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 regulator