ORGANOVO HOLDINGS, INC.
Form 10-K
May 31, 2018

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, 2018

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	Name of each exchange on which registered
Common Stock, par value $0.001 per share	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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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	(Do not check if a smaller reporting company)	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, 2017, the last trading day of the registrant's second fiscal quarter, was $232,023,855. 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 May 29, 2018 was 111,126,625.

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 2018 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, 2018

Table of Contents

Important Information Regarding Forward-Looking Statements

Portions of this annual report on Form 10-K (including information incorporated by reference) include "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. 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 on Form 10-K, as well as other portions of this annual report on Form 10-K. 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 on Form 10-K. 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 a unique set of therapeutic and drug profiling capabilities based on its revolutionary ability to 3D bioprint tissues that emulate human biology and disease. We are developing in vivo liver tissues to treat a range of rare, life-threatening diseases, for which there are few current treatment options other than organ transplantation. Our first program, which focuses on a rare disease known as Alpha-1-antitrypsin deficiency ("A1AT"), received the U.S. Food and Drug Administration's ("FDA") orphan drug designation in December 2017 and is targeted for an Initial New Drug Application ("IND") filing in calendar-year 2020. We are also capitalizing on 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 are accessing these diseased tissue platforms through a growing number of collaborative, revenue-generating agreements.

We aim to grow revenue through product sales, fee-based service agreements and collaborations for our in vitro tissues to help provide a portion of the required cash flow to support our in vivo therapeutics development program. Our in vitro and in vivo tissues are both built upon the same proprietary 3D bioprinting technology and our highly specialized cells, providing valuable synergies in advancing each of our businesses. We are striving to change the face of medicine by enabling translational drug discovery and through clinical development of novel approaches to treating disease.

In the near-term, we will focus on several value-driving inflection points including:

- Partnering with the FDA and expert advisers to finalize the confirmatory animal studies and scientific validation path leading to a successful pre-IND meeting for our first liver therapeutic tissue indication, A1AT;
- Validating a second unmet disease area using the same healthy liver therapeutic tissue patch and moving into an additional IND-track program;
- Deploying a broad range of proof-of-concept disease modeling capabilities in NASH to enable steady-state, high content drug screening collaborations with current and prospective clients;
- Growing our Samsara Sciences, Inc. ("Samsara") division's cell-based product revenue, as well as continuing to generate revenue from grant and licensing agreements; and
- Continuing to present and publish major scientific findings of our tissue platform.

Over the long-term, we will 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 Disease, Fast Track and Breakthrough designations;
- Achieving operational breakeven profitability for our commercial business by securing significant 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 and extended lifespan of our 3D human tissues make them ideally suited for the assessment of drug safety and efficacy, and as implantable tissue patches for augmentation or replacement of organ function. 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. Cells within our bioprinted tissues develop extensive cell-cell interactions and features analogous to those found in native tissues, which drives their extended viability and function outside of the body. Unlike the majority of engineered tissue strategies, where biomaterials are the major component of the tissue and cells are present in relatively low proportions, the Organovo platform builds tissues that are comprised almost entirely of human cells with minimal usage of any biomaterial components. Prior to the invention of our NovoGen® bioprinting platform, the most common fabrication method for 3D tissues was the use of biomaterial scaffolding into which cells were incorporated. While useful for some applications, scaffold-based engineered tissues lack features of native tissue that are critical to function such as dense cellularity where cells have intimate contact with neighboring cells, and an intricate architecture created by the spatial arrangement of specific cellular compartments relative to each other. Moreover, we focus exclusively 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 enables 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 pediatric conditions and/or involving breakthrough regenerative medicine treatment strategies, which is strongly aligned with our market opportunities. Our ultimate goal is to construct surgically implantable tissues that restore significant functional mass to a damaged tissue or organ after delivery. It is our belief that, in most cases, whole organ replacement will 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 may develop specific tissue targets with partners through technology licenses and royalty-bearing deals, or may self-fund the development of our tissue targets through preclinical and clinical development.

During the past year, 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 a high degree of disease clearing through 125 days post-implantation, a significant increase in duration from our earlier preclinical studies. These results demonstrate a significant increase in the reported duration of implanted human hepatocyte synthetic function, demonstrating sustained 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 suggested an approximately 75 percent reduction in the pathologic hallmarks of the disease in treated animals versus non-treated animals in the region of implant.

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 key aspects of human tissues, 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. During the past year, 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 largely lacking in other commercially available liver disease models, are attainable in the fully human 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 becoming an industry-leading 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 custom disease models and therapeutic tissues. In March 2018, we announced a multi-year agreement with Lonza Bioscience Solutions, representing Samsara's largest contract to date, with one of the world's leading suppliers to the pharmaceutical, biotech and specialty ingredient markets.

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, etc.). 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 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.

Our efforts in systems engineering are focused on ensuring the continuous improvement and evolution of our NovoGen Bioprinters® to meet the needs of internally driven and externally partnered tissue programs. To date, several generations of NovoGen Bioprinters® have been designed, developed, and are being used for tissue production.

Generation of bio-ink comprising human cells is the first step in 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 might consist of two to three distinct bio-inks that are each made from a single cell type or combination of multiple cell types. Our NovoGen Bioprinters® can optionally dispense bio-inert hydrogels to 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"), Murdoch Children's Research Institute ("MCRI"), and the University of Virginia ("UVA"). 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, ultimately creating future opportunities for our commercial products and intellectual property licensing. Our collaborations with pharmaceutical and biotechnology companies generally involve the partner providing research funding to cover, in part or in full, the scope of work. 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 had 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 has begun providing us with qualified liver cells for use in our 3D Human 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 enable the generation and optimization of unique, scaffold-free or hybrid tissue prototypes and ultimately support production of the tissue. We may undertake these efforts alone, or as partnered projects with leading therapeutic companies seeking to develop a therapeutic tissue product for a specific application. There are a number of companies pursuing the discovery, development, and commercialization of tissue-based products for a variety of applications, including but not limited to Organogenesis, Poietis and Aspect Biosystems. Primarily, our clinical competition may come from other biotech companies targeting small and large molecule strategies and cell engineering approaches for treating one or more of the same diseases we elect to target. 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 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 on a cost basis.

Research and Development

We continuously engage in research and development to enhance our platform technology, to develop new products and service offerings and to pursue our therapeutic initiatives. Our research and development efforts include internal initiatives as well as collaborative development opportunities with third parties. Our research and development expenses were $18.0 million, $19.5 million and $18.0 million for the fiscal years ended March 31, 2018, 2017, and 2016, respectively. We 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 products and services we develop. We intend to continue our focus on research and development as a key strategy for the growth of our business.

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 18 issued U.S. patents and more than 40 issued international patent applications. We solely or jointly own, or hold exclusive licenses to more than 18 pending U.S. patent applications and more than 90 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, 13 issued international patents and 2 pending international applications. Dr. Gabor Forgacs, one of our founders and a former George H. Vineyard Professor of Biophysics at MU, was one of the co-inventors of all of these works (collectively, the "Forgacs Intellectual Property"). The Forgacs Intellectual Property provides us with intellectual property rights relating to cellular aggregates, the use of cellular aggregates to create engineered tissues, and the use of cellular aggregates to create engineered tissue with no scaffold present. The intellectual property rights derived from the Forgacs Intellectual Property also enables us to utilize our NovoGen 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 application, one issued international patent and 17 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 6 issued U.S. patents and 7 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 and 9,855,369; Australia Patent Nos. 2,011,318,437, 2,015,202,836, and 2,013,249,569; China Patent No. ZL201180050831.4; Hong Kong Patent No. HK1187024, Israel Patent No. 225392, and Russia Patent No. 2,560,393. 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 in relation to 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 No. 9,222,932, U.S. Patent No. 9,442,105, Singapore Patent No. 1,120,157,202Y, Israel Patent No. 241,055, Australia Patent No. 201,423,6780, Canada Patent No. 2,903,844, and Russia Patent No. 2625016. Our ExVive™ Human Kidney Tissue is protected by U.S. Patent No. 9,481,868. 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 types of tissues, 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

We are not aware of any current U.S. Food and Drug Administration (FDA) regulatory requirements for sale or use of our in vitro 3D tissues and models in research applications, and we are not currently conducting research services pursuant to Good Laboratory Practice ("GLP"). GLP data is required in the development of any human therapeutic, and our technology platform has been designed to support compliance with GLP, although no independent certification has been performed to date to confirm this compliance.

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) and cGMP (current Good Manufacturing 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 product candidate for its intended use;
- Submission to the FDA of an Biologic License Application ("BLA"); and
- FDA review and approval, or otherwise, of a BLA.

The testing and approval process requires substantial time, effort, and financial resources. The resource investment necessary to meet the requirements of these regulations will fall on our collaborating partners, or may be shared with us, to the extent that we are developing proprietary products that are the result of a collaboration effort. 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. Although we believe we have adequate available sources of raw materials, there can be no guarantee that we will be able to access the quantity of raw material needed to meet our demands on a timely basis or at a cost effective price.

Employees

As of May 1, 2018, we had approximately 75 full-time employees. 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.

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, and we make them available on the website as soon as reasonably possible after we file them with the SEC. 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.

The reports we file with the SEC can also be inspected and copied at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. Investors may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. Investors can request copies of these documents upon payment of a duplicating fee by writing to 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 Business and Our Industry

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

We were incorporated in 2007, and opened our laboratories in San Diego, California in January 2009. Since our incorporation, we have focused primarily on the development of our platform technology and the development of our biological research, drug discovery and therapeutic products and services based on that technology. We announced the initiation of contracting for our ExVive™ Human Liver Tissue and ExVive™ Human Kidney services in November 2014 and September 2016, respectively, for use in toxicology and other preclinical drug testing. We only recently began focusing on offering our tissues to support in vitro disease modeling. Because of our limited commercial operating history, investors have limited historical financial or other information upon which to base an evaluation of our performance and future prospects. Moreover, our future prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations and competing in new and rapidly developing technology areas. Additionally, our therapeutic tissue programs are in the early stages of development, and there is no assurance if or when we will obtain the required regulatory approvals to be marketing a therapeutic product. We have generated operating losses each year since we began operations, including $35.3 million, $38.6 million and $38.6 million for the years ended March 31, 2018, 2017, and 2016, respectively. As of March 31, 2018, we had incurred cumulative operating losses of $181.1 million and cumulative net losses totaling $234.1 million. We expect to incur substantial additional operating losses over the next several years as our research,

development, regulatory and commercial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things:

- successfully completing the required preclinical and clinical trials required to obtain regulatory approval for our therapeutic tissue program;
- successfully developing drug discovery, biological research, and therapeutic tools, products and services that are more effective than existing technologies and can be offered at competitive prices;
- successfully completing studies and providing the technical information required to support market acceptance of our products, services and technology;
- successfully completing our existing collaborative agreements, and entering into new collaborative relationships;
- successfully developing an effective sales and marketing infrastructure to commercialize our products and services;
- entering into successful manufacturing, distribution and sales and marketing arrangements with third parties; and
- raising sufficient funds to finance our activities and long-term business plan.

We might not succeed at any of these undertakings. If we are unsuccessful at one or more of these undertakings, our business, prospects, and results of operations will be materially adversely affected.

We are an early-stage company with an unproven business strategy, and may never achieve profitability.

We are in the early stages of using our proprietary platform technology to develop and commercialize functional human tissues that can be employed in drug discovery and development and in biological research. We are also in the early stages of developing and completing preclinical studies for our first therapeutic liver tissue candidate, which focuses on a rare disease known as Alpha-1-antitrypsin deficiency ("A1AT"). Our success will depend upon the commercial adoption of our platform technology, as well as on our ability to determine which drug discovery, biological research, and therapeutic tools, products and services can be successfully developed and commercialized with our platform technology. Our success will also depend on our ability to increase customer awareness and demand for our products and services, to enter into additional collaboration agreements on favorable terms and to select an appropriate commercialization strategy for the products and services we or our collaborators choose to pursue. Additionally, our success will depend on our ability to successfully develop, complete preclinical and clinical studies and eventually obtain regulatory approval for any therapeutic tissue candidates we elect to pursue. If we are not successful in implementing our product development, regulatory and commercialization strategies, which are new and unproven, and/or if we underprice or overrun our cost estimates for our contracts or our development, regulatory and commercialization activities, we may never achieve profitability, or even if we achieve profitability, we may not be able to maintain or increase our profitability.

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

We may not correctly predict the amount or timing of future revenues and our operating expenses 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;
- the time and cost of developing, completing preclinical and clinical studies and obtaining required regulatory approvals for the therapeutic tissue candidates we elect to pursue;
- the time and resources required to develop our drug discovery and biological research tools, products and services;
- 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 cost and time to satisfy unique customer requirements regarding validation studies and/or cell sourcing;
- 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 number and scope of ongoing client engagements and collaborations;
- 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.

We will require significant additional financing to support our long-term business plans.

We have used significant funds to develop our current bioprinting technologies, products and services and our tissue platform development and commercialization infrastructure. We will require additional funds to support our long-term business plans, including the development and regulatory approval process for any therapeutic tissue candidates we elect to pursue. We expect that we will be required to issue additional equity or debt securities or enter into other commercial arrangements, including relationships with corporate and other partners, to secure the additional financial resources to support our development and regulatory approval efforts and to implement our long-term business plans. Depending upon market conditions, we may not be successful in raising sufficient additional capital on a timely basis, on favorable terms, or at all. Additionally, the issuance of additional equity securities, including securities convertible into or exercisable for our equity securities, would result in the dilution of the ownership interests of our present stockholders. If we fail to obtain sufficient additional financing, or enter into relationships with others that provide additional financial resources, we may not be able to develop our technology and products or complete the preclinical and clinical studies required to obtain required regulatory approval for any therapeutic tissue candidate in accordance with our long-term business plan, and we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our general and administrative infrastructure, or seek alternative measures to raise additional funds.

Our current therapeutic product candidate portfolio is in the early stages of development.

We are in the early stages of developing potential therapeutic products based on our proprietary technology. In October 2016, we announced our plan to develop 3D bioprinted human liver tissue for direct transplantation to patients. This therapeutic program is in the early stages of preclinical development. The results of our future preclinical studies on our therapeutic liver tissue may be different from our existing studies and preclinical results, and may not support further clinical development of this therapeutic product candidate. Moreover, we have not finalized the design of the preclinical studies required to support an IND submission for our first liver therapeutic tissue indication, A1AT. There is no assurance that we will be successful in obtaining FDA approval of our IND submission, or that our future preclinical studies will support the filling of an IND for our therapeutic tissue candidate. Further, we may not successfully complete the required preclinical and clinical trials required to obtain regulatory approval for our therapeutic liver tissue on a timely basis, or at all. Similarly, there is no assurance that we can successfully identify and develop additional therapeutic product candidates, prove that they are safe and efficacious in clinical trials, or meet applicable regulatory standards. We do not currently have sufficient resources to complete the clinical development of our therapeutic liver tissue or any other therapeutic tissue candidate we identify, and as a result, we will need to raise additional funds or pursue licensing, partnering and other strategic alternatives. There is no assurance, however, that we will be able to do so based on their early stage of development of our therapeutic liver tissue and any other therapeutic tissue candidates we identify. As a result, we may not be successful in developing, showing clinical efficacy, obtaining regulatory approval or raising the required capital for our therapeutic liver tissue or any therapeutic programs we identify and elect to pursue.

If testing of a particular product candidate does not yield successful results, then we will be unable to obtain the regulatory approvals required to commercialize that product candidate.

We must demonstrate our product candidates' safety and efficacy in humans through extensive clinical testing. Our research and development programs are at an early stage of development. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent us from obtaining the regulatory approvals required to commercialization of any of our product candidates, including the following:

- the safety and efficacy results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials;
- after reviewing test results, we may abandon projects that we might previously have believed to be promising;
- we or our regulators may suspend or terminate clinical trials because the participating subjects or patients are being exposed to unacceptable health risks; and
- our product candidates may not have the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

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.

Our platform technology and our drug discovery, biological research, therapeutic tools, products and services are new and unproven.

Our platform technology, as well as our drug discovery, biological research, therapeutic tools, products and services, involve new and unproven models and approaches. We only 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 only began offering our second product (and related research services), our ExVive™ Human Kidney Tissue, for predictive preclinical testing of drug compounds in September 2016. We only recently begin focusing on offering our tissues to support in vitro disease modeling. As a result, we have had a limited time to prove that our ExVive™ Human Liver Tissue and ExVive™ Human Kidney Tissue and related services will enable our customers to conduct drug discovery and biological research, including disease modeling, more effectively than through the use of existing technologies. 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, or validation data in order to utilize our commercial products in their drug discovery, biological research or development programs. Even if we or our collaborators are successful in our respective efforts, we or our collaborators may not be able to discover or develop commercially viable therapeutics or other products therefrom. If our drug discovery and biological research tools, products and services do not assist in the discovery and

development of such therapeutic products or to model diseases, our current and potential collaborators may lose confidence in us and our drug discovery and biological research tools, products and services. Our inability to successfully develop effective and competitive drug discovery, biological research, tools, products and services and achieve and maintain commercial acceptance for those tools, products and services would materially adversely affect our business, financial condition and results of operations.

Our technology, products and services are subject to the risks associated with new and rapidly evolving technologies and industries.

Our proprietary tissue creation technology and our drug discovery and biological research tools, products and services and our therapeutic tissue candidates are subject to the risks associated with new, rapidly evolving technologies and industries. We may experience unforeseen technical complications, unrecognized defects and limitations in the development and commercialization of our tools, products and services, including our ExVive™ Human Liver and ExVive™ Kidney Tissues. Similarly, we may experience unforeseen difficulties in developing our therapeutic tissue candidates. In addition, our customers may request cell sources, validation studies, or features not included in our standard commercial tissue products. These complications could materially delay or limit customer demand for and use of those tools, products and services, substantially increase the anticipated cost of manufacturing, or prevent us or our collaborators from implementing their drug discovery or biological research projects successfully or at all. In addition, the process of developing new technologies, products and services is complex, and if we are unable to develop enhancements to, and new features for, our existing products and services or acceptable new products and services that keep pace with technological developments, customer requirements, or industry standards, our products and services may become obsolete, less marketable and less competitive.

Our ability to successfully commercialize the drug discovery, biological research, and therapeutic tools, products and services we develop is subject to a variety of risks.

The commercialization of our drug discovery, biological research and therapeutic tools, products and services are subject to risks and uncertainties, including:

- failing to develop products or services that are effective 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;
- failing to successfully complete preclinical and clinical studies and obtain any necessary regulatory approvals;
- 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 drug discovery and biological research tools, 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 cannot control our collaborators' allocation of resources or the amount of time that our collaborators devote to developing our programs or potential products, which may have a material adverse effect on our business.

Our existing research and collaboration agreements may allow our collaborators to obtain the options to license or exclusive rights to negotiate licenses to our new technologies. Our collaborators may have significant discretion in electing whether to pursue product development, regulatory approval, manufacturing and marketing of the products they may develop with the help of our technology. We cannot control the amount and timing of resources our collaborators may devote to our programs or potential products. As a result, we cannot be certain that our collaborators will choose to develop and commercialize products utilizing our technology or that we will realize any future milestone payments, royalties and other payments provided for in the agreements with our collaborators. In addition, if a collaborator is involved in a business combination, such as a merger or acquisition, or if a collaborator changes its business focus, its performance pursuant to its agreement with us may suffer. As a result, we may not generate any revenues from royalty, milestone and similar provisions that may be included in our collaborative agreements.

In addition, our collaborative partners or other customers that utilize our research tools will be required to submit their research for regulatory review in order to proceed with human testing of drug candidates. This review by the FDA and other regulatory agencies may result in timeline setbacks or complete rejection of an application to begin human studies, such as an Investigative New Drug (IND) application, or the ultimate failure to receive the regulatory approval required to commercialize the drug candidate or product. Should our collaborative partners or other customers face such setbacks, we would be at risk of not earning any future milestone or royalty payments.

Any termination or breach by or conflict with our collaborators or licensees could harm our business.

Our research and collaboration agreements typically involve various stages in which our collaborators can make a "go" or "no-go" decision in determining whether to continue their collaboration with us. If we or any of our existing or future collaborators or licensees fail to renew or terminate any of our collaboration or license agreements, or if either party fails to satisfy its obligations under any of our collaboration or license agreements or complete them in a timely manner, we could lose significant sources of revenue, which could result in volatility in our future revenues. In addition, our agreements with our collaborators and licensees may have provisions that give rise to disputes regarding the rights and obligations of the parties. These and other possible disagreements could lead to termination of the agreement or delays in collaborative research, development, supply or commercialization of certain products, or could require or result in litigation or arbitration. Moreover, disagreements could arise with our collaborators over rights to our intellectual property or our rights to share in any of the future revenues of products developed by our collaborators. These kinds of disagreements could result in costly and time-consuming litigation. Any such conflicts with our collaborators could reduce our ability to obtain future collaboration agreements and could have a negative impact on our relationship with existing collaborators, adversely affecting our business and revenues. Finally, any of our collaborations or license agreements may prove to be unsuccessful.

Our collaborators could develop competing research tools or services, reducing the available pool of potential collaborators and increasing competition, which may adversely affect our business and revenues.

Our collaborators and potential collaborators could develop in vitro research tools similar to our own, reducing our pool of possible collaborative parties and increasing competition. Any of these developments could harm our commercialization efforts, which could seriously harm our business. In addition, we may pursue opportunities in fields that could conflict with those of our collaborators. Developing products and services that compete with our collaborators' or potential collaborators' products and services could preclude us from entering into future collaborations with our collaborators or potential collaborators. Any of these developments could harm our product development efforts and could adversely affect our business and revenues.

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. Please see the "Competition" section of Item 1. "Business" for a further description of the competition for our products and services, including the identity of certain of our significant competitors.

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 may have product liability exposure from the sale of our research tools and therapeutic products or the services we provide.

We may have exposure to claims for product liability. Product liability coverage is expensive and sometimes difficult to obtain. There can be no assurance that our existing insurance coverage will extend to other products in the future. Our product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management's attention.

We may be dependent on third-party research organizations to conduct some of our future laboratory testing, animal and human studies.

We may be dependent on third-party research organizations to conduct some of our laboratory testing, animal and human studies with respect to therapeutic tissues and other life science products that we may develop in the future. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development or regulatory approval efforts in a timely manner. If we rely on third parties for laboratory testing and/or animal and human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we so request. We may not be able to secure and maintain suitable research organizations to conduct our laboratory testing and/or animal and human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our future product candidates.

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

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. 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 human cells 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. Further, any failure to obtain a reliable supply of human cells may delay or harm our therapeutic tissue development and regulatory approval efforts.

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 currently rely on third-party suppliers for some of our materials, including our supply of human cells, and we may rely on third-party manufacturers in the future to produce our tools and products.

We rely on third-party suppliers and vendors for some of the human cells and other materials we utilize in our products and services and in our research and development activities. We currently acquire our human cells from Samsara and third-party suppliers. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay, interruption or inability to obtain an adequate supply of human cells would negatively affect our operations. In addition, in the future we may require access to, or development of, facilities to manufacture a sufficient supply of our tools and products. If we are unable to manufacture our products in commercial quantities or the third-parties on which we rely to manufacture our tools and products fail to perform as anticipated, our business and future growth will suffer.

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 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.

An inability to manage our growth or expansion of our operations could adversely affect our business, financial condition or results of operations.

Our business operations and activities and employee headcount may grow rapidly, which could place a strain on our management and operational systems. To effectively manage our operations and growth, we may need to expend funds to enhance our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. In addition, our management will need to successfully:

- expand our research and product development efforts;
- implement and expand our sales, marketing and customer support programs;
- expand, train and manage our employee base; and
- effectively address new issues related to our growth as they arise.

We may not manage any required growth and expansion successfully, which could adversely affect our business, financial condition and results of operations.

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 successfully integrate our recently hired key executive officers, such as Taylor Crouch (our Chief Executive Officer) and Craig Kussman (our Chief Financial Officer), as well as the other technical, managerial and sales and marketing personnel required to support 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.

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 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 product 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.

Risks Related to Our Common Stock and Liquidity Risks

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 150,000,000 shares of common stock and 25,000,000 shares of preferred stock. As of March 31, 2018, there were an aggregate of 129,467,796 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 14,674,466 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, 1,285,103 shares of common stock that may be issued through our Employee Stock Purchase Plan ("ESPP"), and 220,000 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.

Our common stock is subject to trading risks created by the influence of third party investor websites.

Our common stock is widely traded and held by retail investors, and these investors are subject to the influence of information provided by third party investor websites and independent authors distributing information on the internet. This information has become influential because it is widely distributed and links to it appear as top company headlines on commonly used stock quote and finance websites, or through services such as Google alerts. These emerging information distribution models are a consequence of the emergence of the internet. Some information and content distribution is by individuals through platforms that mainly serve as hosts seeking advertising revenue. As such, we believe an incentive exists for these sites to increase advertising revenue by increasing page views, and for them to post or allow to be posted inflammatory information to achieve this end. It has been our experience that a significant portion of the information on these websites or distributed by independent authors about our Company is false or misleading, and occasionally, we believe, purposefully misleading. These sites and internet distribution strategies also create opportunity for individuals to pursue both "pump and dump" and "short and distort" strategies. We believe that many of these websites have little or no requirements for authors to have professional qualifications. While these sites sometimes require disclosure of stock positions by authors, as far as we are aware these sites do not

audit the accuracy of such conflict of interest disclosures. We believe that many of these websites have few or lax editorial standards, and thin or non-existent editorial staffs. Despite our best efforts, we have not and may not be able in the future to obtain corrections to information provided on these websites about our Company, including both positive and negative information, and any corrections that are obtained may not be achieved prior to the majority of audience impressions being formed for a given article. These conditions create volatility and risk for holders of our common stock and should be considered by investors. We can make no guarantees that regulatory authorities will take action on these types of activities, and we cannot guarantee that legislators will act responsively, or ever act at all, to appropriately restrict the activities of these websites and authors.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company leases its main facility at 6275 Nancy Ridge Drive, San Diego, CA 92121. The lease consists of approximately 45,580 rentable square feet containing laboratory, clean room, and office space. The lease term for 14,685 of the total rentable square footage expires on December 15, 2018. The remainder of the rentable square footage expires on September 1, 2021, with the Company having an option to terminate this lease on or after September 1, 2019.

We believe our facilities are adequate for our current and near-term needs, and 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 on Form 10-K 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. The following table sets forth, on a per share basis, for the periods indicated, the high and low bid or sales prices of our common stock.

Year Ended March 31, 2018	High	Low
Fourth Quarter	$1.54	$0.93
Third Quarter	$2.28	$1.32
Second Quarter	$2.72	$1.75
First Quarter	$3.19	$2.55

Year Ended March 31, 2017	High	Low
Fourth Quarter	$3.92	$2.76
Third Quarter	$4.14	$2.48
Second Quarter	$4.99	$3.68
First Quarter	$3.74	$2.11

Holders of Record

As of March 31, 2018, there were 117 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, 2018. This graph assumes the investment of $100 on March 31, 2013 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, 2013 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, 2018, 2017, 2016, 2015, and 2014. 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 on Form 10-K. The following table is presented in thousands, except per share amounts.

	Year Ended March 31, 2018	Year Ended March 31, 2017	Year Ended March 31, 2016	Year Ended March 31, 2015	Year Ended March 31, 2014
Selected Consolidated Statement of Operations Data:					
Revenue	$4,603	$4,230	$1,483	$571	$379
Operating loss	$(35,271)	$(38,575)	$(38,643)	$(30,297)	$(20,649)
Net loss	$(34,803)	$(38,447)	$(38,575)	$(30,082)	$(25,848)
Loss per share, basic and diluted	$(0.32)	$(0.39)	$(0.43)	$(0.38)	$(0.35)
Weighted average shares outstanding, basic and diluted	107,243,974	97,763,032	90,057,356	79,650,087	73,139,618

	March 31, 2018	March 31, 2017	March 31, 2016	March 31, 2015	March 31, 2014
Selected Consolidated Balance Sheet Data:					
Working capital (deficit)	$42,102	$59,081	$59,162	$46,501	$47,268
Total assets	$49,827	$69,180	$67,576	$53,489	$50,186
Long-term liabilities	$583	$807	$905	$32	$9
Stockholders’ equity (deficit)	$44,586	$62,362	$62,181	$48,696	$48,284

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 a unique set of therapeutic and drug profiling capabilities based on our revolutionary ability to 3D bioprint liver and kidney tissues which emulate human biology and disease. We are developing our in vivo liver tissues to treat a range of life-threatening, rare diseases, for which there are few current treatment options other than organ transplantation. Our first program, which focuses on a rare disease known as Alpha-1-anityprisin deficiency ("A1AT"), received the U.S. Food and Drug Administration's ("FDA") orphan drug designation in December 2017 and is targeted for an Initial New Drug Application ("IND") filing in calendar-year 2020. We are also capitalizing on our foundational ability to characterize highly specialized human cells and to build robust, functional human tissues by creating a range of novel in vitro disease modeling platforms, including a broad set of non-alcoholic fatty liver disease ("NAFLD") and non-alcoholic steatohepatitis ("NASH") conditions. Our clients are accessing these diseased tissue platforms through a growing number of collaborative, revenue-generating agreements.

We aim to grow revenue through product sales and fee-based service agreements and collaborations for our invitro tissues to help provide a portion of the required cash flow to support our therapeutics development program. Our in vitro and in vivo tissues are both built upon the same proprietary 3D bioprinting technology and our highly specialized cells, providing valuable synergies in advancing each of our businesses. We are striving to change the face of medicine by enabling more relevant and translational drug discovery and by launching novel approaches to treating disease.

In the near-term, we will focus on several value-driving inflection points including:

- Partnering with the FDA and expert advisers to finalize the confirmatory animal studies and scientific validation path leading to a successful pre-IND meeting for our first liver therapeutic tissue indication, A1AT;
- Validating a second unmet disease area using the same healthy liver therapeutic tissue patch and moving into an additional IND-track program;
- Deploying a broad range of proof-of-concept disease modeling capabilities in NASH to enable steady-state, high content screening collaborations with current and prospective clients;
- Growing our Samsara division's cell-based product revenue, as well as continuing to generate revenue from grant and licensing agreements; and
- Continuing to present and publish major scientific findings of our tissue platform.

Over the long-term, we will 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 Disease,

Fast Track and Breakthrough designations;

- Achieving operational breakeven profitability for our commercial business by securing significant 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

Our discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

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

Our revenues are derived from research service agreements, product sales, and collaborative agreements with pharmaceutical and biotechnology companies, grants from the National Institutes of Health ("NIH") and private not-for-profit organizations, and license-payments from academic institutions.

We recognize revenue when the following criteria have been met: (i) persuasive evidence of an arrangement exists; (ii) services have been rendered or product has been delivered; (iii) price to the customer is fixed and determinable; and (iv) collection of the underlying receivable is reasonably assured.

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, 2018 and March 31, 2017, we had approximately $687,000 and $640,000, respectively, in deferred revenue related to our licenses, collaborative agreements, and research service agreements.

Revenue arrangements with multiple deliverables

We follow ASC 605-25 Revenue Recognition – Multiple-Element Arrangements for revenue arrangements that contain multiple deliverables. Judgment is required to properly identify the accounting units of the multiple deliverable transactions and to determine the manner in which revenue should be allocated among the accounting units. Moreover, judgment is used in interpreting the commercial terms and determining when all criteria of revenue recognition have been met for each deliverable in order for revenue recognition to occur in the appropriate accounting period. For multiple deliverable agreements, consideration is allocated at the inception of the agreement to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using vendor-specific objective evidence ("VSOE") of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable.

While changes in the allocation of the arrangement consideration between the units of accounting will not affect the amount of total revenue recognized for a particular sales arrangement, any material changes in these allocations could impact the timing of revenue recognition, which could affect our results of operations.

We periodically receive license fees for non-exclusive research licensing associated with funded research projects. License fees under these arrangements are recognized over the term of the contract or development period as it has been determined that such licenses do not have stand-alone value.

Revenue from research service agreements

For research service agreements that contain only a single or primary deliverable, we defer any up-front fees collected from customers, and recognizes revenue for the delivered element only when it determines there are no uncertainties regarding customer acceptance. For agreements that contain multiple deliverables, we follow ASC 605-25 as described above.

Research and development revenue under collaborative agreements

Our collaboration revenue consists of license and collaboration agreements that contain multiple elements, which may include non-refundable up-front fees, payments for reimbursement of third-party research costs, payments for ongoing research, payments associated with achieving specific development milestones and royalties based on specified percentages of net product sales, if any. We consider a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

We recognize revenue from research funding under collaboration agreements when earned on a “proportional performance” basis as research services are provided or substantive milestones are achieved. We recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is considered substantive when the consideration payable to us for the milestone (i) is consistent with our performance necessary to achieve the milestone or the increase in value to the collaboration resulting from our performance, (ii) relates solely to our past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the risks that must be overcome to achieve the milestone, the level of effort and investment required to achieve the milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

We initially defer revenue for any amounts billed or payments received in advance of the services being performed, and recognize revenue pursuant to the related pattern of performance, using the appropriate method of revenue recognition based on our analysis of the related contractual element(s).

In November 2014, we entered into a collaborative non-exclusive research affiliation with a university medical school and a non-profit medical charity, under which we 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 surgical transplantation research. We have recorded $0 and $32,000 for the twelve months ended March 31, 2018 and 2017, respectively, in revenue related to this collaboration in recognition of the proportional performance achieved. We completed our obligations under this agreement as of November 30, 2016.

In April 2015, we 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, $150,000 and $117,000 in collaboration revenue was recorded for the twelve months ended March 31, 2018 and 2017, respectively. We have completed our obligations under this agreement as of March 31, 2018.

Also in April 2015, we entered into a multi-year research agreement with a third party to develop multiple custom tissue models for use in drug development. Approximately $0 and $835,000 were recorded as revenue in recognition of the proportional performance achieved under this agreement during the twelve months ended March 31, 2018 and 2017, respectively.

In June 2016, we entered into another collaborative non-exclusive research affiliation with a university medical school and a non-profit medical charity, under which we 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. We received an up-front payment in June 2016, which was initially recorded as deferred revenue. Revenue of $65,000 and $34,000 has been recorded under this agreement during the twelve months ended March 31, 2018 and 2017, respectively.

In December 2016, we entered into another collaborative non-exclusive research affiliation with a university medical school and a non-profit medical charity, under which we 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. We received an up-front payment in January and March of 2017, which has been recorded as deferred revenue. Revenue of approximately $39,000 and $3,000 has been recorded under this agreement for the twelve months ended March 31, 2018 and 2017, respectively.

In April 2017, we entered into a collaborative non-exclusive research affiliation with a university, under which we received a one-time non-refundable 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 us in the field of volumetric muscle loss. We received an up-front payment in May of 2017, which has been recorded as deferred revenue. Revenue of approximately $43,000 has been recorded under this agreement for the twelve months ended March 31, 2018, beginning subsequent to the installation of the printer in July of 2017. In addition, during April of 2017, we signed a non-exclusive patent license agreement with the university including an annual fee of $75,000 for each of the two years for the license to our patents for research use limited to the field of volumetric muscle loss. We received the first annual payment of $75,000 in April of 2017, which was initially recorded as deferred revenue. We recorded revenue of $75,000 under this agreement for the twelve months ended March 31, 2018.

In September 2017, we entered into an agreement with a company, under which we 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. We have recorded $50,000 in revenue for the twelve months ended March 31, 2018.

Product revenue

We recognize product revenue at the time of delivery to the customer, provided all other revenue recognition criteria have been met.

We expect to establish a reserve for estimated product returns that will be recorded as a reduction to revenue. This reserve will be maintained to account for future return of products sold in the current period. The reserve will be reviewed quarterly and will be estimated based on an analysis of our historical experience related to product returns.

Grant revenue

During August 2013, we were awarded a research grant by a private, not-for-profit organization for up to $251,700, contingent on go/no-go decisions made by the grantor at the completion of each stage of research as outlined in the grant award. 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 we incur expenses that are related to the grant. Revenue recognized under this grant was approximately $0, $41,000, and $43,000 for the twelve months ended March 31, 2018, 2017, and 2016, respectively. We have completed our obligations under this agreement as of March 31, 2017.

During September of 2014, the NIH awarded the Company a research grant totaling approximately $222,000. 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. Revenue recognized under this grant was approximately $148,000 for the twelve months ended 2016. The Company completed its obligations under this agreement during the year ended March 31, 2016.

During July 2017, the NIH awarded us a research grant totaling approximately $1,657,000. 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. Revenue is recognized upon completion of substantive milestones. Revenue recognized under this grant was approximately $554,000 and $0 for the twelve months ended March 31, 2018 and 2017, respectively.

Cost of revenues

We reported approximately $1.0 million and $1.0 million in cost of revenues for the twelve months ended March 31, 2018 and 2017, respectively. Cost of revenues for the twelve months ended March 31, 2016 was immaterial and was therefore included in research and development expenses. Cost of revenues consists of our costs related to manufacturing and delivering our product and service revenue.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks.

We review the terms of convertible debt and equity instruments it issues to determine whether there are derivative instruments, including an embedded conversion option that is required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where the convertible instrument contains more than one

embedded derivative instrument, including the conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. Also, in connection with the sale of convertible debt and equity instruments, we may issue freestanding warrants that may, depending on their terms, be accounted for as derivative instrument liabilities, rather than as equity.

Derivative instruments are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as non-operating income or expense. When the convertible debt or equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds allocated to the convertible host instruments are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

Fair Value Measurements

We had issued warrants, of which some were classified as derivative liabilities as a result of the terms in the warrants that provide for down round protection in the event of a dilutive issuance. We used Level 3 inputs (unobservable inputs that are supported by little or no market activity, and that are significant to the fair value of the assets or liabilities) for our valuation methodology for the warrant derivative liabilities. The estimated fair values were determined using a Monte Carlo option pricing model based on various assumptions. Our derivative liabilities were adjusted to reflect estimated fair value at each period end, with any increase or decrease in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of the derivative liabilities. Various factors are considered in the pricing models we used to value the warrants, including our current stock price, the remaining life of the warrant, the volatility of our stock price, and the risk-free interest rate. The remaining warrants expired as of March 31, 2017 and were removed from the Balance Sheet.

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. The expected volatility is based on the historical common stock volatility of our peer group over the most recent period commensurate with the estimated expected term of the stock options or ESPP, as the case may be. 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, 2018, 2017, and 2016

The following table summarizes our results of operations for the years ended March 31, 2018, 2017, and 2016 (in thousands):

	Year Ended March 31,			2017 to 2018		2016 to 2017	
	2018	2017	2016	$	%	$	%
Revenues	$4,603	$4,230	$1,483	$373	9 %	$2,747	185%
Cost of revenues	$1,030	$956	$—	$74	8 %	$956	—

Research and development	$17,956	$19,545	$18,008	$(1,589)	(8 %)	$1,537	8 %
Selling, general and administrative	$20,888	$22,304	$22,118	$(1,416)	(6 %)	$186	1 %
Other income	$470	$151	$71	$319	211%	$80	112%

Revenues

Revenues of $4.6 million for the year ended March 31, 2018 increased approximately $0.4 million, or approximately 9%, over revenues of $4.2 million for the year ended March 31, 2017. This change reflects increases of $0.5 million and $0.5 million in product and service revenue and grant revenue, respectively, over the year ended March 31, 2017, due to an increase in primary human cell-based products and the commencement of our NIH SBIR grant. These increases offset a $0.6 million decrease in collaboration revenue resulting from the completion of two collaborations that concluded during fiscal year 2017. Revenues of $4.2 million for the year ended March 31, 2017 increased approximately $2.7 million, or more than 180%, over revenues of $1.5 million for the year ended March 31, 2016. This change reflects an increase of $2.4 million in product and service revenue over the year ended March 31, 2016, due to an increasing number of customer contracts for our tissue research services. In addition, collaboration revenue increased $0.5 million due to substantial milestone achievements under collaboration agreements with multiple partners to develop custom tissue models. These increases were offset by a decrease in grant revenue by $0.2 million primarily related to a grant that concluded during fiscal year 2016.

Costs and Expenses

Cost of Revenues

Cost of product and service revenues, which reflects expenses related to manufacturing our products and delivering services was $1.0 million and $1.0 million for the years ended March 31, 2018 and 2017, respectively. The resulting improvement in our product and service gross margin is due to an increased proportion of higher margin revenues from the sales of primary human cell-based products. Cost of product and service revenues was $1.0 million for the year ended March 31, 2017, compared to zero for the year ended March 31, 2016 as cost of revenues for the year ended March 31, 2016 was immaterial and was therefore included in research and development expenses.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended March 31, 2018, 2017, and 2016 (in thousands):

	Year ended March 31,			2017 to 2018		2016 to 2017	
	2018	2017	2016	$	%	$	%
Research and development	$16,130	$17,332	$16,280	$(1,202)	(7 %)	$1,052	6 %
Non-cash stock-based compensation	1,174	1,646	1,248	(472)	(29%)	398	32%
Depreciation and amortization	652	567	480	85	15 %	87	18%
Total research and development expenses	$17,956	$19,545	$18,008	$(1,589)	(8 %)	$1,537	8 %

Research and development expenses decreased $1.6 million, or 8%, from approximately $19.5 million for the year ended March 31, 2017 to approximately $18.0 million for the year ended March 31, 2018 as we sharpened the focus of our research staff activities to emphasize development of disease modeling research services and reduced our product development staff utilized to support obligations under collaborative research agreements that expired in fiscal 2017. Full-time research and development staffing decreased from an average of eighty full-time employees during the year ended March 31, 2017 to an average of seventy-one full-time employees during the year ended March 31, 2018, resulting in decreases of $1.3 million and $0.6 million in staffing expense and lab services and supply expenses, respectively. These decreases offset a $0.3 million increase in facility allocation costs. Research and development expense increased $1.5 million, or 8%, from approximately $18.0 million for the year ended March 31, 2016 to approximately $19.5 million for the year ended March 31, 2017 as we increased our research staff activities to support development of commercial research services and expanded our product development staff to support obligations under existing collaborative research agreements. Full-time research and development staffing increased from an average of sixty-eight full-time employees during the year ended March 31, 2016 to an average of eighty full-time employees during the year ended March 31, 2017, resulting in increases in staffing expense of approximately $1.5 million.

Selling, General and Administrative Expenses

The following table summarizes our selling, general and administrative expenses for the years ended March 31, 2018, 2017, and 2016 (in thousands):

	Year ended March 31,	2017 to 2018	2016 to 2017

	2018	2017	2016	$	%	$	%
Selling, general and administrative	$14,544	$15,976	$14,475	$(1,432)	(9%)	$1,501	10 %
Non-cash stock-based compensation	5,729	5,746	7,308	(17)	(0%)	(1,562)	(21%)
Depreciation and amortization	615	582	335	33	6 %	247	74 %
Total selling, general and administrative expenses	$20,888	$22,304	$22,118	$(1,416)	(6%)	$186	1 %

Selling, general and administrative expenses decreased approximately $1.4 million, or 6%, from $22.3 million for the year ended March 31, 2017 to approximately $20.9 million for the year ended March 31, 2018. The decrease was primarily driven by a reduction in legal and patent costs of approximately $0.8 million, a reduction in facility costs of $0.3 million and a decrease in compensation costs due to reduced cash incentive payments and a headcount decrease from an average of thirty-six full-time employees during the year ended March 31, 2017 to an average of thirty-three full-time employees during the year ended March 31, 2018, resulting from a sharpened strategic focus and the prioritization of projects. Selling, general and administrative expenses increased approximately $0.2 million, or 1%, from $22.1 million for the year ended March 31, 2016 to approximately $22.3 million for the year ended March 31, 2017. This increase was primarily driven by an increase in staffing-related expenses of approximately $1.1 million due to a headcount increase from an average of twenty-eight full-time employees during the year ended March 31, 2016 to an average of thirty-six full-time employees during the year ended March 31, 2017, to provide strategic infrastructure in developing collaborative relationships and the commercializing of research-derived product introductions. Additionally, the increase was related to higher executive recruiting costs of $0.3 million, and outside services in the amount of $0.2 million. This increase was offset by a $1.6 million decrease in share-based compensation related to the absence of non-recurring expenses for two departed executives.

Other Income (Expense)

Other income was approximately $0.5 million for the year ended March 31, 2018, and consisted primarily of interest income. For the year ended March 31, 2017, other income of approximately $0.2 million consisted primarily of interest income. Interest income increased from fiscal 2017 due to higher average yields. For the year ended March 31, 2016, other income of approximately $0.1 million consisted primarily of interest income. Interest income increased from fiscal 2016 due to higher average yields.

Financial Condition, Liquidity and Capital Resources

We have primarily devoted our efforts to developing and commercializing 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, 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 $28.9 million, $29.2 million, and $29.4 million for the years ended March 31, 2018, 2017 and 2016, respectively.

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. At March 31, 2017, we had total current assets of $65.1 million and current liabilities of $6.0 million, resulting in working capital of $59.1 million.

The following table sets forth a summary of the primary sources and uses of cash for the years ended March 31, 2018, 2017, and 2016 (in thousands):

	Year ended March 31,		
	2018	2017	2016
Net cash (used in) provided by:			
Operating activities	$(28,857)	$(29,185)	$(29,368)
Investing activities	(292)	(1,391)	(2,135)
Financing activities	10,113	31,247	43,452
Effect of currency exchange rate	11	(11)	—
Net increase (decrease) in cash and cash equivalents	$(19,025)	$660	$11,949

Operating activities

Net cash used by operating activities was approximately $28.9 million, $29.2 million, and $29.4 million for the years ended March 31, 2018, 2017, and 2016, respectively. This $0.3 million decrease, for the year ended March 31, 2018, is a result of a $3.2 million improvement in operating cost offset by a $2.9 million increase in working capital requirements.

Investing activities

Net cash used in investing activities was approximately $0.3 million, $1.4 million, and $2.1 million for the years ended March 31, 2018, 2017, and 2016, 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 $10.1 million, $31.2 million, and $43.5 million for the years ended March 31, 2018, 2017 and 2016, respectively.

Operations funding requirements

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.

During the year ended March 31, 2017, we raised net proceeds of approximately $25.7 million from our public offering of 10,065,000 shares of our common stock in October 2016, approximately $4.5 million through the sale of 997,181 shares of our common stock in “at-the-market” offerings and approximately $1.1 million through warrant exercises, stock option exercises and the sale of shares through the ESPP.

During the year ended March 31, 2016, we raised net proceeds of approximately $43.1 million through the sale of 10,838,750 shares of our common stock. In addition, we raised approximately $0.3 million from stock option exercises during the year ended March 31, 2016.

Through March 31, 2018, we have financed our operations primarily through the sale of convertible notes, the private placement of equity securities, the sale of common stock through public offerings, and from revenue derived from products and research-based services, grants, and collaborative research agreements. 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 additional capital to further fund the development of our therapeutic tissues and the implementation of our business plan. We intend to cover our future operating expenses through cash on hand, revenue derived from research service agreements, product sales, grants, and collaborative research agreements 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.

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. 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, 2018, we sold 5,307,105 shares of common stock in at-the-market offerings, with net proceeds of approximately $9.2 million under its 2015 Shelf, which expired on March 17, 2018.

Based on our use of the 2018 Shelf through March 31, 2018, we cannot raise more than an aggregate of $100.0 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, 2018, we had 111,032,957 total issued and outstanding shares of common stock and 220,000 warrants with remaining terms between one and two years and exercise prices between $6.84 and $7.62 per share.

In addition, our 2008 Equity Incentive Plan provides for the issuance of up to 896,256 shares of common stock upon the exercise of outstanding stock options and the 2012 Equity Incentive Plan, as amended, provides for the issuance of up to 17,553,986 shares of our common stock, of which 4,595,021 shares remain available for issuance as of March 31, 2018, 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 1,285,103 shares remain available for future issuance as of March 31, 2018. Lastly, 2,288,682 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 129,501,208 shares of common stock as of March 31, 2018.

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, 2018 (in thousands):

	Total	2019	2020 to 2021	2022 to 2023	2024 and thereafter
Operating lease obligations (A)	$4,030	$1,385	$2,177	$468	$ —
Total	$4,030	$1,385	$2,177	$468	$ —

(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, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows for each of the years in the three year period ended March 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2018, 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, 2018, 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 May 31, 2018 expressed an unqualified opinion.

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

May 31, 2018

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, 2018, 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, 2018, 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, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the years in the three year period ended March 31, 2018, and our report dated May 31, 2018, expressed an unqualified opinion.

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

May 31, 2018

F-3

ORGANOVO HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands except per share data)

	March 31, 2018	March 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$43,726	$62,751
Accounts receivable	883	647
Grant receivable	145	—
Inventory, net	842	550
Prepaid expenses and other current assets	1,164	1,144
Total current assets	46,760	65,092
Fixed assets, net	2,788	3,840
Restricted cash	127	127
Other assets, net	152	121
Total assets	$49,827	$69,180
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$464	$1,171
Accrued expenses	3,341	4,101
Deferred revenue	668	582
Deferred rent	185	157
Total current liabilities	4,658	6,011
Deferred revenue, net of current portion	19	58
Deferred rent, net of current portion	564	749
Total liabilities	$5,241	$6,818
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 111,032,957 and 104,551,466 shares issued and outstanding at March 31, 2018 and March 31, 2017, respectively	111	104
Additional paid-in capital	278,595	261,586
Accumulated deficit	(234,120)	(199,317)
Accumulated other comprehensive income (loss)	—	(11)
Total stockholders' equity	44,586	62,362
Total Liabilities and Stockholders' Equity	$49,827	$69,180

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 per share data)

	Year Ended March 31, 2018	Year Ended March 31, 2017	Year Ended March 31, 2016
Revenues			
Products and services	$3,627	$3,167	$806
Collaborations and licenses	422	1,022	486
Grants	554	41	191
Total Revenues	4,603	4,230	1,483
Cost of revenues	1,030	956	—
Research and development expenses	17,956	19,545	18,008
Selling, general, and administrative expense	20,888	22,304	22,118
Total costs and expenses	39,874	42,805	40,126
Loss from Operations	(35,271)	(38,575)	(38,643)
Other Income (Expense)			
Change in fair value of warrant liabilities	—	4	(17)
Gain (loss) on fixed asset disposals	4	(51)	—
Interest income	478	198	88
Other income (expense)	(12)	—	—
Total Other Income (Expense)	470	151	71
Income Tax Expense	(2)	(23)	(3)
Net Loss	$(34,803)	$(38,447)	$(38,575)
Net loss per common share—basic and diluted	$(0.32)	$(0.39)	$(0.43)
Weighted average shares used in computing net loss per common share—basic and diluted	107,243,974	97,763,032	90,057,356
Comprehensive Loss:			
Net Loss	$(34,803)	$(38,447)	$(38,575)
Currency Translation Adjustment	11	(11)	—
Comprehensive Loss	$(34,792)	$(38,458)	$(38,575)

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	Accumulated	Accumulated Other Comprehensive Income	
	Shares	Amount	Capital	Deficit	(Loss)	Total
Balance at March 31, 2015	81,537	$ 82	$ 170,909	$ (122,295)	$ —	$ 48,696
Issuance of common stock from warrant exercises, net	32	—	—	—	—	—
Restricted stock forfeitures	(132)	—	—	—	—	—
Issuance of common stock from public offering, net	10,839	10	43,127	—	—	43,137
Stock-based compensation expense	—	—	8,556	—	—	8,556
Warrant liability removed due to exercises of warrants	—	—	139	—	—	139
Stock option exercises	116	—	320	—	—	320
Issuance of warrants to consultant	—	—	38	—	—	38
Expense related to potential equity bonus issuance	—	—	(130)	—	—	(130)
Net loss	—	—	—	(38,575)	—	(38,575)
Balance at March 31, 2016	92,392	$ 92	$ 222,959	$ (160,870)	$ —	$ 62,181
Issuance of common stock from warrant exercises, net	700	1	335	—	—	336
Issuance of common stock under employee and director stock option, RSU and purchase plans	397	—	705	—	—	705
Stock-based compensation expense	—	—	7,392	—	—	7,392
Issuance of common stock from public offering, net	11,062	11	30,195	—	—	30,206
Net loss	—	—	—	(38,447)		(38,447)
Currency translation adjustment	—	—	—	—	(11)	(11)
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

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, 2018	Year Ended March 31, 2017	Year Ended March 31, 2016
Cash Flows From Operating Activities			
Net loss	$ (34,803)	$ (38,447)	$ (38,575)
Adjustments to reconcile net loss to net cash used in operating activities:			
Amortization of deferred financing costs	—	—	(92)
(Gain) loss on disposal of fixed assets	(4)	56	—
Depreciation and amortization	1,267	1,149	815
Change in fair value of warrant liabilities	—	(4)	17
Stock-based compensation	6,903	7,392	8,556
Donation of fixed assets	25	—	—
Increase (decrease) in cash resulting from changes in:			
Accounts receivable	(236)	(388)	(259)
Grants receivable	(145)	—	—
Inventory	(292)	(216)	(268)
Prepaid expenses and other assets	5	(154)	83
Accounts payable	(707)	384	(600)
Accrued expenses	(760)	1,651	193
Deferred rent	(157)	(138)	(89)
Deferred revenue	47	(470)	851
Net cash used in operating activities	(28,857)	(29,185)	(29,368)
Cash Flows From Investing Activities			
Deposits released from restriction (restricted cash deposits)	—	(48)	—
Purchases of fixed assets	(226)	(1,354)	(2,114)
Proceeds from disposals of fixed assets	4	11	14
Purchases of intangible assets	(70)	—	(35)
Net cash used in investing activities	(292)	(1,391)	(2,135)
Cash Flows From Financing Activities			
Proceeds from issuance of common stock and exercise of warrants, net	9,287	30,665	43,137
Proceeds from exercise of stock options	826	582	320
Principal payments on capital lease obligations	—	—	(5)
Net cash provided by financing activities	10,113	31,247	43,452
Effect of currency exchange rate changes on cash and cash equivalents	11	(11)	—
Net Increase in Cash and Cash Equivalents	(19,025)	660	11,949
Cash and Cash Equivalents at Beginning of Period	62,751	62,091	50,142
Cash and Cash Equivalents at End of Period	$ 43,726	$ 62,751	$ 62,091
Supplemental Disclosure of Cash Flow Information:			
Interest	$ —	$ —	$ —

Income Taxes	$ 2	$ 23	$ 3

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

Supplemental Disclosure of Noncash Investing and Financing Activities ($ in thousands):

During the year ended March 31, 2016, the warrant liability was reduced by approximately $139 as a result of warrant exercises.

During the year ended March 31, 2016, approximately $374 of leasehold improvements were funded by the Company’s landlord as a lease incentive. The Company capitalized these costs as property, plant and equipment, with a corresponding increase in deferred rent that will be amortized over the remaining lease term.

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

A summary of significant accounting policies, consistently applied in the preparation of the accompanying consolidated financial statements follows:

Nature of operations and basis of presentation

References in these notes to the consolidated financial statements to “Organovo Holdings, Inc.,” “Organovo Holdings,” “we,” “us,” “our,” “the Company” and “our Company” refer to Organovo Holdings, Inc. and its consolidated subsidiaries. Our consolidated financial statements include the accounts of the Company as well as its wholly-owned subsidiaries, with all material intercompany accounts and transactions eliminated in consolidation. In December 2014, we established a wholly-owned subsidiary, Samsara Sciences, Inc., to focus on the acquisition of qualified cells in support of our commercial and research endeavors. In September 2015, we established another wholly-owned subsidiary in the United Kingdom, Organovo U.K., Ltd., for the primary purpose of establishing a sales presence in Europe. At March 31, 2018, the U.K. operations have been combined with Organovo, Inc.’s operations.

Since its inception, the Company has devoted its efforts primarily to developing and commercializing a proprietary platform technology to produce and study living tissues that emulate key aspects of human biology and disease, raising capital and building infrastructure. We provide client access to our proprietary ExVive™ tissue platform to facilitate drug discovery and development through a range of research services, collaborative agreements, licenses, and grants. We also are applying our therapeutic tissue expertise to progress multiple Investigational New Drug (“IND”) Application track therapeutic programs, focusing on critical unmet medical needs in the liver disease space, including our lead program for NovoTissues® targeting Alpha-1 antitrypsin deficiency, for which we have received orphan drug designation (“ODD”) from the Food and Drug Administration (“FDA”).

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.

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, 2018, the Company had cash and cash equivalents of approximately $43.7 million and an accumulated deficit of approximately $234.1 million. The Company also had negative cash flows from operations of approximately $28.9 million during the year ended March 31, 2018.

Through March 31, 2018, 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, 2018, the Company issued 5,307,105 shares of its common stock through its ATM facility and received net proceeds of approximately $9.2 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 that emulate key aspects of human biology and disease that can be used to facilitate drug discovery and development, as well as its therapeutic 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 recognized under the proportional performance model, the valuation of stock-based compensation expense, and the valuation allowance on deferred tax assets.

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.

Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency. At March 31, 2018 and at March 31, 2017, the Company did not have any derivative liabilities measured on a fair value basis.

Historically, the Company reviewed the terms of convertible debt and equity instruments it issued to determine if they were derivative instruments, including an embedded conversion option that is required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where a host instrument contains more than one embedded derivative instrument, including a conversion option, that is required to be bifurcated, the bifurcated derivative instruments were accounted for as a single, compound derivative instrument. Also, in connection with the sale of convertible debt and equity instruments, the Company may have issued freestanding warrants that may, depending on their terms, have been accounted for as derivative instrument liabilities, rather than as equity.

Derivative instruments were initially recorded at fair value and were revalued at each reporting date with changes in the fair value reported as non-operating income or expense. When the convertible debt or equity instruments contain embedded derivative instruments that were to be bifurcated and accounted for as liabilities, the total proceeds allocated to the convertible host instruments were first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, were then allocated to the convertible instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

Foreign Currency

The functional currency of our wholly owned subsidiary in the United Kingdom is the pound sterling. Accordingly, all assets and liabilities of this subsidiary are translated to US dollars based on the applicable exchange rate on the balance sheet date. Revenue and expense components are 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 US dollar-denominated receivables and payables, are recorded in our Consolidated Statements of Operations and Other Comprehensive Loss. For the years ended March 31, 2018, 2017 and 2016, we recognized foreign currency translation losses of approximately $1,000, $11,000 and $0, respectively.

As of March 31, 2018, we realized $12,000 of cumulative foreign currency translation losses as Other Expense on the Consolidated Statement of Operations and Other Comprehensive Loss for the year ending March 31, 2018. No further foreign currency translation losses will be recorded as Organovo U.K., Ltd. operations have been combined with Organovo, Inc.’s operations.

Restricted cash

As of March 31, 2018 and 2017, the Company had approximately $127,000 of restricted cash, 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 market (first-in, first-out). Inventory at March 31, 2018 consists of approximately $578,000 in raw materials, approximately $26,000 in work-in-process inventory, and approximately $238,000 in finished goods net of reserve. Inventory at March 31, 2017 consisted of approximately $467,000 in raw materials, approximately $83,000 in work-in progress inventory, and approximately $0 in finished goods.

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, 2018.

Fair value measurement

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

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

The Company had issued warrants, of which some were classified as derivative liabilities as a result of the terms in the warrants that provide for down round protection in the event of a dilutive issuance. The Company used Level 3 inputs (unobservable inputs that are supported by little or no market activity, and that are significant to the fair value of the assets or liabilities) for its valuation methodology for the warrant derivative liabilities. The estimated fair values were determined using a Monte Carlo option pricing model based on various assumptions. The Company's derivative liabilities were adjusted to reflect estimated fair value at each period end, with any increase or decrease in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the fair value of the

derivative liabilities. Various factors were considered in the pricing models the Company used to value the warrants, including the Company's current stock price, the remaining life of the warrant, the volatility of the Company's stock price, and the risk-free interest rate.

During the years ended March 31, 2017 and 2016, the Company valued its derivative liabilities in accordance with ASC 820. The remaining warrants expired as of March 31, 2017 and were removed from the Balance Sheet. The Company does not have any financial assets or liabilities measured on a fair value basis as of March 31, 2018.

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the years ended March 31, 2018 and 2017:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Derivative Liability (in thousands)
Balance at March 31, 2016	$ 4
Issuances	—
Adjustments to estimated fair value	(4)
Warrant liability removal due to settlements	—
Balance at March 31, 2017	$ —
Issuances	—
Adjustments to estimated fair value	—
Warrant liability removal due to settlements	—
Balance at March 31, 2018	$ —

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’s revenues are derived from research service agreements, product sales, and collaborative agreements with pharmaceutical and biotechnology companies, grants from the National Institutes of Health (“NIH”) and private not-for-profit organizations, and license-payments from academic institutions.

The Company recognizes revenue when the following criteria have been met: (i) persuasive evidence of an arrangement exists; (ii) services have been rendered or product has been delivered; (iii) price to the customer is fixed and determinable; and (iv) collection of the underlying receivable is reasonably assured.

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, 2018 and 2017, the Company had approximately $687,000 and $640,000, respectively, in deferred revenue related to its commercial products and research service agreements, grants, and collaborative research programs.

Revenue arrangements with multiple deliverables

The Company follows ASC 605-25 Revenue Recognition – Multiple-Element Arrangements for revenue arrangements that contain multiple deliverables. Judgment is required to properly identify the accounting units of the multiple deliverable transactions and to determine the manner in which revenue should be allocated among the accounting units. Moreover, judgment is used in interpreting the commercial terms and determining when all criteria of revenue recognition have been met for each deliverable in order for revenue recognition to occur in the appropriate accounting period. For multiple deliverable agreements, consideration is allocated at the inception of the agreement to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using vendor-specific objective evidence (“VSOE”) of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable.

While changes in the allocation of the arrangement consideration between the units of accounting will not affect the amount of total revenue recognized for a particular sales arrangement, any material changes in these allocations could impact the timing of revenue recognition, which could affect the Company's results of operations.

The Company periodically receives license fees for non-exclusive research licensing associated with funded research projects. License fees under these arrangements are recognized over the term of the contract or development period as it has been determined that such licenses do not have stand-alone value.

Revenue from research service agreements

For research service agreements that contain only a single or primary deliverable, the Company defers any up-front fees collected from customers, and recognizes revenue for the delivered element only when it determines there are no uncertainties regarding customer acceptance. For agreements that contain multiple deliverables, the Company follows ASC 605-25 as described above.

Research and development revenue under collaborative agreements

The Company's collaboration revenue consists of license and collaboration agreements that contain multiple elements, including non-refundable up-front fees, payments for reimbursement of third-party research costs, payments for ongoing research, payments associated with achieving specific development milestones and royalties based on specified percentages of net product sales, if any. The Company considers a variety of factors in determining the appropriate method of revenue recognition under these arrangements, such as whether the elements are separable, whether there are determinable fair values and whether there is a unique earnings process associated with each element of a contract.

The Company recognizes revenue from research funding under collaboration agreements when earned on a "proportional performance" basis as research services are provided or substantive milestones are achieved. The Company recognizes revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is considered substantive when the consideration payable to us for the milestone (i) is consistent with our performance necessary to achieve the milestone or the increase in value to the collaboration resulting from our performance, (ii) relates solely to our past performance and (iii) is reasonable relative to all of the other deliverables and payments within the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the risks that must be overcome to achieve the milestone, the level of effort and investment required to achieve the milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

The Company initially defers revenue for any amounts billed or payments received in advance of the services being performed, and recognizes revenue pursuant to the related pattern of performance, using the appropriate method of revenue recognition based on its analysis of the related contractual element(s).

In November 2014, 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 surgical transplantation research. The Company completed its obligations under this agreement during the year ended March 31, 2017. The Company recorded approximately $0, $32,000, and $50,000 for the years ended March 31, 2018, 2017, and 2016, respectively, in revenue related to this collaboration in recognition of the proportional performance achieved.

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, 2018, 2017, and 2016, the Company has recorded approximately $150,000, $117,000, and $352,000, respectively, in collaboration revenue. The Company has completed its obligations under this agreement as of March 31, 2018.

Also in April 2015, the Company entered into a multi-year research agreement with a third party to develop multiple custom tissue models for use in drug development. Approximately $0, $835,000, $80,000, under this agreement was recognized as revenue in recognition of the proportional performance achieved during the years ended March 31, 2018, 2017, and 2016, respectively.

In June 2016, the Company announced it had entered into 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 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 $65,000 and $34,000 were recognized under this agreement during the years ended March 31, 2018 and 2017, respectively.

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 $3,000 have been recorded under this agreement during the years ended March 31, 2018 and 2017, 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 $43,000 has been recorded during the year ended March 31, 2018, 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.

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 $50,000 in revenue during the year ended March 31, 2018.

Product revenue

The Company recognizes product revenue at the time of delivery to the customer or distributor, provided all other revenue recognition criteria have been met.

As our commercial sales increase, we expect to establish a reserve for estimated product returns that will be recorded as a reduction to revenue. That reserve will be maintained to account for future return of products sold in the current period. The reserve will be reviewed quarterly and will be estimated based on an analysis of our historical experience related to product returns.

Cost of revenue

The Company reported $1.0 million in cost of revenue for the years ended March 31, 2018 and 2017. Cost of revenues consists of our costs related to manufacturing and delivering our product and service revenue. Cost of revenue for the year ended March 31, 2016 was minimal and was included in research and development expense.

Grant revenues

During August of 2013, the Company was awarded a research grant by a private, not-for-profit organization for up to $251,700, contingent on go/no-go decisions made by the grantor at the completion of each stage of research as outlined in the grant award. 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 completed its obligations under this agreement during the year ended March 31, 2017. Revenue recognized under this grant was approximately $0, $41,000 and $43,000 for the years ended March 31, 2018, 2017 and 2016, respectively.

During September of 2014, the NIH awarded the Company a research grant totaling approximately $222,000. 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. Revenue recognized under this grant was approximately $148,000 for the year ended 2016. The Company completed its obligations under this agreement during the year ended March 31, 2016.

During July 2017, the NIH awarded the Company a research grant totaling approximately $1,657,000. 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. Revenue recognized under this grant was approximately $554,000 during the year ended March 31, 2018.

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, 2018, 2017 and 2016, the comprehensive loss was materially equal to the net loss, and consisted of net loss and foreign currency translation. As of March 31, 2018, 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, 2018, 2017 and 2016 as the Company reported a net loss for each respective period and the effect would have been anti-dilutive. Total common stock equivalents that were excluded from computing diluted net loss per share were approximately 12.6 million, 12.4 million, and 10.7 million for the years ended March 31, 2018, 2017 and 2016, respectively.

2. Fixed Assets

Fixed assets consisted of the following (in thousands):

	March 31, 2018	March 31, 2017
Laboratory equipment	$3,695	$3,727
Leasehold improvements	2,177	2,045
Computer software and equipment	656	656
Furniture and fixtures	319	319
Vehicles	9	9
	6,856	6,756
Less accumulated depreciation	(4,068)	(2,916)

	$2,788	$3,840

Depreciation expense for the years ended March 31, 2018, 2017 and 2016 was approximately $1,253,000, $1,139,000, and $805,000, respectively.

3. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2018	March 31, 2017
Accrued compensation	$2,735	$3,318
Accrued legal and professional fees	99	572
Other accrued expenses	507	211
	$3,341	$4,101

4. Derivative Liability

During 2011 and 2012, the Company issued 22,847,182 five-year warrants to purchase the Company's common stock in connection with financing transactions. The exercise price of the warrants was protected against down-round financing throughout the term of the warrants. Pursuant to ASC 815-15 and ASC 815-40, the fair value of the warrants was recorded as a derivative liability on the issuance dates.

The Company revalued the warrants as of the end of each reporting period. There were no warrants classified as derivative liabilities outstanding as of March 31, 2018 or 2017. The change in fair value of the derivative liabilities for the year ended March 31, 2017 was a decrease of $4,000. The change in fair value of the derivative liabilities for the year ended March 31, 2016 was an increase of $17,000. These changes are included in other income (expense) in the statements of operations.

During the years ended March 31, 2018 and 2017, no warrants classified as derivative liabilities were exercised. During the year ended March 31, 2017, 3,350 warrants expired. As of March 31, 2017, all warrants subject to derivative treatment were exercised or have expired.

5. Stockholders' Equity

Stock-based compensation expense and valuation information

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

	Year Ended March 31, 2018	Year Ended March 31, 2017	Year Ended March 31, 2016 (1)
Research and development	$1,174	$1,646	$1,248
General and administrative	$5,729	$5,746	$7,308
Total	$6,903	$7,392	$8,556

(1) Included in total stock-based compensation for the year ended March 31, 2016 is additional expense resulting from acceleration of the vesting schedule to fully vest options held by a terminated executive as pursuant to the 2012 Equity Incentive Plan. Additionally, as part of the severance agreement, a modification was made to extend the exercise period of the fully vested options, resulting in an incremental expense.

The total unrecognized compensation cost related to unvested stock option grants as of March 31, 2018 was approximately $5,650,000 and the weighted average period over which these grants are expected to vest is 2.42 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, 2018 was approximately $4,281,000, which will be recognized over a weighted average period of 2.76 years.

The total unrecognized stock-based compensation cost related to unvested performance-based restricted stock units as of March 31, 2018 was approximately $308,000, which will be recognized over a weighted average period of 2.00 years.

The total unrecognized stock-based compensation cost related to unvested employee stock purchase plan (“ESPP”) shares as of March 31, 2018 was approximately $19,000, which will be recognized over a period of 5 months.

The Company calculates the grant date fair value of all stock-based awards in determining the stock-based compensation expense. Stock-based awards include (i) stock options, (ii) restricted stock units, (iii) performance-based restricted stock units, and (iv) rights to purchase stock granted under the 2016 Employee Stock Purchase Plan (“ESPP”).

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 assumptions:

	Year Ended March 31, 2018	Year Ended March 31, 2017	Year Ended March 31, 2016
Dividend yield	—	—	—
Volatility	76.86%	72.17%	73.96%
Risk-free interest rate	1.81 %	1.16 %	1.57 %
Expected life of options	6.00 years	6.00 years	6.00 years
Weighted average grant date fair value	$1.73	$2.41	$2.52

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Due to the Company's limited historical data, the estimated volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available, in addition to our own. The risk-free interest rate assumption was based on the 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, 2018	Year Ended March 31, 2017
Dividend yield	—	—
Volatility	43.0% - 74.7%	72.9% - 74.7%
Risk-free interest rate	0.79% - 1.85%	0.47% - 0.79%
Expected term	6 months	6 months
Grant date fair value		

	$ 0.30 - $1.04	$ 1.04 - $1.22

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, due to the Company's limited historical data as an early-stage commercial business, the estimated volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available. As of September 1, 2017 and the beginning of the second year of ESPP offering periods, the Company is using our Company-specific volatility rate. 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 terminates on July 1, 2018. No shares have been issued under the 2008 Plan since 2011, and the Company does not intend to issue any additional shares from the 2008 Plan in the future.

In January 2012, the Board of Directors of the Company approved the 2012 Equity Incentive Plan (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 addition, 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, bringing the aggregate shares issuable under the 2012 Plan to 17,553,986. The 2012 Plan as amended and restated became effective on August 20, 2015 and terminates ten years after such date. As of March 31, 2018, 4,595,021 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").

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 years ended March 31, 2018, 2017, and 2016, the Company issued 5,307,105, 997,181, and 0 shares of common stock in at-the-market offerings under the sales agreement with net proceeds of $9.2 million, $4.6, and $0 million, respectively. As of March 31, 2018, the Company had 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 effected 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.

As of March 31, 2018, the Company cannot raise more than an aggregate of $100.0 million in future offerings under the 2018 Shelf including $50.0 million remaining 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, 2018, 2017, and 2016, the Company issued 0, 700,379, and 32,914 shares of common stock upon exercise of 0, 822,903, and 43,796 warrants, respectively.

During the years ended March 31, 2018, 2017, and 2016, the Company issued 500,000, 245,271, and 116,001 shares of common stock upon exercise of 500,000, 245,271, and 116,001 stock options, respectively.

Restricted stock units

During the year ended March 31, 2018, the Company issued restricted stock units for an aggregate of 1,996,478 shares of common stock to its employees and directors. These shares of common stock will be issued upon vesting of the restricted stock units.

A summary of the Company's restricted stock unit activity for the year ended March 31, 2018 is as follows:

	Number of Shares	Weighted Average Price
Unvested at March 31, 2017	1,178,114	$ 3.57
Granted	1,996,478	$ 2.59
Vested	(578,605)	$ 3.22
Canceled / forfeited	(560,642)	$ 2.91
Unvested at March 31, 2018	2,035,345	$ 2.89

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. As of March 31, 2018, no tranches had vested, but 120% of the Negative Adjusted EBITDA tranche is expected to vest in a future year.

The grant date fair value of the PBRSU was $393,000 of which one-fifth is being recognized over each tranches' service period. The Company began recording stock-based compensation expense for these tranches after the August 23, 2017 grant date when the financial performance goals were established and approved. As of March 31, 2018, the Negative Adjusted EBITDA tranche is expected to vest in the amount of 41,766 shares.

A summary of the Company's performance-based restricted stock unit activity from March 31, 2017 through March 31, 2018 is as follows:

	Number of Shares	Maximum Number of Shares Eligible to be Issued	Weighted Average Price
Unvested at March 31, 2017	—	—	$ —
Awarded at target	208,822	208,822	$ 1.88
Vested	—	—	$ —
Canceled / forfeited	(41,764)	(8,352)	$ 1.88
Unvested at March 31, 2018	167,058	200,470	$ 1.88

Stock options

During the year ended March 31, 2018 under the 2012 Equity Incentive Plan, 281,956 stock options were issued at various exercise prices.

In addition, on April 24, 2017, the Company granted a stock option for 2,088,212 shares of common stock to its newly hired Chief Executive Officer. This stock option award 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 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.

The following table summarizes stock option activity for the year ended March 31, 2018:

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2017	10,956,201	$ 4.63	$4,876,437
Options granted	2,370,168	$ 2.64	$—
Options canceled	(2,694,057)	$ 5.78	$—
Options exercised	(500,000)	$ 1.65	$235,000
Outstanding at March 31, 2018	10,132,312	$ 4.01	$591,082
Vested and Exercisable at March 31, 2018	6,211,427	$ 4.54	$591,082

The weighted-average remaining contractual term of stock options exercisable and outstanding at March 31, 2018 was approximately 5.91 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"). We 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 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, 2018, 162,340 shares were issued under the ESPP. At March 31, 2018, there were 1,285,103 shares remaining available for the purchase under the ESPP.

Warrants

During the years ended December 31, 2012 and 2011, the Company issued warrants to investors to purchase 21,347,182 and 2,909,750 shares, respectively, of its common stock.

During the years ended March 31, 2018, 2017 and 2016, 0, 353,093 and 0 of these warrants were exercised for cash proceeds of approximately $0, $336,000 and $0, respectively, and 0, 469,000 and 43,796 of these warrants were exercised through a cashless exercise for issuance of 0, 347,286 and 32,914 shares of common stock, respectively.

In 2012, 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, 2018, 2017, and 2016, no warrants held by consultants were exercised. As of March 31, 2018, 220,000 of these warrants are outstanding.

Additionally, during September 2014, the Company issued 50,000 warrants 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, 2018:

	Warrants	Weighted-Average Exercise Price
Balance at March 31, 2017	221,370	$ 7.16
Granted	—	—
Expired / Canceled	(1,370)	$ 2.28
Exercised	—	—
Balance at March 31, 2018	220,000	$ 7.19

The warrants outstanding at March 31, 2018 are immediately exercisable at prices between $6.84 and $7.62 per share, and have a weighted average remaining term of approximately 1.21 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at March 31, 2018:

Common stock warrants outstanding	220,000
Common stock options outstanding under the 2008 Plan	622,192
Common stock options outstanding under the 2012 Plan	7,421,908
Common stock reserved under the 2012 Plan	4,595,021
Common stock reserved under the 2016 Employee Stock Purchase Plan	1,285,103
Restricted stock units outstanding under the 2012 Plan	2,035,345
Common stock options outstanding and reserved under the Incentive Award Agreement	2,088,212
Restricted stock units outstanding under the Incentive Award Agreement	200,470

Total	18,468,251

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 and 2016, 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 term for 14,685 of the total rentable square footage expires on December 15, 2018, with the remainder of the rentable square footage expiring on September 1, 2021, with the Company having an option to terminate this lease on or after September 1, 2019.

From February 1, 2015 through January 31, 2018 the Company leased a second facility 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, which increased by 3% each 12-month anniversary of the 36 month lease.

The Company also previously leased a third facility from February 1, 2016 through January 31, 2017, consisting of 12,088 rentable square feet of office space located at 6166 Nancy Ridge Drive, San Diego, California 92121 with a monthly rent of $15,000.

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.

Rent expense was approximately $1,458,000, $1,295,000, and $1,088,000 for the years ended March 31, 2018, 2017 and 2016, 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, 2018, are as follows (in thousands):

Fiscal year ended March 31, 2019	1,385
Fiscal year ended March 31, 2020	1,073
Fiscal year ended March 31, 2021	1,104
Fiscal year ended March 31, 2022	468
Fiscal year ended March 31, 2023	—
Thereafter	—
Total	$4,030

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.

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 a minimum annual royalty of $25,000 in January 2017 for the calendar year 2017 and of $25,000 in January 2018 for the calendar year 2018, which is credited against royalties due during the subsequent twelve months. 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.

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, 2018	March 31, 2017
License fees	$ 218	$ 148
Less accumulated amortization	(67)	(53)
License fees, net	$ 151	$ 95

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 $13,600, $10,300, and $9,700 for the years ended March 31, 2018, 2017 and 2016, respectively. At March 31, 2018, the weighted average remaining amortization period for all licenses was approximately 12 years. The annual amortization expense of licenses for the next five years is estimated to be approximately $14,300 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, 2018, March 31, 2017, and March 31, 2016 (in thousands):

	March 31, 2018	March 31, 2017	March 31, 2016
Deferred tax assets:			
Net operating loss carry forwards	$—	$—	$—

Research and development credits	—	—	—
Depreciation and amortization	25	(71)	(105)
Accrued expenses and reserves	1,050	1,373	862
Stock compensation	3,753	6,720	5,584
Other, net	8	7	12
Total deferred tax assets	4,836	8,029	6,353
Valuation allowance	(4,836)	(8,029)	(6,353)
	$—	$—	$—

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, 2018. 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 decreased by approximately $3,193,000 and increased by approximately $1,676,000 for the years ended March 31, 2018 and 2017, respectively.

The Company had federal, state, and foreign net operating loss carryforwards of approximately $146,320,000 and $78,034,000, respectively, as of March 31, 2018. The federal and state net operating loss carryforwards (“NOLs”) will begin to expire in 2028, unless previously utilized.

In March 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Updated No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). The Company adopted ASU 2016-09 on April 1, 2017. Under the new guidance, companies will no longer record excess tax benefits and certain tax deficiencies related to share-based payments to employees in additional paid in capital. Instead, the Company will recognize all income tax effects of awards in its income statement when awards vest or are settled. All excess tax benefits not previously recognized were to be recorded to retained earnings as a cumulative effect adjustment upon adoption. No adjustment to retained earnings was necessary upon adoption; however, as the Company has removed the deferred tax assets related to net operating losses from its deferred tax asset schedule as well as the Company's valuation allowance position. Approximately $2,331,000 attributable to excess tax benefits on stock compensation that had not previously been recognized would have been added to the deferred tax asset for NOLs with a corresponding increase to the valuation allowance.

The Company had federal and state research tax credit carryforwards of approximately $3,404,000 and $3,105,000 at March 31, 2018 and March 31, 2017, 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. In accordance with Staff Accounting Bulletin No. 118, as of March 31, 2018, we have not completed our accounting for the tax effects of enactment of the Act; however, in certain cases, as described below, we have made a reasonable estimate of the effects on our existing deferred tax balances and the one-time transition tax. In other cases, we have not been able to make a reasonable estimate and continue to account for those items based on our existing accounting under ASC 740, Income Taxes, and the provisions of the tax laws that were in effect immediately prior to the enactment. For the items for which we were able to determine a reasonable estimate, we recognized a provisional amount of $2.7 million. In all cases, we will continue to refine our calculations as additional analysis is completed. In addition, our estimates may also be affected as we gain a more thorough understanding of the tax law.

Deferred tax assets and liabilities: We 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%. However, we are still analyzing certain aspects of the Act and refining our calculations, which could potentially affect the measurement of these balances or potentially give rise to new deferred tax amounts. The provisional amount recorded related to the remeasurement of our deferred tax balance was $2,700,000, which was fully offset by a decrease in our valuation allowance.

Foreign tax effects: The one-time transition tax is based on the total post-1986 earnings and profits (E&P) previously deferred from US income taxes. The Company has a deficit in post-1986 E&P from its foreign subsidiary resulting in no increase to income tax expense. No amounts have been provided for any additional outside basis difference inherent in this entity, as these amounts continue to be indefinitely reinvested in foreign operations.

In 2009, the Company adopted the accounting guidance for uncertainty in income taxes pursuant to ASC 740-10. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. The Company did not record any accruals for income tax accounting uncertainties for the year ended March 31, 2018.

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, 2018.

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, in various state jurisdictions, and in the United Kingdom. As of March 31, 2018, 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, 2018.

10. Related Parties

The Company has entered into two agreements with related parties 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. Each agreement was 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 Tx, Inc., 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 amounting to $161,000 recognized as revenue in the year ended March 31, 2018. The agreement contains another $7,000 of ExVive™ Liver Tissue Services to be completed in the first quarter of fiscal 2019.

In November 2017, the Company entered into a collaboration agreement with Viscient Biosciences, 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, the parties intend to develop a custom research platform for studying liver disease. The Company expects the platform to expand its current service portfolio for compound screening in disease models, which aids the drug discovery work for other customers. Viscient intends to target early discovery work for non-alcoholic fatty liver disease ("NAFLD") and non-alcoholic steatohepatitis ("NASH"). Under this agreement and its amendments, the Company provided research services to Viscient amounting to $358,000 recognized as revenue in the year ended March 31, 2018. Additionally, Viscient purchased primary human cell-based products from our subsidiary, Samsara, in the amount of $13,500 recognized as revenue in the year ended March 31, 2018.

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, 2018, 2017, and 2016 were approximately $337,000, $352,000, and $277,000, respectively.

12. Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers, which 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 standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. 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 that defers by one year the effective date for all entities, with application permitted as of the original effective date. The updated standard becomes effective for us on April 1, 2018. The

standard permits the use of either the retrospective or cumulative effect transition method. The Company adopted the new standard for the fiscal year beginning April 1, 2018 using the modified retrospective application method. The Company has substantially completed its assessment of the new standard and the Company believes that there will not be a material impact on its financial statements or disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases, which requires an entity to recognize lease assets and lease liabilities on the balance sheet for leases with terms of more than 12 months and to disclose key information about leasing arrangements. This new guidance is effective for us on April 1, 2019, with early adoption permitted in any interim or annual period. The Company is currently evaluating the impact that this guidance will have on its financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718), which requires an entity recognize excess tax benefits and deficiencies as income tax expense or benefit, the cash flows of which should be included as operating activity in the statement of cash flows. An entity is allowed to either continue accruing compensation cost based on expected forfeitures or to begin recognizing expense as forfeitures occur. In addition, an entity may withhold the maximum statutory tax, increasing the allowable cash settlement portion of awards. The cash paid by an employer when directly withholding shares for tax purposes should be included in the financing activity section of the statement of cash flows. This new guidance was effective for us on April 1, 2017. The requirements of ASU 2016-09 did not have a significant impact on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation: 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 in Topic 718. The standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within those annual reporting periods. The adoption of this guidance will have no impact on our financial statements unless we have modification accounting in accordance with Topic 718.

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 our financial statements as the Company's only derivative liabilities were all exercised or expired as of March 31, 2017 and were removed from the Balance Sheet.

In December 2017, the United States ("U.S.") enacted the Tax Cuts and Jobs Act (the "Act"), which changes existing U.S. tax law and includes various provisions that are expected to affect public companies. 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, and (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. In accordance with Staff Accounting Bulletin No. 118, as of March 31, 2018, we have not completed our accounting for the tax effects of enactment of the Act; however, in certain cases we have made a reasonable estimate of the effects on our existing deferred tax balances and the one-time transition tax. In other cases, we have not been able to make a reasonable estimate and continue to account for those items based on our existing accounting under ASC 740, Income Taxes, and the provisions of the tax laws that were in effect immediately prior to the enactment. For the items for which we were able to determine a reasonable estimate, we recognized a provisional amount of $2.7 million. In all cases, we will continue to refine our calculations as additional analysis is completed. In addition, our estimates may also be affected as we gain a more thorough understanding of the tax law.

13. Quarterly Financial Data (unaudited)

The following quarterly financial data, in the opinion of management, fairly presents the results for the periods presented (in thousands, except per share data):

	Year Ended March 31, 2018			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	$990	$1,355	$1,153	$1,105
Net loss	(10,102)	(9,461)	(7,791)	(7,449)
Net loss per common share - basic and diluted	(0.10)	(0.09)	(0.07)	(0.07)
Weighted average shares used in computing net loss per common share—basic and diluted	104,689,391	106,297,699	107,345,623	110,690,335

	Year Ended March 31, 2017			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	$891	$1,376	$1,151	$812
Net loss	(8,767)	(9,442)	(9,581)	(10,657)
Net loss per common share - basic and diluted	(0.09)	(0.10)	(0.09)	(0.10)
Weighted average shares used in computing net loss per common share—basic and diluted	92,391,964	93,185,400	101,174,734	104,385,617

14. Subsequent Events

On April 17, 2018, the Company undertook the second phase of its business restructuring to better focus and align resources, reducing approximately 13 positions, or 15% of its overall workforce. This second phase of restructuring allows the Company to improve its operational efficiency, consolidate overlapping positions, and streamline its management structure. As a result, the Company expects to record a restructuring charge in the fiscal first quarter of approximately $0.4 million, primarily related to employee severance and benefits costs. The actions associated with the restructuring announcement are anticipated to be complete by the end of fiscal first quarter 2019, with liabilities anticipated to be paid by the end of fiscal fourth quarter 2019.

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 on Form 10-K.

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 on Form 10-K.

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, 2018. 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, 2018.

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 on Form 10-K and has issued an attestation report, included herein, on the effectiveness of our internal control over financial reporting as of March 31, 2018.

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, 2018 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 2018 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 2018 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, 2018:

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)	10,299,445	$ 3.55	5,880,124
Equity compensation plans not approved by security holders (4)	2,288,682	$ 2.49	—

(1) Includes the 2008 Equity Incentive Plan, the 2012 Equity Incentive Plan, and the 2016 Employee Stock Purchase Plan.
(2) Includes stock options and warrants to purchase 8,044,100 shares of common stock with a per share weighted-average exercise price of $4.34. Also includes 2,035,345 restricted stock units with no exercise price.
(3) Includes 1,285,103 shares of common stock available for purchase under the ESPP as of March 31, 2018.
(4) Includes 2,088,212 stock options with a per share exercise price of $2.73 and 200,470 performance-based restricted stock units with no exercise price, collectively, the "Inducement Award Agreements," granted to the Chief Executive Officer upon commencement of his 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 2018 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 2018 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 2018 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 on Form 10-K:

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, 2018 and 2017 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 on Form 10-K.

EXHIBIT INDEX

Exhibit No.	Description
3.1	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the February 2012 Form 8-K)
3.2	Bylaws of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.2 to the February 2012 Form 8-K)
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 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)
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)

Exhibit No.	Description
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)
21.1	Subsidiaries of Organovo Holdings, Inc. (incorporated by reference from Exhibit 21.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
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: May 31, 2018

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)	May 31, 2018
/s/ Craig Kussman Craig Kussman	Chief Financial Officer (Principal Financial Officer)	May 31, 2018
/s/ Kirk Malloy Kirk Malloy	Chairman of the Board	May 31, 2018
/s/ Robert Baltera, Jr. Robert Baltera, Jr.	Director	May 31, 2018
/s/ James Glover James Glover	Director	May 31, 2018
/s/ Tamar Howson Tamar Howson	Director	May 31, 2018
/s/ Mark Kessel	Director	May 31, 2018

Mark Kessel		
/s/ Richard Maroun Richard Maroun	Director	May 31, 2018