total unrecognized compensation cost related to unvested stock option grants as of March 31, 2019 was approximately $7,439,000 and the weighted average period over which these grants are expected to vest is 2.74 years.

The total unrecognized stock-based compensation cost related to unvested restricted stock units (not including performance-based restricted stock units) as of March 31, 2019 was approximately $3,234,000, which will be recognized over a weighted average period of 2.49 years.

The total unrecognized stock-based compensation cost related to unvested performance-based restricted stock units as of March 31, 2019 was approximately $136,000, which will be recognized over a weighted average period of 4.07 years.

The total unrecognized stock-based compensation cost related to unvested employee stock purchase plan ("ESPP") shares as of March 31, 2019 was approximately $10,000, which will be recognized over a period of 5 months.

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. 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, 2019	Year Ended March 31, 2018
Dividend yield	—	—
Volatility	72.99%	76.86%
Risk-free interest rate	2.75%	1.81%
Expected life of options	6.00 years	6.00 years
Weighted average grant date fair value	$ 0.84	$ 1.73

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Considering the expected life of these options, the Company determined that a blend of historical volatility and implied volatility of comparable companies whose share prices are publicly available is more reflective of market conditions and a better indicator of expected volatility than using purely Company-specific historical volatility. 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. Certain options granted to consultants are subject to variable accounting treatment and are required to be revalued until vested.

The fair value of each restricted stock unit 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. The fair value of ESPP shares was estimated at the purchase period commencement date using the following weighted average assumptions:

	Year Ended March 31, 2019	Year Ended March 31, 2018
Dividend yield	—	—
Volatility	43.7 - 80.2%	43.0% - 74.7%
Risk-free interest rate	1.85 - 2.52%	0.79% - 1.85%
Expected term	6 months	6 months
Grant date fair value	$ 0.29 - $0.45	$ 0.30 - $1.04

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. For the first full year of ESPP offering periods, beginning September 1, 2016, the Company determined that a blend of historical volatility and implied volatility of comparable companies whose share prices are publicly available was more reflective of market conditions and a better indicator of expected volatility than using purely Company-specific historical volatility. As of September 1, 2017 and the beginning of the second year of ESPP offering periods, the Company is using the Company-specific historical volatility rate as the 6-month historical volatility is now a better 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 of Directors of the Company approved the 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan authorized the issuance of up to 1,521,584 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, 2019, 896,256 shares under the 2008 Plan have been issued.

In January 2012, the Board of Directors of the Company approved the 2012 Plan. The 2012 Plan authorized the issuance of up to 6,553,986 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, performance shares, and other stock or cash awards. The Board of Directors 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 5,000,000 shares. In August 2015, the Board of Directors and stockholders of the Company approved an amendment to the 2012 Plan in August 2015 to further increase the number of shares of common stock that may be issued under the 2012 Plan by 6,000,000 shares. In July 2018, the Board of Directors 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 11,000,000 shares, bringing the aggregate shares issuable under the 2012 Plan to 28,553,986. The 2012 Plan as amended and restated became effective on July 26, 2018 and terminates ten years after such date. As of March 31, 2019, 13,464,720 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 SEC authorizing the issuance of 2,297,034 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 "Inducement Award Agreements").

On August 14, 2018 the Company filed a Registration Statement on Form S-8 with the SEC authorizing the issuance of 1,135,408 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 "Inducement Award Agreements").

The Company filed a shelf registration statement on Form S-3 (File No. 333-189995), or the 2013 Shelf, with the SEC on July 17, 2013 authorizing the offer and sale in one or more offerings of up to $100,000,000 in aggregate of common stock, preferred stock, debt securities, or warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities. This 2013 Shelf was declared effective by the SEC on July 26, 2013.

A shelf registration statement on Form S-3 (File No. 333-202382), or the 2015 shelf, was filed with the SEC on February 27, 2015 authorizing the offer and sale in one or more offerings of up to $190,000,000 in aggregate of common stock, preferred stock, debt securities, warrants to purchase common stock, preferred stock or debt securities, or any combination of the foregoing, either individually or as units comprised of one or more of the other securities. The 2015 shelf was declared effective by the SEC on March 17, 2015.

In December 2014, the Company entered into an equity offering sales agreement ("2014 Sales Agreement") with an investment banking firm. Under the terms of the sales agreement, the Company was eligible to offer and sell shares of its common stock, from time to time, through the investment bank in at-the-market offerings, as defined by the SEC, and pursuant to the Company's 2013 Shelf. During the year ended March 31, 2018, the Company issued 5,307,105 shares of common stock in at-the-market offerings under the sales agreement with net proceeds of $9.2 million. The 2014 Sales Agreement expired on March 17, 2018. Prior to its expiration, the Company sold an aggregate of 7,304,286 shares of common stock in at-the-market offerings under the 2014 Sales Agreement, with net proceeds of approximately $19.9 million.

On July 20, 2016, the Company filed a prospectus supplement to move the remaining shares of common stock that previously could have been sold pursuant to the 2014 Sales Agreement under the 2013 Shelf to the 2015 Shelf. On the same date, the Company filed a post-effective amendment to the 2013 Shelf de-registering all remaining securities that could have been offered by the Company pursuant to the 2013 Shelf.

On June 18, 2015, the Company entered into an Underwriting Agreement with Jefferies LLC and Piper Jaffray & Co., acting as representatives of the underwriters named in the 2015 Underwriting Agreement and as joint book-running managers, relating to the issuance and sale of 9,425,000 shares of the Company's common stock, par value $0.001 per share (the "2015 Offering"). The price to the public in the 2015 Offering was $4.25 per share, and the Underwriters agreed to purchase the shares from the Company pursuant to the 2015 Underwriting Agreement at a price of $3.995 per share. Under the terms of the 2015 Underwriting Agreement, the Company granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 1,413,750 shares. The Company issued 10,838,750 shares of common stock pursuant to the 2015 Underwriting Agreement, including shares issuable upon the exercise of the over-allotment option, with net proceeds of approximately $43.1 million, after deducting underwriting discounts and commissions and expenses payable by the Company. The shares were issued pursuant to the 2015 Shelf.

On October 25, 2016, the Company closed the issuance and sale of 10,065,000 shares (the "2016 Offering") of its common stock. The 2016 Offering was affected pursuant to an Underwriting Agreement (the "2016 Underwriting Agreement") with Jefferies LLC (the "Representative"), acting as representative of the underwriters named in the 2016 Underwriting Agreement. The price to the public in the 2016 Offering was $2.75 per share, and the underwriters purchased the shares from the Company pursuant to the 2016 Underwriting Agreement at a price of $2.585 per share. The net proceeds to the Company from the 2016 Offering were approximately $25.7 million after deducting underwriting discounts and commissions and expenses payable by the Company. The 2016 Offering was made pursuant to the Company's 2015 Shelf.

The Company has an effective shelf registration statement on Form S-3 (File No. 333-222929) and the related prospectus previously declared effective by the Securities and Exchange Commission (the "SEC") on February 22, 2018, as supplemented by a prospectus supplement, dated March 16, 2018 (the "2018 Shelf"), that expires on February 22, 2021. This replaces the 2015 Shelf which expired on March 17, 2018.

On March 16, 2018, the Company entered into a Sales Agreement ("2018 Sales Agreement") with H.C. Wainwright & Co., LLC and Jones Trading Institutional Services LLC (each an "Agent" and together, the "Agents"), 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" sales transactions having an aggregate offering price of up to $50,000,000 (the "Shares"). Any shares offered and sold will be issued pursuant to the Company's 2018 Shelf. During the year ended March 31, 2019, the Company issued 11,631,803 shares of common stock in at-the-market offerings under the sales agreement with net proceeds of $13.2 million.

As of March 31, 2019, the Company had sold an aggregate of 11,631,803 shares of common stock in at-the-market offerings under the 2018 Sales Agreement, with net proceeds of approximately $13.2 million. Based on these sales, the Company cannot raise more than an aggregate of $86.4 million future offerings under the 2018 Shelf, including the $36.4 million remaining available for future issuance through its at-the-market program under the 2018 Sales Agreement. The Company intends to use the net proceeds raised through any at-the-market sales for general corporate purposes, general administrative expenses, and working capital and capital expenditures.

In addition, during the years ended March 31, 2019 and 2018, the Company issued no shares of common stock upon exercise of no warrants, respectively.

During the years ended March 31, 2019 and 2018, the Company issued 622,192 and 500,000 shares of common stock upon exercise of 622,192 and 500,000 stock options, respectively.

Restricted stock units

During the year ended March 31, 2019, the Company issued restricted stock units for an aggregate of 1,916,802 shares of common stock to its employees and directors. These shares of common stock will be issued upon vesting of the restricted stock units.

On August 14, 2018, in connection with the appointment of a new Chief Medical Officer ("CMO"), the Company allocated 160,714 Restricted Stock Units ("RSUs") outside of the 2012 Plan. The Company intends for these to be "inducement awards" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While outside the Company's 2012 Plan, the terms and conditions of these awards are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan.

A summary of the Company's restricted stock unit (not including performance-based restricted stock units) activity for the year ended March 31, 2019 is as follows:

	Number of Shares		Weighted Average Price
Unvested at March 31, 2018	2,035,345	$	2.89
Granted	1,916,802	$	1.18
Vested	(766,187)	$	2.39
Canceled / forfeited	(1,105,237)	$	2.33
Unvested at March 31, 2019	2,080,723	$	1.80

Performance-based restricted stock units

On April 24, 2017, the Company issued a Performance-Based Restricted Stock Unit Award for 208,822 shares of common stock (the "PBRSU") to its newly hired Chief Executive Officer. The PBRSU was issued outside of the 2012 Plan, in the Inducement Award Agreement, as an "inducement award" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While outside the Company's 2012 Plan, the terms and conditions of this award are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan. On August 23, 2017, the Board of Directors formally approved the vesting criteria for the PBRSU. The vesting of the PBRSU is divided into five separate tranches each with independent vesting criteria. The first four tranches have performance criteria related to annual revenue goals with measurement at the end of fiscal year 2018 (20 percent), fiscal year 2019 (20 percent), fiscal year 2020 (20 percent), and fiscal year 2021 (20 percent). The fifth tranche has a performance metric related to a path to profitability goal measured as Negative Adjusted Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA") achievable at any point between the grant date and the end of fiscal year 2020 (20 percent). The number of units that ultimately vest for each tranche will range from 0 percent to 120 percent of the target amount, not to exceed 208,822 in aggregate. Based on changes to the Company's strategy, on December 12, 2018, the Board of Directors formally approved an amendment to the vesting criteria for the PBRSUs. As of March 31, 2019, 100% of the Negative Adjusted EBITDA tranche, or 41,764 shares had vested and 8,352 units had been forfeited. Based on the amendment to the vesting criteria, the remaining 158,706 units eligible to vest upon future performance were divided into three separate but equal tranches with independent vesting criteria based on the achievement of certain regulatory milestones. As of March 31, 2019, no tranches had vested.

Based on the amended PBRSU vesting terms, which the Company believes are probable of being achieved, a Type III modification, the modified grant date fair value of the PBRSUs is $165,000 of which one-third is being recognized over the expected service period of each tranche ending April 23, 2023. The Company began recording stock-based compensation expense for the initial performance tranches after the August 23, 2017 grant date when the initial financial performance goals were established and approved and has modified its recording of compensation expense in accordance with the amended performance tranches beginning on December 12, 2018.

A summary of the Company's performance-based restricted stock unit activity from March 31, 2018 through March 31, 2019 is as follows:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2018	200,470	$ 1.88
Granted	—	$ —
Vested	(41,764)	$ 1.88
Canceled / forfeited	—	$ —
Unvested at December 12, 2018	158,706	$ 1.88
Impact of modification	—	$ (0.74)
Granted	—	$ —
Vested	—	$ —
Canceled / forfeited	—	$ —
Unvested at March 31, 2019	158,706	$ 1.04

Stock options

During the year ended March 31, 2019 under the 2012 Equity Incentive Plan, 7,049,500 stock options were issued at various exercise prices.

On April 24, 2017, in connection with the appointment of a new CEO, the Company granted 2,088,212 stock options outside of the 2012 Plan. The Company intends for these to be "inducement awards" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While granted outside the Company's 2012 Plan, the terms and conditions of this stock option award are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan. On August 14, 2018, in connection with the appointment of a new CMO, the Company allocated 974,694 stock options outside of the 2012 Plan. The Company intends for these to be "inducement awards" within the meaning of Nasdaq Marketplace Rule 5635(c)(4). While outside the Company's 2012 Plan, the terms and conditions of these awards are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan. These stock options vest over a four-year period, with a quarter of the option shares vesting on the one-year anniversary of the vesting commencement date and the remaining options shares vesting in equal quarterly installments over the next 12 quarterly periods.

The following table summarizes stock option activity for the year ended March 31, 2019:

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2018	10,132,312	$ 4.01	$ 591,082
Options granted	8,024,194	$ 1.29	$ —
Options canceled	(5,495,050)	$ 4.37	$ —
Options exercised	(622,192)	$ 0.08	$ 561,591
Outstanding at March 31, 2019	12,039,264	$ 2.24	$ —
Vested and Exercisable at March 31, 2019	3,810,831	$ 3.68	$ —

The weighted-average remaining contractual term of stock options exercisable and outstanding at March 31, 2019 was approximately 6.9 years.

Employee Stock Purchase Plan

In June 2016, our Board of Directors adopted, and in August 2016 stockholders subsequently approved, the 2016 Employee Stock Purchase Plan ("ESPP"). The Company reserved 1,500,000 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 10,000 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, 2019, 96,385 shares were issued under the ESPP. At March 31, 2019, there were 1,188,718 shares remaining available for the purchase under the ESPP.

Warrants

From 2012 to 2014, the Company issued a total of 650,000 warrants to purchase common stock, in connection with consulting agreements, at prices ranging from $1.70 to $3.24, with lives ranging from two to five years, to be earned over service periods of up to six months. During the years ended March 31, 2019 and 2018, no warrants held by consultants were exercised. As of March 31, 2019, none of these warrants are outstanding.

Additionally, during September 2014, the Company issued 50,000 warrants to purchase common stock, at a price of $7.62 with a life of five years to a consultant in recognition of services previously provided. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. As of December 31, 2014, the full amount of the warrants related to these services, approximately $237,000 had been recognized.

In November 2014, in connection with a consulting agreement, the Company issued 145,000 warrants to purchase common stock, at a price of $6.84, with a life of five years, to be earned over a seventeen month service period ended on March 31, 2016. The final number of vested warrant shares was 95,000, based on management's judgment of the satisfaction of specific performance metrics. The fair value of the warrants was estimated to be approximately $74,000, which was revalued and amortized over the term of the consulting agreement. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using a volatility rate of 73.4% and a risk-free interest rate factor of 1.21%, was used to determine the value as of March 31, 2016. The Company recognized approximately $6,000 during the year ended March 31, 2016 related to these services. As of March 31, 2016, these warrants were fully expensed.

The following table summarizes warrant activity for the year ended March 31, 2019:

	Warrants		Weighted-Average Exercise Price
Balance at March 31, 2018	220,000	$	7.19
Granted	—	$	—
Expired / Canceled	(75,000)	$	7.36
Exercised	—	$	—
Balance at March 31, 2019	145,000	$	7.11

The warrants outstanding at March 31, 2019 are exercisable at prices of $6.84 and $7.62 per share and have a weighted average remaining term of approximately 0.53 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at March 31, 2019:

Common stock warrants outstanding	145,000
Common stock options outstanding and reserved under the 2012 Plan	8,976,358
Common stock reserved under the 2012 Plan	13,464,720
Common stock reserved under the 2016 Employee Stock Purchase Plan	1,188,718
Restricted stock units outstanding under the 2012 Plan	1,920,009
Common stock options outstanding and reserved under the Incentive Award Agreement	3,062,906
Restricted stock units outstanding under the Incentive Award Agreement	160,714
Performance-based restricted stock units outstanding under the Incentive Award Agreement	158,706
Total	29,077,131

6. Commitments and Contingencies

Operating leases

Since July 2012, the Company has leased its main facilities at 6275 Nancy Ridge Drive, San Diego, CA 92121. The lease, as amended in 2013, 2015, 2016, 2018, and 2019, consisted of approximately 45,580 rentable square feet containing laboratory, clean room and office space. Monthly rental payments are currently approximately $120,000 per month with 3% annual escalators. The lease term for 14,685 of the total rentable square footage was amended to accelerate the expiration date from December 15, 2018 to October 31, 2018. On November 30, 2018, the Company agreed to extend the term for the remainder of the total rentable square footage under the lease from August 31, 2021 to August 31, 2024 in exchange for $500,000 of landlord funded tenant improvements and a rescission of its option to terminate the lease on or after September 1, 2019 with 9 months prior written notice.

The Company also previously leased a second facility from February 1, 2015 through January 31, 2018 consisting of 5,803 rentable square feet of office and lab space located at 6310 Nancy Ridge Drive, San Diego, CA 92121, with a monthly rent of $12,000 commencing on April 1, 2015, which increased by 3% each 12-month anniversary of the 36 month lease.

The Company records rent expense on a straight-line basis over the life of the leases and records the excess of expense over the amounts paid as deferred rent. In addition, one of the leases provides for certain improvements made for the Company's benefit to be funded by the landlord. Such costs, totaling approximately $518,000 to date, have been capitalized as fixed assets and included in deferred rent. As a result of the Company's lease amendment, which extends the term of the lease from August 31, 2021 to August 31, 2024, the landlord agreed to fund up to $500,000 in additional tenant improvements, which have not been capitalized or included in deferred rent

Rent expense was approximately $1,173,000 and $1,458,000 for the years ended March 31, 2019 and 2018, respectively.

Future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of March 31, 2019, are as follows (in thousands):

Fiscal year ended March 31, 2020	$	1,084
Fiscal year ended March 31, 2021		1,116
Fiscal year ended March 31, 2022		1,158
Fiscal year ended March 31, 2023		1,183
Fiscal year ended March 31, 2024		1,218
Thereafter		514
Total	$	6,273

Legal matters

In addition to commitments and obligations in the ordinary course of business, the Company may be subject, from time to time, to various claims and pending and potential legal actions arising out of the normal conduct of its business. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its financial statements. Because litigation is inherently unpredictable and unfavorable resolutions could occur, assessing litigation contingencies is highly 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 such 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.

As of March 31, 2019, the Company had no claims outstanding.

7. Licensing Agreements and Research Contracts

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 2018, and January 2019 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, 2019 and 2018.The license agreement

terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement, which are expected to expire after 2029.

In March 2010, 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 engineered biological nerve grafts. 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 depending on the level of net sales achieved by the Company each year. The license agreement terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement. No payments have been made in the years ended March 31, 2019 and 2018.

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 is 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. The annual minimum royalty is creditable against royalties owed during the same calendar year.

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

	March 31, 2019	March 31, 2018
License fees	$ 218	$ 218
Less accumulated amortization	(81)	(67)
License fees, net	$ 137	$ 151

The above license fees, net of accumulated amortization, are included in Other Assets in the accompanying balance sheets and are being amortized over the life of the related patents. Amortization expense of licenses was approximately $14,000 and $13,600 for the years ended March 31, 2019 and 2018, respectively. At March 31, 2019, the weighted average remaining amortization period for all licenses was approximately 11 years. The annual amortization expense of licenses for the next five years is estimated to be approximately $14,000 per year.

8. Income Taxes

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, 2019 and March 31, 2018 (in thousands):

	March 31, 2019	March 31, 2018
Deferred tax assets:		
Net operating loss carry forwards	$ —	$ —
Research and development credits	—	—
Depreciation and amortization	28	25
Accrued expenses and reserves	886	1,050
Stock compensation	3,941	3,753
Other, net	20	8
Total deferred tax assets	4,875	4,836
Valuation allowance	(4,875)	(4,836)
	$ —	$ —

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 our net operating loss and research tax credit carryforwards to offset taxable income may be limited based on cumulative changes in ownership. We

have not completed an analysis to determine whether any such limitations have been triggered as of March 31, 2019. Until this analysis is completed, we have removed the deferred tax assets related to net operating losses and research credits from our 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 increased by approximately $39,000 and decreased by approximately $3.2 million for the years ended March 31, 2019 and 2018, respectively.

The Company had federal and state net operating loss carryforwards of approximately $170.3 million and $49.2 million, respectively, as of March 31, 2019. The federal net operating loss carryforward generated during the year ended March 31, 2019 of approximately $24.1 million will carryforwards indefinitely and be available to offset up to 80% of future taxable income each year. Federal net operating losses generated previously 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 $4.0 million and $3.6 million at March 31, 2019, respectively. The federal research tax credit carryforwards begin expiring in 2028. The state research tax credit carryforwards do not expire.

The Tax Cuts and Jobs Act ("the Act") was enacted on December 22, 2017. The Act (i) reduces the US federal corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, (ii) generally reduces a company's ability to utilize accumulated net operating losses, an (iii) requires the calculation of a one-time transition tax on certain previously unrepatriated foreign earnings and profits ("E&P"). The Act also impacts the valuation of a company's deferred tax assets and liabilities. The Company applied the guidance in Staff Accounting Bulletin No. 118 when accounting for the enactment-date effects of the Act in the year ended March 31, 2019.

As of December 31, 2017, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future (which is generally 21%), by recording a provisional amount of $2.7 million, which was fully offset by the valuation allowance.

Due to the deficit in post-1986 E&P from the foreign subsidiary, there was no increase in income tax expense related to the one-time transition tax. As of March 31, 2019, the Company has completed its accounting for the Act and determined that no adjustment was necessary to the provisional amounts.

The Company did not record any accruals for income tax accounting uncertainties for the year ended March 31, 2019.

The Company's policy is to recognize interest and penalties that would be assessed in relation to the settlement value of unrecognized tax benefits as a component of income tax expense. The Company did not accrue either interest or penalties from inception through March 31, 2019.

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 various state jurisdictions. As of March 31, 2019, 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.

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 primarily 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, 2019.

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 and on terms and conditions it believes are as fair as those it offers and receives from independent third parties. These agreements are ratified by the Company's Board of Directors or a committee thereof pursuant to its related party transaction policy.

In August 2017, the Company entered into a services agreement with Cirius Therapeutics, Inc. ("Cirius"), an entity for which Robert Baltera, Jr., a director of the Company, serves as Chief Executive Officer. Under this agreement and its amendments, the Company has provided ExVive™ Liver Tissue Services for Cirius in the amount of $281,000 to date, of which $120,000 and $161,000 was recognized as revenue in the years ended March 31, 2019 and March 31, 2018, respectively.

In November 2017, the Company entered into a collaboration agreement with Viscient Biosciences ("Viscient"), an entity for which Keith Murphy, a former director and former Chief Executive Officer of the Company, serves as Chief Executive Officer. Under this agreement and its amendments, the Company provided research services amounting to $358,000 recognized as revenue in the year ended March 31, 2018. In September 2018, Viscient purchased study materials from Organovo in the amount of $2,000 to date, pursuant to the terms of a Quote, of which $2,000 was recognized as revenue in the year ended March 31, 2019. In November 2018, Viscient executed a Quote to purchase research services from Organovo in the amount of $142,000, of which $42,000 was recognized as revenue in the year ended March 31, 2019. Additionally, Viscient purchased primary human cell-based products from our subsidiary, Samsara, in the amount of $165,000 to date, pursuant to the terms of multiple Quotes entered into throughout the 2018 and 2019 fiscal years, of which $96,000 and $14,000 were recognized as revenue in the years ended March 31, 2019 and March 31, 2018, respectively.

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, 2019 and 2018 were approximately $240,000 and $337,000, respectively.

12. Recent Accounting Pronouncements

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

Adoption of New Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, which supersedes most existing revenue recognition guidance in GAAP, including most industry-specific guidance. The standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The new standard was originally effective for public companies for annual reporting periods beginning after December 15, 2016, with no early application permitted. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers*, which deferred by one year the effective date for all entities, with application permitted as of the original effective date. The standard allows for either a full retrospective or modified retrospective method of adoption. The Company adopted this standard on its effective date, April 1, 2018, under the modified retrospective method of adoption. Under this method, entities recognize the cumulative impact of applying the new standard at the date of adoption without restatement of prior periods presented. The cumulative effect of applying the new standard to contracts that were not completed as of April 1, 2018 did not have a material impact on the Company's consolidated financial position, results of operations, or cash flows. The new standard also requires enhanced disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. See "Note 2. Summary of Significant Accounting Policies" for further discussion. Topic 606 supersedes the revenue recognition requirements in ASC Topic 605, *Revenue Recognition* ("Topic 605"). While results for reporting periods beginning after April 1, 2018 are presented under Topic 606, all prior period amounts are not adjusted and continue to be reported under the accounting standards in effect during these prior periods. The accounting policies for revenue recognition for periods prior to April 1, 2018 are described in "Note 1. Description of Business and Summary of Significant Accounting Policies". Adoption of this ASC did not have a material impact on the Company's financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows* (Topic 230): *Restricted Cash*. The standard clarifies the presentation of restricted cash and cash equivalents and requires companies to include restricted cash and cash equivalents in the beginning and ending balances of cash and cash equivalents on the statement of cash flows. The standard also requires additional disclosures to describe the amount and detail of the restriction by balance sheet line item. The new standard was effective for the Company on April 1, 2018. The Company adopted this standard using the retrospective transition method by restating its condensed consolidated statements of cash flows to include restricted cash of $0.1 million in the beginning and ending cash, cash equivalents,

and restricted cash balance. Net cash flows for the twelve months ended March 31, 2018, did not change as a result of including restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period amounts presented on the statements of cash flows.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation - Stock Compensation* (Topic 718): *Scope of Modification Accounting*, which provides clarity and guidance around which changes to the terms or conditions of a stock-based payment award require an entity to apply modification accounting. The new standard was effective for annual reporting periods beginning after April 1, 2018, and interim periods within those annual reporting periods. The adoption of this guidance had no impact on the Company's financial statements.

In December 2017, the United States ("U.S.") enacted the Tax Cuts and Jobs Act (the "2017 Act"), which changes existing U.S. tax law and includes various provisions that are expected to affect public companies. The 2017 Act (i) changes U.S. corporate tax rates, (ii) generally reduces a company's ability to utilize accumulated net operating losses, and (iii) requires the calculation of a one-time transition tax on certain previously unrepatriated foreign earnings and profits ("E&P"). The 2017 Act will also impact estimates of a company's deferred tax assets and liabilities. The Company applied the guidance in Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* ("SAB 118"), which resulted in a minimal impact to its financial statements. See "Note 8. Income Taxes" for more information.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes the lease guidance under ASC 840 – Leases. The new accounting standard requires an entity to recognize right-of-use assets and corresponding lease liabilities on the balance sheet for all leases with terms of more than 12 months and to disclose key information about leasing arrangements. This new guidance is effective for the Company on April 1, 2019, with early adoption permitted in any interim or annual period. The Company will adopt ASU 2016-02 on April 1, 2019 and will elect the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and will not restate prior periods. The Company will elect the package of practical expedients permitted under the transition guidance, but not the hindsight practical expedient. As a result of the adoption, the Company will record right-of-use assets and liabilities of approximately $4.5 million and $5.0 million, respectively, on its Consolidated Balance Sheet as of April 1, 2019, primarily associated with its operating leases.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share* (Topic 260); *Distinguishing Liabilities from Equity* (Topic 480); *Derivatives and Hedging* (Topic 815): *(Part I) Accounting for Certain Financial Instruments with Down Round Features*, (Part II) *Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. These amendments simplify the accounting for certain financial instruments with down round features. The amendments require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. Companies that provide earnings per share (EPS) data will adjust their basic EPS calculation for the effect of the feature when triggered (i.e., when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down round feature) and will also recognize the effect of the trigger within equity. This standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The adoption of this guidance will have no impact on the Company's financial statements as the Company's only derivative liabilities were all exercised or expired as of March 31, 2017.

In February 2018, the FASB issued ASU No. 2018-02, *Income Statement – Reporting Comprehensive Income* ("Topic 220"), which allows stranded tax effects resulting from the Tax Cuts and Jobs Act to be reclassified from accumulated other comprehensive income to retained earnings. The amendment only relates to the reclassification of the income tax effects of the Tax Cuts and Jobs Act; thus, the underlying guidance relating to the effect of a change in tax laws be included in income from continuing operations is not affected. The amendments in Topic 220 are effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. This new guidance is effective for the Company on April 1, 2019. The requirements of ASU 2018-02 are not expected to have a significant impact on the Company's financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation - Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting*, which aligns the measurement and classification guidance for share-based payment to non-employees with the guidance for share-based payments to employees. Under the new guidance, the measurement period for equity-classified non-employee awards will be fixed at the grant date. This update is effective for annual periods beginning after December 15, 2018, and interim periods within those periods and early adoption is permitted. This new guidance is effective for the Company on April 1, 2019. The requirements of ASU 2018-07 are not expected to have a significant impact on the Company's financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which provides guidance on whether certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606. The amendments in this update provide more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. The key improvements to GAAP for collaborative arrangements resulting from this amendment are to (i) clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit-of-account, (ii) add unit-of-account guidance in Topic 808 to align with the guidance in Topic 606, and (iii) require that in a

transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments in this ASU are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years with early adoption permitted. This new guidance is effective for the Company on April 1, 2020. The Company is currently evaluating the impact that this guidance will have on its financial statements.

13. Subsequent Events

Between April 1, 2019 and the date of filing, the Company issued 6,087,382 shares of its common stock pursuant to its ATM facility for net proceeds of approximately $5.0 million.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

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

Under the supervision of our Chief Executive Officer 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 principal executive officer 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 and the report of our independent registered public accounting firm is included on page F-3 of this Annual Report.

Management's 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 Board of Directors regarding the preparation and fair presentation of our consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, under the supervision of our Chief Executive Officer and our Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of March 31, 2019. 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, 2019.

Auditor's Attestation Report on Internal Control Over Financial Reporting

Mayer Hoffman McCann P.C., our independent registered public accounting firm, has audited our consolidated financial statements included in this Annual Report and has issued an attestation report, included herein, on the effectiveness of our internal control over financial reporting as of March 31, 2019.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of the fiscal year ended March 31, 2019 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 Chief Executive Officer 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.

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 2019 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our 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 2019 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our 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, 2019:

Plan category	(A) Number of securities to be issued upon exercise/vesting of outstanding options, warrants, units and rights (2)	(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)) (3)
Equity compensation plans approved by security holders (1)	11,041,367	$ 1.91	14,653,438
Equity compensation plans not approved by security holders (4)	3,382,326	$ 2.01	—

(1) Includes the 2008 Equity Incentive Plan, the Amended and Restated 2012 Equity Incentive Plan (the "2012 Plan"), and the 2016 Employee Stock Purchase Plan (the "ESPP").

(2) Includes stock options and warrants to purchase 8,976,358 shares of common stock with a per share weighted-average exercise price of $2.24. Also includes 1,920,009 restricted stock units with no exercise price.

(3) Includes 1,188,718 shares of common stock available for purchase under the ESPP as of March 31, 2019.

(4) Includes 3,062,906 stock options with a per share exercise price of $2.22, 158,706 performance-based restricted stock units with no exercise price, and 160,714 restricted stock units with no exercise price, collectively, the "Inducement Award Agreements," granted to the Chief Executive Officer and Chief Medical Officer upon commencement of their employment. While outside the Company's 2012 Plan, the terms and conditions of this award are consistent with awards granted to the Company's executive officers pursuant to the 2012 Plan.

Information relating to the beneficial ownership of our common stock will be included in the proxy statement for the 2019 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our 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 2019 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our 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 2019 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our 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, 2019 and 2018 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
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	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)
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. 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.15 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
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	First Amendment to Lease, dated December 4, 2013, by and between Organovo, Inc. and ARE-SD Region No. 25, LLC. (incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on February 6, 2014)
10.9+	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)
10.10+	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)
10.11+	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)
10.12+	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)
10.13+	Offer Letter, between Craig Kussman and Organovo Holdings, Inc., dated July 29, 2016 (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 2, 2016)
10.14+	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)
10.15+	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)
10.16+	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)

Exhibit No.	Description
10.17+	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)
10.18+	Continued Service, Consulting and Separation Agreement, dated April 7, 2017, by and between Organovo Holdings, Inc. and Keith Murphy (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 11, 2017)
10.19+	Offer Letter, dated April 11, 2017, by and between Organovo Holdings, Inc. and Taylor Crouch (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on April 11, 2017)
10.20+	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)
10.21+	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)
10.22+	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 July 27, 2018)
10.23+	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)
10.24+	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)
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	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase*
101.DEF	XBRL Taxonomy Extension Definition Linkbase*
101.LAB	XBRL Taxonomy Extension Label Linkbase*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase*

* 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.

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/ Taylor Crouch
Taylor Crouch
Chief Executive Officer and President

Date: June 3, 2019

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Taylor Crouch and Jennifer Bush, 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/ Taylor Crouch Taylor Crouch	Chief Executive Officer and President (Principal Executive Officer)	June 3, 2019
/s/ Craig Kussman Craig Kussman	Chief Financial Officer (Principal Financial Officer)	June 3, 2019
/s/ Kirk Malloy Kirk Malloy	Chairman of the Board	June 3, 2019
/s/ Robert Baltera, Jr. Robert Baltera, Jr.	Director	June 3, 2019
/s/ James Glover James Glover	Director	June 3, 2019
/s/ Tamar Howson Tamar Howson	Director	June 3, 2019
/s/ Mark Kessel Mark Kessel	Director	June 3, 2019
/s/ Richard Maroun Richard Maroun	Director	June 3, 2019
/s/ David Shapiro David Shapiro	Director	June 3, 2019
/s/ Carolyn D. Beaver Carolyn D. Beaver	Director	June 3, 2019

Exhibit 21.1

Subsidiaries of Organovo Holdings, Inc.

I. Organovo, Inc., a Delaware corporation

   a. Organovo UK Ltd, a United Kingdom private company

II. Samsara Sciences, 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. 333-226839, 333-226837, 333-217437, 333-213345, 333-209395, 333-192248 and 333-181324 on Forms S-8 and Registration Statement No. 333-222929 on Form S-3, of our reports dated June 3, 2019, relating to the consolidated financial statements of Organovo Holdings, Inc. ("Company"), and the effectiveness of Organovo Holdings, Inc.'s internal control over financial reporting, included in this Annual Report on Form 10-K for the year ended March 31, 2019.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
June 3, 2019

Exhibit 31.1

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

I, Taylor Crouch, Chief Executive Officer and President 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(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 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 3, 2019

/s/ Taylor Crouch
Taylor Crouch
Chief Executive Officer and President (Principal Executive Officer)

Exhibit 31.2

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

I, Craig Kussman, 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 consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(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 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 3, 2019

/s/ Craig Kussman

Craig Kussman
Chief Financial Officer
(Principal Financial and Accounting 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, 2019, as filed with the Securities and Exchange Commission (the "Report"), Taylor Crouch, Chief Executive Officer and President of the Company, and Craig Kussman, Chief Financial Officer of the Company, do hereby certifies, 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 3, 2019

/s/ Taylor Crouch
Taylor Crouch
Chief Executive Officer and President (Principal Executive Officer)

/s/ Craig Kussman
Craig Kussman
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.