ORGANOVO HOLDINGS, INC.
Form 10-K
June 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended March 31, 2016

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 of incorporation)	(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	NYSE MKT

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 x

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 x

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 x 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 x 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. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨	Smaller reporting company	¨

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

The aggregate market value of the voting common stock held by non-affiliates based on the closing stock price as reported on the NYSE MKT on September 30, 2015, the last trading day of the registrant's second fiscal quarter, was $227,966,466. For purposes of this computation only, all executive officers, directors and 10% or greater stockholders have been deemed affiliates.

The number of outstanding shares of the registrant's common stock, as of June 1, 2016 was 92,391,989.

Documents Incorporated by Reference

Certain information required for Part III of this report is incorporated herein by reference to the proxy statement for the 2016 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, 2016

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Important Information Regarding Forward-Looking Statements

Portions of this Annual Report on Form 10-K (including information incorporated by reference) include "forward-looking statements" based on our current beliefs, expectations and projections regarding our technology, our product development opportunities and timelines, our business strategies, the market potential of our technology and products, 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 an early commerci stage company focused on developing and commercializing functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. We intend to introduce a paradigm shift in the approach to the generation of three-dimensional ("3D") human tissues, by utilizing our proprietary platform technology to create human tissue constructs in 3D that mimic native human tissue composition, architecture, and function. We believe we will leverage our highly unique 3D human tissue models to improve the current industry standard cell-based and animal model testing approaches to drug discovery and development by creating 3D tissues constructed solely of human cells. We believe our foundational approach to the 3D printing of living tissues, as disclosed in peer-reviewed scientific publications, and the continuous evolution of our core bioengineering technology platform combine to provide us with the opportunity to fill many critical gaps in commercially available preclinical human tissue modeling and tissue transplantation.

Our foundational proprietary technology, grounded in over a decade of peer-reviewed scientific publications, derives from research led by Dr. Gabor Forgacs, the 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 outright more than 90 additional patents and pending patent applications around the world. We believe that our broad and exclusive commercial rights to patented and patent-pending 3D bioprinting technology, 3D tissues and applications provides us with a strong and defensible market position for the successful commercialization of 3D bioprinted human tissues serving a broad array of unmet preclinical and clinical needs.

We believe we have the potential to build and maintain a sustainable business by leveraging our core technology platform across a variety of applications. We have entered into multiple collaborative research agreements with pharmaceutical corporations and academic medical centers. We have also secured federal grants, including Small Business Innovation Research grants, to support the development of our technology. We developed the NovoGen MMX Bioprinter™ (our first-generation 3D bioprinter) less than two years after commencing operations, and the Bioprinter was named one of the "Best Inventions of 2010" by TIME Magazine, and won a number of engineering innovation awards. Our first tissue product, exVive3D™ Liver, Bioprinted Human Tissue, was launched in 2014 and received the CONNECT Most Innovative Product award for 2014 in Life Sciences (Diagnostics & Research Tools). The exVive3D Liver was also selected as one of the Top 10 Innovations of 2014 by The Scientist magazine. We were selected by MIT's Technology Review magazine among the Most Innovative Companies of 2012, by Inc. Magazine as one of the Most Audacious Companies in 2013, by Fast Company as one of the most innovative companies in healthcare for 2015, and as a Technology Pioneer for 2015 by the World Economic Forum in Davos, Switzerland. We believe these corporate achievements provide strong validation for the commercial potential of our 3D bioprinting platform and the tissues it produces.

Our Platform Technology

Our platform technology is centered on multiple 3D bioprinting technologies, which we have utilized to develop our proprietary instrument platform, our NovoGen Bioprinters®. Our 3D bioprinting technologies enable a wide array of tissue compositions and architectures to be created, using purely cellular 'bio-ink' (building blocks comprised of only living cells), biocompatible hydrogels, or combinations of the two. A key distinguishing feature of our bioprinting

platform is the ability to generate complex 3D tissues that have all or some of their components comprised entirely of cells. 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 wherein cells have intimate contact with neighboring cells, and an intricate architecture created by the spatial arrangement of specific cellular compartments relative to each other. Organovo's 3D bioprinting platform can deliver tissues that are truly three-dimensional with a cellularity and architecture that closely resembles native tissue. Moreover, most tissues can be generated using human cells as inputs, yielding functional models of human tissue that can be used in vitro for drug discovery and development. In the future, 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 have sustained significant damage by trauma or disease.

We are focused on developing the following products:

- A suite of standardized, 3D human tissues for the preclinical assessment of drug effects, including applications in predictive toxicology, absorption, distribution, metabolism, excretion ("ADME"), and drug metabolism and pharmacokinetics ("DMPK").
- Highly customized human tissues as living, dynamic models of human biology or disease, for use in drug discovery and development.
- Three-dimensional human tissues for clinical applications, such as blood vessels for bypass grafting, nerve grafts for nerve damage repair and functional tissue patches for the repair or replacement of damaged tissues and organs.

Our Market Opportunity

We believe that our proprietary 3D bioprinting platform enables us to deliver highly unique functional human tissues to the drug discovery and development market and to multiple clinical markets:

1) Standardized, Normal 3D Human Tissues for Predictive Toxicology and Preclinical Testing: We believe that our NovoGen MMX Bioprinter delivers highly differentiated 3D tissues for use in assays aimed at predicting human clinical outcomes. Our products in this area may replace or complement traditional two-dimensional ("2D") cell culture based cell assays, or cellular co-culture systems. Because our 3D tissues are made of human cells and reproduce many aspects of in vivo tissue architecture and function, we believe they may provide advantages over non-human animal models with respect to prediction of in vivo human outcomes. Bioprinted 3D human tissue products may be provided to the market as kits that are sold by us or distributed by a partner. Additionally, our tissue products may be marketed as a compound screening service, for customers who prefer to provide their compounds to a testing laboratory that will conduct short- or long-term tests involving the exposure of our bioprinted 3D human tissues to their compound(s) and providing them with results and samples. The compound screening service may be conducted by us or may be offered by one or more partners, such as contract research organizations ("CROs").

Our 3D tissue products are anticipated to be compatible with a broad range of in vitro preclinical tests, including some aspects of assessments of ADME, DMPK, and predictive toxicology. DMPK testing is a subset of ADME. Determining the DMPK properties of a drug helps the drug developer to better predict its safety and efficacy. The ADME and DMPK properties of a drug essentially determine the bioavailability of that drug, including how long and at what concentrations it is exposed to the target tissue(s). Toxicology testing is a further requirement to assess the potential for a particular drug to seriously damage one or more organs systems while it is present in the body. Many aspects of preclinical drug testing can be altered significantly by age, genetics, disease state, and the presence of other drugs or chemicals. Most companies perform preclinical ADME, DMPK, and toxicology tests using a combination of biochemical and cell-based assays and animal testing. 3D bioprinted tissue products may replace or complement traditional cell based assays that typically employ primary hepatocytes, intestinal cell lines, renal epithelial cells and cell lines grown in traditional two-dimensional formats. Because 3D bioprinted tissues share more features with native tissue in vivo than standard 2D cell cultures, and they persist for extended time periods in vitro (>40 days), we believe they can provide highly differentiated and valuable outcomes and give clients "human preclinical data" with greater depth and accuracy than has previously been possible.

Additional opportunities in this area include the testing of environmental toxins and cosmetic products on living human tissues. Due to ethical concerns and regulatory considerations, there is a growing market opportunity for the use of 3D human tissue models as alternatives to non-human animal studies. For example, human skin models have substantial potential value as a means to test the effects of candidate cosmetic products prior to commercialization. We have established a collaborative research program in this field with the intention of developing products and services for this type of testing. In addition, many of the standard tissue models developed within this aspect of our business may be used to assess the potential human health impacts and toxicological properties of a large number of chemical products, environmental toxins, or biowarfare agents.

2)

Specialized 3D Tissue Models for Drug Discovery and Development: Our NovoGen bioprinting platform, comprised of multicellular inputs ("bio-ink") and a family of bioprinters with unique capabilities, can produce highly specialized human tissues that model physiology or disease. We have used our bioprinting platform to create a wide array of human tissues, including blood vessels, liver tissues, skin tissues, kidney tissues, lung tissues, and tumor tissues. 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 cardiovascular disease, lung disease, liver disease, kidney disease, and oncology. Market opportunities within this aspect of our business may include externally-partnered or internally-directed drug discovery and the clinical development and commercialization of new molecular entities using highly customized 3D tissue models.

3) Implantable 3D Tissues for Therapeutic Use: Cell- and tissue-based therapeutic products have advanced through research and development via multiple strategic approaches, with current clinical efforts in the field focused on systemic or localized delivery of cell suspensions or surgical installation of combination products that consist of a predominant biomaterial component and cellular component(s). The architectural precision and flexibility of our bioprinting platform may facilitate the prototyping, optimization, development, and clinical use of three-dimensional tissue constructs. Importantly, our platform enables all or part of a three-dimensional tissue to be generated without dependence on scaffolding or biomaterial components, using only living cells as raw materials. The 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. Three-dimensional tissues with tightly defined architecture and composition can create a new product category within cell and tissue therapies. 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, and may self-fund the development of additional tissue targets through preclinical and clinical development.

Background on Bioprinting

The formation of ‘bio-ink’, the cell-based building blocks that can be dispensed by our suite of NovoGen Bioprinters®, relies on the demonstrated principle that groups of individual cells will self-assemble to generate aggregates, through the actions of cell surface proteins that bind to each other and form junctions between cells. Furthermore, if two or more compatible self-assembled aggregates are placed in close proximity, under the proper conditions they will merge to generate larger, more complex structures via physical properties analogous to those that drive fusion of liquid droplets. The concept of tissue liquidity originated in studies of developmental biology, where it was noted that developing tissues have liquid-like properties that enable individual cellular components to pattern each other, migrate, organize, and differentiate. As development progresses, tissues transition from a dynamic viscous liquid state to a more static semi-solid state, largely driven by the compartmentalized organization of cellular components and production within the organized tissue of extracellular matrix proteins that provide the mature tissue with the biomechanical properties required for tissue specific function.

Early publications describing scaffold-free bioprinting demonstrate self-assembly and tissue liquidity using cellular aggregates generated from developing chicken heart tissue, showing that adjacent aggregates will fuse over time and generate a larger cellular structure. This basic behavior can be leveraged to form more complex structures whereby aggregates are arranged in a specific geometry that can recapitulate shapes and architectures commonly found in tissues and organs, including tubes and multi-layered structures.

Additional published results demonstrated that the observed fusion of aggregates in embryonic tissue can be extended to adult-derived cultured mammalian cells, as demonstrated by the fusion of adult hamster ovary epithelial cell aggregates to form toroid (ring) structures when placed into that geometry and held for about 120 hours.

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 first-generation NovoGen MMX Bioprinter™ went from in-licensing and initial design to commercial production in less than two years. 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 released for tissue production.

Generation of bio-ink building blocks is the first step in bioprinting. A wide variety of cells can serve as the raw materials for bio-ink, including cell lines, primary cells, stromal cells, epithelial cells, endothelial cells, and 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 tumor might consist of both stromal and epithelial bio-inks, a vascular tube may consist of both fibroblast and smooth muscle bio-inks, and a liver tissue may consist of two bio-inks made from distinct liver cell types. Our NovoGen Bioprinters

dispense two or more bio-inks layer by layer in the geometry specified by the user, with bio-inert hydrogels serving as an optional physical support for the bioprinted tissue as well as occupying any negative space included in the design.

Our NovoGen MMX Bioprinter™ is a powerful enabling tool for the design, optimization, and fabrication of viable functional human tissues, based on our internal product discovery and development efforts as well as the experience of our corporate partners and customers. Continuous use of NovoGen Bioprinters in the pursuit of multiple in vitro and in vivo applications provides key insights that drive design features and specifications for next-generation instrumentation. We believe that we are uniquely positioned to deliver commercially viable 3D tissue products for drug development and clinical uses.

We currently collaborate with the following institutions, providing access to our NovoGen Bioprinters for research purposes: Yale School of Medicine, University of California, San Francisco ("UCSF"), Knight Cancer Institute at Oregon Health & Science University ("OHSU"), the National Center for Advancing Translational Sciences ("NCATS") and the National Eye Institute ("NEI"). We believe that the use of our bioprinting platform by major research institutes will help to advance the basic capabilities of the platform and generate new and exciting applications for bioprinted tissues, ultimately creating future opportunities for our commercial products and intellectual property licensing.

Research Collaborations

We currently have research collaborations with pharmaceutical, biotechnology and cosmetic companies, academic and research institutions and government agencies. These collaborations are focused on a variety of research projects, including: developing tissue-based drug discovery assays and tissues, developing more clinically predictive in vitro three-dimensional cancer models, exploring the use of our 3D liver tissues in toxicology, and exploring the use of 3D skin for testing skin care products. 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 revenues in our financial statements. Upon entering into a collaboration, we disclose the financial details only to the extent that they are material to our business. Our academic and research institute 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 plus research headcount, depending on the project scope.

Our Products and Product Candidates

We have utilized and intend to utilize our bioprinting technology to develop functional human tissues that can be employed in drug discovery and development, biological research and as therapeutic implants. Our first commercial tissue offered is exVive3D™ Human Liver Tissue, which was designed to be used for predictive preclinical testing of drug compounds. In April 2014, we announced that we had begun to sign contracts with pharmaceutical and biotechnology companies for toxicity research services using our 3D Human Liver Tissue. In November 2014, we began to offer 3D Human Liver services more broadly. We currently focus on contract research services, though we also intend to offer our 3D Human Liver Tissue directly to end user customers as a product in a kit for toxicological and other testing over time. Our second commercial product under development is our 3D Human Kidney Tissue. Similar to our 3D Human Liver Tissue, we are designing our 3D Human Kidney Tissue to be used for predictive preclinical testing of drug compounds.

Samsara Sciences

In January 2016, we announced that our wholly-owned subsidiary, Samsara Sciences, Inc. ("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. We believe Samsara can help us optimize our supply chain and 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 or through distribution partners.

Competition

We are subject to significant competition from pharmaceutical, biotechnology, and diagnostic companies; academic and research institutions; and government or other publicly-funded agencies that are pursuing the development of tissue models and therapeutic products that otherwise address the needs of our potential customers. We believe our future success will depend, in large part, on our ability to maintain a competitive position in our field. Biopharmaceutical technologies have undergone and are expected to continue to undergo rapid and significant change. We or our competitors may make rapid technological developments which may cause our research tools or therapeutic products to become obsolete before we recover the development expenses we have incurred. The

introduction of less expensive or more effective therapeutic discovery and development technologies, including technologies that may be unrelated to our field, may also make our technology or products less valuable or obsolete. We may not be able to make the necessary enhancements to our technologies or products to compete successfully with newly emerging technologies. The failure to maintain a competitive position in the biopharmaceutical field may result in decreased revenues.

We are a platform technology company dedicated to the development and production of functional human tissues that service the drug discovery and development, biological research, and cell- and tissue-based therapy industries.

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

1) Standardized 3D Tissues for in vitro Preclinical Testing: We intend to employ our technology to provide an array of broadly applicable 3D tissue models for use in preclinical assessments of safety and efficacy as an adjunct or alternative to animal studies. Examples of products in this segment of the business include cell-based models for ADME/TOX/DMPK markets.

We believe that we are the first and only company to leverage a bioprinting system in the commercial production of 3D tissue products. Importantly, our fabrication platform remains highly unique in its ability to fabricate 3D tissues from human cells without reliance on biomaterial scaffolding. Consequently, the tissues that we produce have unique features that to date have not been attainable in 3D tissues generated by alternative strategies. Specifically, we believe the dense cellularity, compartmentalized 3D geometry, and microarchitectural features of our bioprinted tissues offer unparalleled in vitro modeling of native tissues. Current competition in this area, and predominant market share, arises mainly from two sources, traditional cell-based in vitro culture approaches and traditional in vivo animal models and testing. Additional competition exists from non-bioprinted cell-based assays offered by such companies as InSphero AG, Ascendance Biotechnology, Inc., RegeneMed Inc., and Hurel Corporation, some of which have a three-dimensional aspect. Although assays from these companies have limited market share today, they may improve market share and competitive position in the future. Future competition may also exist from companies developing cellular models “on a chip”, such as Emulate, or developing tissues with alternative biofabrication methods, such as Cyfuse.

2) Specialized 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. In addition to revenue generated from the tissue production work, additional revenues are possible in the form of up-front license fees, milestone payments, know-how payments, and royalties. We can provide the customer access to tissues as a service or can produce and supply the tissues to customers; both options are designed to generate continuing revenue. Competition in this area arises mainly from two sources, traditional cell-based in vitro culture approaches and traditional in vivo animal models and testing. Future competition from companies like Cyfuse Biomedical (including service companies using their instrument platform), and Aspect Biosystems is also possible.

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.

3) 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. These efforts will be undertaken by us alone, or as partnered projects with leading therapeutic companies seeking to develop a therapeutic tissue product for a specific application. Near-term revenues would

come from the funding of development work and, in some cases, licensing fees for access to our platform technologies. We expect longer-term revenues may arise from shared profits and royalties or other forms of income from successful clinical and commercial development of the tissue products. There are many companies pursuing the discovery, development, and commercialization of tissue-based products for a variety of applications, including but not limited to Organogenesis and Cyfuse. These companies uniquely represent potential competition for us while also being partner candidates. 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.

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, $12.9 million

and $8.0 million for the fiscal years ended March 31, 2016, March 31, 2015, and March 31, 2014, 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 technologies and our products and services. We rely on a combination of patents, trademarks, trade secrets and a variety of contractual mechanisms such as confidentiality, material transfer, licenses, 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 applications and negotiating additional licenses and purchases.

We own or hold exclusive licenses to 12 issued U.S. patents and 22 pending U.S. patent applications. Outside of the U.S., we own or hold exclusive licenses to 15 issued patents and over 90 pending applications, related to our bioprinting technology and its various uses in areas of tissue creation, in vitro testing, and utilization in drug discovery, including filings covering specific tissue constructs.

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, 4 pending U.S. applications, 8 issued international patents and 15 pending international applications. Dr. Gabor Forgacs, one of our founders and the 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.

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 to Consolidated Financial Statements "Licensing Agreements and Research Contracts" in our audited financial statements that are 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 3 issued U.S. patents directed to our NovoGen MMX Bioprinter and methods of bioprinting: U.S. Patent No. 8,931,880; No. 9,149,952; and No. 9,227,339. We have additional U.S. continuation applications pending in this family as well foreign counterpart applications in multiple countries. We recently received a notice of allowance in the U.S. for a patent in a second family covering additional features of our bioprinter. Additional continuation applications are pending in the U.S. in this second family, as well as 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.

Organovo is also pursuing U.S. and foreign patents covering our 3D bioprinted tissues and methods of fabricating such tissues. Our exVive3D Human Liver Tissue is protected by U.S. Patent No. 9,222,932. We have additional U.S. patent applications pending in this family, 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.

We believe that protection of the proprietary nature of our products and technologies 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. We also will continue to rely upon trade secret protection of our methods and technology. 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 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 FDA regulatory requirements for sales or use of 3D tissue models for use in research applications. All human cells utilized in our research activities and, ultimately in our bioprinted tissue products, are collected in compliance with the FDA's guidance for current Good Tissue Practices (cGTP). However, our collaboration partners face regulatory review of the research data generated using our technology platform and research tools. Good Laboratory Practice (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. In addition, as our 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.

Therapeutic tissues and other regenerative medicine products are subject to an extensive, lengthy and uncertain regulatory approval process by the U.S. 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 human studies is lengthy and expensive. 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 formed our wholly-owned subsidiary, Samsara Sciences, Inc. ("Samsara"), to serve as a key source of the primary human cells we utilize in our products and services and in the development of therapeutic products. Samsara is currently supplying us with qualified human liver cells for use in manufacturing our exVive 3D Human Liver Tissue, as well as certain cells for research and development activities. We believe that Samsara can help us optimize our supply chain and operating expenses and ensure that the human cells we utilize 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. We work closely with Samsara and our third-party suppliers to assure continuity of supply while maintaining high quality and reliability. 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 June 1, 2016, we have 116 employees, of whom 115 are employed full time. We also engage consultants and temporary employees from time to time to provide services that relate to our bioprinting business and technology as well as for general administrative services.

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. In April 2014, we announced that we had begun to sign contracts for research services using our 3D Human Liver Tissue product, and in November 2014, we announced the full commercial release of our first product, the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing. 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. We have generated operating losses each year since we began operations, including $38.6 million, $30.3 million, and $20.6 million for the years ended March 31, 2016, 2015, and 2014, respectively. As of March 31, 2016, we had incurred cumulative operating losses of $107.2 million and cumulative net losses totaling $160.9 million. We expect to incur substantial additional operating losses over the next several years as our research, development, 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 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;
- entering into collaborative relationships with strategic partners;
- obtaining any necessary regulatory approval for our drug discovery, biological research, and therapeutic tools, products and services;
- entering into successful manufacturing, sales and marketing arrangements with third parties or developing an effective sales and marketing infrastructure to commercialize our products and services; 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, biological research, and potentially as therapeutic implants for the treatment of damaged or degenerating tissues and organs. Our success will depend upon the commercial viability 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. If we are not successful in implementing our development and commercialization strategies, which are new and unproven, and/or if we underprice or overrun our cost estimates for our contracts or our development 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 resources required to develop our drug discovery, biological research, and therapeutic tools, products and services;
- the time and cost of obtaining any necessary regulatory approvals;
- we may elect to pursue additional research and development programs as part of our long-term business plan;
- the cost and time required to create effective sales and marketing capabilities and commercialization strategies;
- the expenses we incur to maintain and improve our platform technology;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

In addition, our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our products and services, and from collaborations with third parties. However, we may not correctly predict the amount or timing of future revenues. In addition, we may not be able to adjust our operations in a timely manner to compensate for any unexpected shortfall in our revenues or we may increase 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.

We may need to secure additional financing to support our long-term business plans.

We may require additional funds to support our long-term business plans. We expect that we may 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 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 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 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 3D Human Liver Tissue, on a limited basis in April 2014 and more broadly in November 2014. The second product (and related research services) we are developing is our 3D Human Kidney Tissue, which we plan to offer for predictive preclinical testing of drug compounds. As a result, we have had a limited time to prove that our 3D Human Liver Tissue and related services will enable our customers to conduct drug discovery and biological

research more effectively than through the use of existing technologies. Our 3D Human Kidney Tissue and our other products under development are unproven at this time, 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. 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. To date, there has not been sufficient time for our collaborators to develop or commercialize any therapeutic products based on our drug discovery and biological research tools, products and services. If our drug discovery and biological research tools, products and services do not assist in the discovery and development of such therapeutic products, 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, biological research, therapeutic tools, products and services 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 3D Human Liver and Kidney Tissues. These complications could materially delay or limit the 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 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 and biological research tools and products 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 or otherwise failing to achieve market acceptance of such products or services;
- failing to be cost effective;
- failing to obtain any necessary regulatory approvals;
- 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 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 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 typically 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 these products 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.

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 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; and
- sales and marketing of products, services and technologies.

Principal competitive factors in our industry include the quality, 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, manufacturing and marketing; and the availability of substantial capital resources to fund these activities. Please see Item 1. “Business – Competition” 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.

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. There is no assurance that we can successfully identify and develop therapeutic products, prove that they are safe and efficacious in clinical trials, or meet applicable regulatory standards. Given the potential costs of these therapeutic programs, we may pursue licensing, partnering and other strategic alternatives to help fund further investigation and clinical development, but there is no assurance that we will be able to do so based on their early stage of development. As a result, we may not be successful in developing, showing clinical efficacy, obtaining regulatory approval or raising the required capital for any therapeutic programs we identify and elect to pursue.

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 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 commercialize our tools and products.

We require a reliable supply of human cells for our commercial products and services and for our research and development activities. We also purchase 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 will 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. Although we believe we have adequate available sources of raw materials to meet our commercial demands, 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.

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 even 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 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 planned growth or expansion of our operations could adversely affect our business, financial condition or results of operations.

Our business operations and activities have grown rapidly, and we expect this growth to continue as we expand our ability to develop and commercialize functional human tissues. The rapid expansion of our business and addition of new personnel may place a strain on our management and operational systems. To effectively manage our operations and growth, we must continue 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 continue to successfully:

- expand and 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 our planned growth and expansion successfully, which could adversely affect our business, financial condition or results of operations.

Our business will be adversely impacted if we are unable to successfully attract and hire 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 timely attract and hire a highly skilled and experienced 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 platform technology is subject to the requirements of Good Laboratory Practice (GLP) to provide suitable data for 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. As a result, the 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.

Any therapeutic implants 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 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 IDE (Investigational Device Exemption), 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; performance of a consistent and reproducible manufacturing process intended for commercial use; Pre-Market Approval Application (PMA); and FDA approval of the PMA before any commercial sale or shipment of the product.

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 NYSE MKT, 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 NYSE MKT. 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.

We may have undisclosed liabilities and any such liabilities could harm our revenues, business, prospects, financial condition and results of operations.

Prior to our reverse merger in February 2012, the assets and liabilities of the public company shell we eventually merged into were transferred in a split-off transaction (the "Split-Off") to a separate entity (the "Split-Off Entity") owned by the then outstanding stockholders of the public company shell (the "Split-Off Stockholders"). Even though the pre-merger assets and liabilities were transferred to the Split-Off Entity in the Split-Off, there can be no assurance that we will not be liable for any or all of such liabilities. Any such liabilities that survived our reverse merger could harm our revenues, business, prospects, financial condition and results of operations upon our acceptance of responsibility for such liabilities. The transfer of the operating assets and liabilities to Split-Off Entity, coupled with the Split-Off, will result in taxable income to us in an amount equal to the difference between the fair market value of the assets transferred and the pre-merger tax basis of the assets. Any gain recognized, to the extent not offset by our net operating loss carryforward, if any, will be subject to federal income tax at regular corporate income tax rates.

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;
- regulatory actions regarding our products or services;
- 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, 2016, there were an aggregate of 109,540,165 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 16,101,363 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, and 1,046,813 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, resulting in the dilution of the ownership interests of our present stockholders. 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 presently outstanding warrants, hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. 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 NYSE MKT.

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.

Our common stock is controlled by insiders.

Our current executive officers and directors beneficially own approximately 13.2% of our outstanding shares of common stock as of March 31, 2016. Although we are not aware of any voting arrangements between our officers and directors, such concentrated control may adversely affect the price of our common stock. Investors who acquire our common stock may have no effective voice in the management of our operations.

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.

Since July 2012, the Company has leased its main facility at 6275 Nancy Ridge Drive, San Diego, CA 92121, consisting of approximately 30,895 rentable square feet containing laboratory, clean room and office space. Monthly rental payments are approximately $83,000 per month with 3% annual escalators. The lease term expires September 1, 2021 with the option to terminate on or after September 1, 2019. The Company also has a right of first refusal on adjacent additional premises of approximately 14,500 square feet.

On January 9, 2015, the Company entered into an agreement to lease 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. The term of the lease is 36 months, beginning on February 1, 2015 and ending on January 31, 2018, with monthly rental payments of approximately $12,000 commencing on April 1, 2015. In addition, there are annual rent escalations of 3% on each 12-month anniversary of the lease commencement date.

On December 28, 2015, the Company entered into an agreement to lease a third facility consisting of 12,088 rentable square feet of office space located at 6166 Nancy Ridge Drive, San Diego, CA 92121. The term of the lease is 12 months, beginning on February 1, 2016 and ending on January 31, 2017, with monthly rental payments of $15,000 commencing on February 1, 2016.

Item 3. Legal Proceedings.

The Company is not involved in any material legal proceedings or legal matters at this time. See Note 6 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

On February 8, 2012, Organovo, Inc., a privately held Delaware corporation, merged with and into Organovo Acquisition Corp., a wholly-owned subsidiary of the Company, a publicly traded Delaware corporation, with Organovo, Inc. surviving the merger as a wholly-owned subsidiary of the Company (the "Merger"). Organovo Holdings, Inc. commenced trading on the QB tier of the OTC on February 15, 2012, and upgraded from the QB to the QX tier of the OTC on October 8, 2012. On July 11, 2013, the Company's shares began trading on the NYSE MKT under the symbol "ONVO".

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, 2016	High	Low
Fourth Quarter	$2.64	$1.60
Third Quarter	$3.48	$2.37
Second Quarter	$4.13	$1.90
First Quarter	$5.82	$3.50

Year Ended March 31, 2015	High	Low
Fourth Quarter	$7.42	$3.29
Third Quarter	$7.68	$5.35
Second Quarter	$9.25	$6.17
First Quarter	$9.10	$5.12

As of March 31, 2016, we had 92,391,989 outstanding shares of common stock, with a closing price of $2.17 per share. On this date, there were 100 holders of record of the Company's common stock.

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 our total stockholder returns since we commenced trading on February 15, 2012 through March 31, 2016 to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. This graph assumes the investment of $100 on February 15, 2012 in our common stock, the NASDAQ Composite Index and the NASDAQ Biotech Index, and assumes the reinvestment of dividends. No cash dividends have been declared or paid on our common stock. The comparisons in the graph

below are required by the SEC and are 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.

	February 15, 2012	March 31, 2012	March 31, 2013	March 31, 2014	March 31, 2015	March 31, 2016
Organovo Holdings, Inc. — ONVO	100.00	149.70	223.03	463.03	214.55	131.52
NASDAQ Composite — IXIC	100.00	106.03	112.06	144.01	168.08	167.01
NASDAQ Biotechnology — NBI	100.00	102.25	133.23	197.05	287.10	217.65

Equity Compensation Plans

The following table summarizes information about the Company's equity compensation plans by type as of March 31, 2016 (in thousands, except per share amounts):

Plan category	Number of securities to be issued upon exercise/vesting of outstanding options, warrants, units and rights (1)	Weighted average exercise price (1)	Number of securities available for future issuance
Equity compensation plans approved by security holders	9,835,997	$ 4.12	6,486,736
Equity compensation plans not approved by security holders	—	—	—

(1) Does not include outstanding restricted stock units for 6,250 shares of common stock as of March 31, 2016.

Item 6. Selected Financial Data (in thousands except per share data).

You should read the following selected consolidated financial data in conjunction with our consolidated financial statements, the notes to the consolidated financial statements and Item 7—"Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this report. The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements and the related notes included elsewhere in this report.

On March 31, 2013, our Board of Directors approved a change in our fiscal year end from December 31st to March 31st. As a result of this change, we filed a Transition Report on Form 10-K/T for the three-month transition period ended March 31, 2013. References to any of our pre-2013 fiscal years mean the fiscal years ending on December 31st.

The table below shows selected consolidated financial data. The consolidated statements of operations data for the years ended March 31, 2016, 2015 and 2014, and the consolidated balance sheet data at March 31, 2016 and 2015 are derived from our consolidated financial statements included elsewhere in this report. The consolidated statement of operations data for the three months ended March 31, 2013 and 2012 and the years ended December 31, 2012 and 2011 and the consolidated balance sheet data as of March 31, 2014, 2013 and 2012, and as of December 31, 2012 and 2011 are derived from our consolidated financial statements not included in this report. The historical results presented below are not necessarily indicative of financial results to be achieved in future periods.

	Year Ended March 31, 2016	Year Ended March 31, 2015	Year Ended March 31, 2014	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012 (unaudited)	Year Ended December 31, 2012	Year Ended December 31, 2011
Selected Consolidated Statement of Operations Data:							
Revenue	$1,483	$571	$379	$215	$120	$1,197	$969
Operating loss	$(38,643)	$(30,297)	$(20,649)	$(4,025)	$(1,329)	$(9,319)	$(2,305)
Net loss	$(38,575)	$(30,082)	$(25,848)	$(16,120)	$(37,081)	$(43,553)	$(4,383)
Loss per share, basic and diluted	$(0.43)	$(0.38)	$(0.35)	$(0.26)	$(1.17)	$(1.01)	$(0.19)
Weighted average shares outstanding, basic and diluted	90,057,356	79,650,087	73,139,618	61,750,157	31,591,663	43,149,657	22,925,694

	March 31, 2016	March 31, 2015	March 31, 2014	March 31, 2013	March 31, 2012 (unaudited)	December 31, 2012	December 31, 2011
Selected Consolidated Balance Sheet Data:							
	$59,162	$46,501	$47,268	$7,762	$9,724	$(6,169)	$(946)

Working capital (deficit)							
Total assets	$67,576	$53,489	$50,186	$17,375	$11,241	$16,749	$1,409
Long-term liabilities	$905	$32	$9	$24	$47,515	$17	$1,267
Stockholders' equity (deficit)	$62,181	$48,696	$48,284	$8,969	$(37,385)	$(5,303)	$(1,835)

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 statement. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this Annual Report. Except as required by applicable law we do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.

The management's 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.

Overview

We are an early commercial stage company focusing on developing and commercializing functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. We intend to introduce a paradigm shift in the approach to the generation of three-dimensional human tissues, by utilizing our proprietary platform technology to create human tissue constructs in 3D that mimic native human tissue composition, architecture and function. We intend to leverage our unique 3D human tissue models to improve the current industry standard cell-based and animal model testing approaches to drug discovery and development by creating 3D tissues constructed solely of human cells. We believe our foundational approach to the 3D printing of living tissues, as disclosed in peer-reviewed scientific publications, and the continuous evolution of our core bioengineering technology platform combine to provide us with the opportunity to fill many critical gaps in commercially available preclinical human tissue modeling and tissue transplantation. In November 2014, we announced the commercial release of our first product, the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing. Initial revenues derived from the product have been and will continue to be predominantly through our research service model, which involves testing compounds provided to us for analysis by our customers. Prior to initiating the service, our technical staff assists customers in determining the extent of testing to be conducted utilizing our exVive3D Human Liver Tissue. Testing may include the analysis of one or multiple compounds under various dosing and duration protocols to determine toxicity and metabolic effects of the test compounds on the tissue model. Projects may involve multiple deliverables, which are clearly defined and based on pricing as stated in the related customer agreements. Consistent with our revenue recognition policies, revenue related to each deliverable will be recognized when delivered and the period of customer acceptance has been met. Revenue from projects without multiple deliverables will be recognized when the data package has been delivered to the customer and the term of customer acceptance has been met. In general, project duration is in the four to six month range.

In addition to our exVive3D Human Liver Tissue product and research service contracts, we have entered into collaborative research agreements with pharmaceutical corporations and academic medical centers. We have also

secured federal grants, including Small Business Innovation Research grants, to support the development of our technology.

We continuously engage in research and development to enhance our platform technology, to develop new product 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 second commercial product under development is our 3D Human Kidney Tissue. Similar to our 3D Human Liver Tissue, we are designing our 3D Human Kidney Tissue to be used for predictive preclinical testing of drug compounds.

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 that we utilize in our products and services and in the development of therapeutic products. In addition to serving as one of our key suppliers, Samsara offers human cells for use by life science customers, both directly or through distribution partners.

Reverse Merger Transaction

On February 8, 2012 (the "Closing Date"), Organovo Acquisition Corp., a wholly-owned subsidiary of Organovo Holdings, Inc. ("the Company"), merged (the "Merger") with and into Organovo, Inc., a privately held Delaware corporation ("Organovo"). Organovo was the surviving corporation of that Merger, and became a wholly-owned subsidiary of the Company. As a result of the Merger, the Company acquired the business of Organovo, and has continued the existing business operations of Organovo.

Simultaneously with the Merger, on the Closing Date, all of the issued and outstanding shares of Organovo common stock converted, on a 1 for 1 basis, into shares of the Company's common stock, par value $0.001 per share ("Common Stock"). Also on the Closing Date, all of the issued and outstanding options to purchase shares of Organovo Common Stock, all of the issued and outstanding Bridge Warrants (as defined below) to purchase shares of Organovo Common Stock, and other outstanding warrants to purchase Organovo Common Stock converted, respectively, into options (the "New Options"), new bridge warrants (the "New Bridge Warrants") and new warrants (the "New Warrants") to purchase shares of Common Stock on a 1 for 1 basis. The New Options are being administered under Organovo's 2008 Equity Incentive Plan (the "2008 Plan"), which the Company assumed and adopted on the Closing Date in connection with the Merger.

Specifically, on the Closing Date, (i) 22,445,254 shares of Common Stock were issued to former Organovo stockholders; (ii) New Options to purchase 896,256 shares of Common Stock granted under the 2008 Plan were issued to optionees pursuant to the assumption of the 2008 Plan; (iii) New Warrants to purchase 1,309,750 shares of Common Stock at $1.00 per share were issued to holders of Organovo warrants; and (iv) New Bridge Warrants to purchase 1,500,000 shares of Common Stock at $1.00 per share were issued to Bridge Investors (as defined below).

Additionally, New Warrants to purchase 100,000 shares of Common Stock at $1.00 per share were issued to a former note holder of Organovo in connection with the repayment at the Closing Date of a promissory note in the principal amount of $100,000.

The Merger was treated as a recapitalization of the Company for financial accounting purposes. The historical financial statements of Organovo Holdings, Inc. before the Merger were replaced with the historical financial statements of Organovo before the Merger.

In connection with the Merger, Organovo Holdings, Inc.'s Board of Directors and stockholders adopted the 2012 Equity Incentive Plan (the "2012 Plan"). The 2012 Plan, as amended on August 20, 2015, provides for the issuance of up to 17,553,986 shares to executive officers, directors, advisory board members, consultants and employees. In addition, we assumed and adopted the 2008 Plan, and as described above option holders under that plan were granted New Options to purchase Common Stock. No further options will be granted under the 2008 Plan. The parties have taken all actions necessary to ensure that the Merger was treated as a tax-free exchange under Section 368(a) of the Internal Revenue Code of 1986, as amended.

As of June 1, 2016, the Company had 92,391,989 total issued and outstanding shares of Common Stock, and four- and five-year warrants for the opportunity to purchase an additional 1,046,813 shares of Common Stock at exercise prices ranging from $0.85 to $7.62 per share. The Company had outstanding stock options to purchase an aggregate of 9,600,089 shares of Common Stock at exercise prices ranging from $0.08 to $9.92 and 6,250 outstanding unvested restricted stock units, with each unit representing the right to receive one share of Common Stock.

Critical Accounting Policies

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, which appear under Item 8 of Part II, and have been prepared in accordance with accounting principles generally accepted in the United States,

which require that we make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 1 to our consolidated financial statements. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

Revenue Recognition

The Company derives its revenues from research service agreements, product sales, collaborative research agreements, and grants from the National Institutes of Health (“NIH”), U.S. Treasury Department and private not-for-profit organizations.

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.

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. 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.

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).

Product Revenue

The Company recognizes product revenue at the time of shipment to the customer, provided all other revenue recognition criteria have been met. To date, the Company has not recognized significant revenue from commercial product sales.

As our commercial sales increase, 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 Revenues

Grant revenue recognition is based on the terms of the grant. The Company generally receives two kinds of grants: cost reimbursement-based grants, and fixed price grants for which payments are due upon the achievement of specific milestones. For cost reimbursement-based grants, revenues are based upon internal and subcontractor costs incurred that are specifically covered by the grants, and where applicable, an additional facilities and administrative rate that provides funding for overhead expenses. These revenues are recognized as grant-related expenses are incurred by the Company or its subcontractors. Fixed price grants that provide for payments upon the completion of specific milestones are considered revenue arrangements with multiple deliverables, and as such, revenue is allocated among the accounting units as described above and is recognized only as elements are delivered and the Company determines there are no uncertainties regarding customer acceptance.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks.

The Company reviews 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, the Company 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

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 has issued warrants, of which some are 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 uses Level 3 inputs 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 are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded

in other income or expense accordingly, as adjustments to fair value of derivative liabilities. Various factors are considered in the pricing models we use to value the warrants, including the Company's current stock price, the remaining life of the warrants, the volatility of the Company's stock price, and the risk free interest rate. Future changes in these factors may have an impact on the computed fair value of the warrant liability.

Stock-Based Compensation

For purposes of calculating stock-based compensation, we estimate the fair value of stock options 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 volatility of our common stock over the most recent period commensurate with the estimated expected term of the stock options. 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, 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 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.

Results of Operations

Overview

Organovo was founded in Delaware in April 2007. Activities since the Company's inception have been devoted primarily to developing a platform technology and functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs, raising capital and building infrastructure. In November 2014, the Company announced the full commercial release of its first product, the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing. In September 2015, we established another wholly-owned subsidiary in the United Kingdom, Organovo U.K., Ltd., primarily for the purpose of establishing a sales presence in Europe. In January 2016, we announced that our wholly-owned subsidiary, Samsara, commenced operations. We formed Samsara to serve as a key source of certain primary human cells that we utilize in our products and services and in the development of therapeutic products. As of March 31, 2016, the Company has not yet realized significant revenues from its planned principal operations. The Company's activities are subject to significant risks and uncertainties including failing to secure additional funding to fully operationalize the Company's current technology and continue to implement its business plan.

Comparison of the Years Ended March 31, 2016 and March 31, 2015

Revenues

Revenues of $1.5 million for the year ended March 31, 2016 increased approximately $0.9 million, or 150%, over revenues of $0.6 million for the year ended March 31, 2015. This change reflects an increase of $0.5 million in product and service revenue over the year ended March 31, 2015, due to an increasing number of customer contracts for our exVive3D Human Liver Tissue during the year ended March 31, 2016. In addition, collaboration revenue increased $0.3 million due to two new collaborative research agreements that began during the fiscal year ended March 31, 2016, and grant revenue increased $0.1 million due to activities under an NIH grant that was ongoing during the first half of fiscal 2016.

Operating Expenses

Operating expenses increased approximately $9.2 million, or 30%, from $30.9 million for the year ended March 31, 2015 to $40.1 million for the year ended March 31, 2016. Of this increase, approximately $4.1 million is related to increased selling, general and administrative expense, while the other $5.1 million relates to increased investment in research and development expense. These increases are attributed to the Company's continued implementation of its business plan, including hiring additional staff to support research and development initiatives, incremental investments associated with strategic growth and commercialization initiatives following the commercial launch of our exVive3D Human Liver Tissue in November 2014, expenses related to operating as a publicly traded corporation, and expansion of its facility.

Research and Development Expenses

Research and development expense increased $5.1 million, or 40%, from approximately $12.9 million for the year ended March 31, 2015 to approximately $18.0 million for the year ended March 31, 2016 as the Company significantly increased its research staff to support its obligations under certain collaborative research agreements and grants, to complete additional research studies for its liver product and to expand its kidney product development team. Full-time research and development staffing increased from an average of forty-four full-time employees during the year ended March 31, 2015 to an average of sixty-eight full-time employees during the year ended March 31, 2016, resulting in increases in staffing expense of approximately $2.6 million, facility costs of approximately $1.2 million, lab supply costs of approximately $1.0 million, and outsourced research and consulting related to new product development of approximately $0.3 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased approximately $4.1 million, or 23%, from $18.0 million for the year ended March 31, 2015 to approximately $22.1 million for the year ended March 31, 2016. This increase was primarily driven by an increase in staffing-related expenses of approximately $2.3 million due to the headcount increase from an average of sixteen full-time

employees during the year ended March 31, 2015 to an average of twenty-eight full-time employees during the year ended March 31, 2016, to support the commercial launch of our exVive3D Human Liver Tissue and to provide strategic infrastructure in developing collaborative relationships and the commercialization of research-derived product introductions. Non-cash stock-based compensation costs also increased approximately $1.5 million, $1.3 million of which is related to the acceleration of vesting and modification to extend the exercise period for an employee who terminated employment due to disability (as defined in the Company's Amended and Restated 2012 Equity Plan) in addition to new grants during the period. In addition, due to the Company's overall growth and expansion of the commercial business during the year ended March 31, 2016, strategic consulting and facility-related costs increased significantly over the previous year. Partially mitigating these increases was a $0.8 million decrease in expense related to vendor warrants due to fewer warrants issued and outstanding as well as the reversal of approximately $0.1 million of expense related to a potential bonus equity issuance to a consultant during the year ended March 31, 2016.

Other Income (Expense)

Other income was approximately $0.1 million for the year ended March 31, 2016, and consisted primarily of interest income. For the year ended March 31, 2015, other income of approximately $0.2 million consisted primarily of gains related to the revaluation of warrant derivative liabilities, and to a lesser extent, interest income. As a result of fewer outstanding warrants underlying the derivative liabilities in fiscal 2016, changes in fair value have had a lesser impact on other income (expense).

Comparison of the Years Ended March 31, 2015 and March 31, 2014

Revenues

Revenues of $0.6 million for the year ended March 31, 2015 increased approximately $0.2 million, or 50%, over revenues of $0.4 million for the year ended March 31, 2014. This increase reflects the recognition of $0.3 million in commercial revenue since the Company's product launch in November 2014, partially offset by a $0.1 million decrease in collaboration revenue due to the completion of one of the Company's larger collaborative research agreements during the year ended March 31, 2014.

Operating Expenses

Operating expenses increased approximately $9.9 million, or 47%, from $21.0 million for the year ended March 31, 2014 to $30.9 million for the year ended March 31, 2015. Of this increase, approximately $5.0 million is related to increased selling, general and administrative expense, while the other $4.9 million relates to increased investment in research and development expense. Those increases are attributed to the Company's continued implementation of its business plan, including hiring additional staff to support its research and development initiatives, incremental investment associated with commercialization project initiatives, expenses related to operating as a publicly traded corporation, expansion to a larger facility, and increased stock compensation expense relative to employees and certain consulting services.

Research and Development Expenses

Research and development expense increased $4.9 million, or 61%, from approximately $8.0 million for the year ended March 31, 2014 to approximately $12.9 million for the year ended March 31, 2015 as the Company significantly increased its research staff to support its obligations under certain collaborative research agreements and grants, and to expand product development efforts in preparation for commercial revenues. Full-time research and development staffing increased from an average of twenty-five full-time employees for the year ended March 31, 2014 to an average of forty-four full-time employees for the year ended March 31, 2015. In addition to the incremental payroll, benefits and stock-based compensation resulting from increased staffing levels, the Company

increased its facility space to accommodate its growing research staff, and increased its spending on lab equipment and supplies in proportion to its increased research activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased approximately $5.0 million, or 38%, from $13.0 million for the year ended March 31, 2014 to approximately $18.0 million for the year ended March 31, 2015. Increased staffing expenses of approximately $1.0 million was due to the headcount increase from an average of twelve full-time employees for the year ended March 31, 2014 to an average of sixteen full-time employees as of March 31, 2015, to provide strategic infrastructure in developing collaborative relationships and preparing for commercialization of products and services, and to address the additional compliance requirements of operating as a publicly traded corporation. Stock-based compensation costs also increased approximately $1.7 million due to additional grants to employees and consultants. In addition, due to the Company’s overall growth and transition into the commercial phase during the year ended March 31, 2015, fees for legal services, investor outreach, marketing, insurance and consulting increased over the previous year. Finally, facility costs increased due the expansion of the Company’s facility during the latter part of the year ended March 31, 2014.

Other Income (Expense)

Other income was approximately $0.2 million for the year ended March 31, 2015, and consisted primarily of interest income and a gain related to the revaluation of warrant derivative liabilities. This gain was caused by a declining stock price during the period that decreased the value of the derivative liability. For the year ended March 31, 2014, other expense consisted primarily of a $5.1 million loss related to the revaluation of warrant derivative liabilities due to rising stock prices during the period that caused an increase in the value of the derivative liability. In addition, the majority of the underlying warrants to which the derivative relates were exercised or converted to equity instruments during fiscal 2014, significantly lessening the impact of subsequent changes in our stock price.

Various factors are considered in the pricing models we use to value the warrants, including the Company's current stock price, the remaining life of the warrants, the volatility of the Company's stock price, and the risk free interest rate. Future changes in these factors may have a significant impact on the computed fair value of the warrant liability. As such, we expect future changes in the fair value of the warrants could continue to vary significantly from period to period.

Financial Condition, Liquidity and Capital Resources

The Company has primarily devoted its efforts to technology and product development, raising capital and building infrastructure. In November 2014, the Company announced the full commercial release of its first product, the exVive3D Human Liver Tissue for use in toxicology and other preclinical drug testing, and has built a sales and marketing and research and development infrastructure to support the commercialization of research services of the exVive3D Human Liver Tissue.

The Company has incurred negative cash flows from operations. Net cash used in operations is primarily driven by our operating results (net income adjusted for stock-based compensation, depreciation, amortization, changes in fair value, and other non-cash charges). As of March 31, 2016, the Company had cash and cash equivalents of $62.1 million and an accumulated deficit of $160.9 million. The Company also had negative cash flows from operations of $29.4 million, $19.6 million, and $15.6 million for the years ended March 31, 2016, 2015 and 2014, respectively.

At March 31, 2016, we had total current assets of $63.7 million and current liabilities of $4.5 million, resulting in working capital of $59.2 million. At March 31, 2015, we had total current assets of $51.3 million and current liabilities of $4.8 million, resulting in working capital of $46.5 million.

Net cash used in investing activities was approximately $2.1 million, $1.5 million, and $0.3 million for the years ended March 31, 2016, 2015 and 2014, 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 the Company's facilities related to its expanded research capabilities and the commercialization of its first product.

Net cash provided by financing activities was approximately $43.5 million, $23.1 million, and $48.4 million for the years ended March 31, 2016, 2015 and 2014, respectively.

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.

During the year ended March 31, 2015, we raised net proceeds of approximately $22.3 million through the sale of 3,197,768 shares of our common stock through at-the-market offerings. In addition, we raised approximately $0.4 million from the exercise of warrants, and $0.4 million from stock option exercises during the year ended March 31, 2015.

Through March 31, 2016, 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 offerings, and from revenue derived from products and research-based services, grants, and collaborative research agreements. Based on its current operating plan and available cash resources, the Company 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 and commercialization of its human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. The Company intends to cover its future operating expenses through cash on hand, through revenue derived from research services 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 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.

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 Organovo's significant contractual obligations and related scheduled payments as of March 31, 2016 (in thousands):

	Total	2017	2018 to 2019	2020 to 2021	2022 and Thereafter
Operating lease obligations (A)	$6,148	$1,313	$2,192	$2,176	$ 467
Total	$6,148	$1,313	$2,192	$2,176	$ 467

(A) Operating lease obligations include the remaining payments due under the Company's facility leases.

Recent Accounting Pronouncements

For information regarding recently adopted and issued accounting pronouncements, see Note 11 to the 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 any foreign currency or 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.

San Diego, California

We have audited the accompanying consolidated balance sheets of Organovo Holdings, Inc. and Subsidiaries (the "Company") as of March 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three year period ended March 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Organovo Holdings, Inc. and Subsidiaries as of March 31, 2016 and 2015, and the results of their consolidated operations and their cash flows for each of the three years in the period ended March 31, 2016, 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 effectiveness of Organovo Holdings, Inc. and Subsidiaries' internal control over financial reporting as of March 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated June 9, 2016 expressed an unqualified opinion.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

June 9, 2016

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Organovo Holdings, Inc.

San Diego, California

We have audited Organovo Holdings, Inc. and Subsidiaries' internal control over financial reporting as of March 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Organovo Holdings, Inc. and Subsidiaries' 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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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.

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 generally accepted accounting principles. 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.

In our opinion, Organovo Holdings, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of March 31, 2016, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets and the related consolidated statements of operations, stockholders' equity, and cash flows of Organovo Holdings, Inc. and Subsidiaries, and our report dated June 9, 2016 expressed an unqualified

opinion.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

June 9, 2016

ORGANOVO HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands except per share data)

	March 31, 2016	March 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	$62,091	$50,142
Accounts receivable	259	—
Inventory, net	334	66
Prepaid expenses and other current assets	968	1,054
Total current assets	63,652	51,262
Fixed assets, net	3,711	2,042
Restricted cash	79	79
Other assets, net	134	106
Total assets	$67,576	$53,489
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$787	$1,387
Accrued expenses	2,450	2,257
Deferred rent	139	759
Deferred revenue	1,110	227
Capital lease obligation	—	5
Warrant liabilities	4	126
Total current liabilities	4,490	4,761
Deferred revenue, net of current portion	—	32
Deferred rent, net of current portion	905	—
Total liabilities	$5,395	$4,793
Commitments and Contingencies (Note 6)		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 92,391,989 and 81,536,724 shares issued and outstanding at March 31, 2016 and March 31, 2015, respectively	92	82
Additional paid-in capital	222,959	170,909
Accumulated deficit	(160,870)	(122,295)
Total stockholders' equity	62,181	48,696
Total Liabilities and Stockholders' Equity	$67,576	$53,489

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

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands except per share data)

	Year Ended March 31, 2016	Year Ended March 31, 2015	Year Ended March 31, 2014
Revenues			
Product and service	$806	$314	$—
Collaborations	486	134	248
Grants	191	123	131
Total Revenues	1,483	571	379
Selling, general, and administrative expenses	22,118	17,947	13,054
Research and development expenses	18,008	12,921	7,974
Loss from Operations	(38,643)	(30,297)	(20,649)
Other Income (Expense)			
Change in fair value of warrant liabilities	(17)	196	(5,120)
Loss on disposal of fixed assets	—	(12)	(84)
Interest expense	—	(1)	(13)
Interest income	88	32	18
Total Other Income (Expense)	71	215	(5,199)
Income Tax Expense	(3)	—	—
Net Loss	$(38,575)	$(30,082)	$(25,848)
Net loss per common share—basic and diluted	$(0.43)	$(0.38)	$(0.35)
Weighted average shares used in computing net loss per common share—basic and diluted	90,057,356	79,650,087	73,139,618

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

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (in thousands)

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at March 31, 2013	64,687	$ 65	$ 75,269	$ (66,365)	$ 8,969
Issuance of common stock from warrant exercises, net	2,713	3	1,098	—	1,101
Issuance of restricted common stock	60	—	—	—	—
Restricted stock forfeitures	(215)	—	—	—	—
Issuance of common stock from public offering, net	10,684	10	46,905	—	46,915
Stock-based compensation expense	—	—	4,600	—	4,600
Expense related to modification of warrants	—	—	12	—	12
Warrant liability removed due to exercises of warrants	—	—	10,874	—	10,874
Warrant liability reclassified to equity	—	—	767	—	767
Stock option exercises	184	—	402	—	402
Issuance of warrants to consultant	—	—	492	—	492
Net loss	—	—	—	(25,848)	(25,848)
Balance at March 31, 2014	78,113	$ 78	$ 140,419	$ (92,213)	$ 48,284
Issuance of common stock from warrant exercises, net	211	—	445	—	445
Restricted stock forfeitures	(190)	—	—	—	—
Issuance of common stock from public offering, net	3,198	4	22,303	—	22,307
Stock-based compensation expense	—	—	7,020	—	7,020
Warrant liability removed due to exercises of warrants	—	—	55	—	55
Stock option exercises	205	—	351	—	351
Issuance of warrants to consultant	—	—	316	—	316
Net loss	—	—	—	(30,082)	(30,082)
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
Adjustment related to potential equity bonus issuance	—	—	(130)	—	(130)
Net loss	—	—	—	(38,575)	(38,575)
Balance at March 31, 2016	92,392	$ 92	$ 222,959		