ORGANOVO HOLDINGS, INC.
Form 10-K
June 09, 2015

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, 2015

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 on September 30, 2014, the last trading day of the registrant's second fiscal quarter, was $451,713,082. 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, 2015 was 81,580,538.

Documents Incorporated by Reference

Certain information required for Part III of this report is incorporated herein by reference to the proxy statement for the 2015 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, 2015

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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

We are an early commercial 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, and outright ownership of patents and pending patent applications. 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 the 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 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 human 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: The 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

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.

The 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.

The 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.

From 2011 to 2015, we provided access to NovoGen Bioprinters for use by the following institutions, for research purposes: Harvard Medical School, Wake Forest University, Knight Cancer Institute at Oregon Health & Science University ("OHSU"), the Sanford Consortium for Regenerative Medicine ("SCRM"), 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 but is solely meant to offset the costs, in part or in full, of the collaborative research. 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.

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. To our knowledge, there are no other companies with a similar “pure play” focus on a 3D tissue platform technology or marketed products.

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, Hepregen Corporation, 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.

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 and to develop new products and service offerings. Our research and development efforts include internal initiatives as well as collaborative development opportunities with third parties. Our research and development expenses were $12.9

million, $8.0 million and $3.4 million for the fiscal years ended March 31, 2015, March 31, 2014, and December 31, 2012, 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 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 products. We rely on a combination of patents, trademarks, trade secrets and in-licensed technology. 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 eight U.S. and twelve international issued patents, and have pending nineteen U.S. and sixty international patent 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 and Purchased IP

In March 2009, we obtained a world-wide exclusive license to a suite of intellectual property owned by MU and the Medical University of South Carolina covering the following two patents as well as future child patents derived from the same applications:

- "Self-Assembling Cell Aggregates and Methods of Making Engineered Tissue Using the Same" U.S. Pat. No. 8,241,905, which provides us with intellectual property rights in the creation of engineered tissue.
- "Self-Assembling Multicellular Bodies and Methods of Producing a Three-Dimensional Biological Structure Using the Same" Int'l App. No. PCT/US 2009/48530 and U.S. Pat. No. 8,143,055, which provides us with intellectual property rights in the creation of cellular aggregates, the use of cellular aggregates to create engineered tissue, and the employment of cellular aggregates to create engineered tissue with no scaffold present.

In March 2010, we licensed additional intellectual property from MU covering the composition and method of manufacture of a nerve conduit. Dr. Gabor Forgacs is one of our Founders and the unique co-inventor of all of these works (the "Forgacs Intellectual Property"). The Forgacs Intellectual Property provides us with intellectual property rights relating to cellular aggregates, to use cellular aggregates to create engineered tissue, and to employ cellular aggregates to create engineered tissue with no scaffold present. The intellectual property rights derived from the Forgacs Intellectual Property also enables us to utilize our NovoGen Bioprinter ® to create engineered tissues, and provides us with rights relating to specific compositions with utility in the creation of nerve conduit. These patents are not only foundational within the field of 3D Bioprinting, but provide us with a favorable priority date.

The Forgacs Intellectual Property is the result of years of research by Dr. Gabor Forgacs, the George H. Vineyard Professor of Biophysics at MU and his collaborators and research teams. Dr. Forgacs is a sought after expert in biofabrication with a long record of peer-reviewed publications. The Forgacs Intellectual Property derives from work performed in the labs of Dr. Forgacs and his collaborators, including the work performed under a $5 million Frontiers in Biological Research grant that Dr. Forgacs and his collaborators received from the National Science Foundation.

In May 2011, we obtained an exclusive license to a patent entitled "Ink Jet Printing of Viable Cells" (U.S. Pat. No. 7,051,654) from the Clemson University Research Foundation ("CURF Patent"). The CURF Patent provides us with the 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.

We will be required to make pass through payments for sublicenses of the Forgacs Intellectual Property and the CURF Patent based on the license fees or royalty payments we receive. In addition, following commercialization, we are required to make ongoing royalty payments equal to a low single digit percentage of net sales of the licensed products.

In February 2013, we purchased the exclusive rights to patents from Becton Dickinson and Company that represent the acquisition of bioreactor technology for the support of our 3D tissues for use in drug discovery and development. No future royalties or milestone payments are owed to Becton Dickinson and Company for these patents.

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 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 and, ultimately in our bioprinted tissue products, are collected in compliance with the FDA's guidance for Current Good Tissue Practices (CGTP). However, pharmaceutical industry corporate customers with whom we will enter into collaboration arrangements will face regulatory review of the research data they generate 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.

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 to the extent we are developing proprietary products 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.

As 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.

Raw Materials

We use live human cells to produce our 3D tissues. We purchase human cells from selected suppliers based on quality assurance, cost effectiveness and constraints resulting from regulatory requirements. We work closely with our 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 sustain operations as well as at a cost effective price.

Employees

As of May 31, 2015, we have eighty-two employees, of whom eighty 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

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, can 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. In any 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. As a result, as of March 31, 2015, we had not generated significant revenues from our planned principal operation. Because of our limited operating history, there is limited historical financial or other information upon which to base an evaluation of our performance and future prospects. 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 since we began operations, including $30.3 million, $20.6 million, and $9.3 million for the years ended March 31, 2015, March 31, 2014, and December 31, 2012, respectively, and $4.0 million and $1.3 million for the three months ended March 31, 2013 and March 31, 2012, respectively. As of March 31, 2015, we had incurred cumulative operating losses of $68.6 million and cumulative net losses totaling $122.3 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, therapeutic tools, products and services that are more effective than existing technologies; entering into collaborative relationships with strategic partners; obtaining any necessary regulatory approval for our drug discovery, biological research, 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 any future products and services; and raising sufficient funds to finance our activities and business plan. We might not succeed at any of these undertakings. If we are unsuccessful at some or all 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, therapeutic tools, products and services can be successfully developed with our platform technology. Our success will also depend on our ability to obtain any necessary regulatory approvals 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, 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, 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 to create effective sales and marketing capabilities;
- 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, to secure the additional financial resources to support our development efforts and future operations. 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 will 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, our 3D Human Liver Tissue, on a limited basis in April 2014 and more broadly in November 2014. As a result, we have not had sufficient time to prove that our existing and planned products and services will enable our customers to conduct drug discovery and biological research more effectively than through the use of existing technologies. Our success depends on commercial acceptance of 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, no one has developed or commercialized any therapeutic or other life science 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 or life science 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, therapeutic 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. 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 any drug discovery, biological research, therapeutic tools, products or 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;
- 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 product and technology development 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 and breadth of technology; management and the execution of strategy; 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 and sales and marketing activities. There is no assurance that we will be successful in commercializing and gaining significant market share for any products developed in part through use of our technology. Our technologies, products and services also may be rendered obsolete or noncompetitive as a result of products and services introduced by our competitors.

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

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

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

We may be dependent on third-party research organizations to conduct some of our laboratory testing, animal and human studies with respect to therapeutic tissues and other life science products that we may develop in the future. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development 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.

Commercialization of our tools and products will require that we have access to a constant, steady and reliable supply of human cells. We will also 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, our business and future results will suffer.

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 may rely on third-party suppliers and vendors for some of the materials we require in our drug discovery and biological research products and services businesses as well as for the manufacture of any therapeutic product candidates that we may develop in the future. For example, commercialization of our tools and products require that we have access to a constant, steady and reliable supply of human cells. We currently acquire our human cells from 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 or interruption 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 results will suffer.

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. Current steps to reduce the federal budget deficit include reduced National Institute of Health

and other research and development allocations. 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 has 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.

In connection with the commercial release of the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing and to pursue our research and development plans, we intend to significantly expand our employee headcount. As a result, our future success depends in part on our ability to timely attract and hire highly skilled technical, managerial and sales and marketing personnel. 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 product liability claims. In addition, our platform technology is subject to the requirements of Good Laboratory Practice (GLP) to provide suitable data for INDs and other regulatory filings. No regulatory review of data from our platform technology has yet been conducted and there is no guarantee that our technology will be acceptable under GLP. As a result, the violation of government regulations or quality programs could harm demand for our products or services, and the evolving nature of government regulations could have an adverse impact on our business.

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

Any therapeutic and other life science products we develop will be subject to extensive, lengthy and uncertain regulatory approval process by the Food and Drug Administration (FDA) and comparable agencies in other countries. The regulation of new products is extensive, and the required process of laboratory testing and clinical studies is lengthy, expensive and uncertain. We may not be able to obtain FDA approvals for any therapeutic products we develop in a timely manner, or at all. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses. Even if we obtain FDA regulatory approvals, the FDA extensively regulates manufacturing, labeling, distributing, marketing, promotion and advertising after product approval. Moreover, several of our product development areas may involve relatively new technologies and have not been the subject of extensive laboratory testing and clinical studies. The regulatory requirements governing these products and related clinical procedures remain uncertain and the products themselves may be subject to substantial review by the FDA and other

foreign governmental regulatory authorities that could prevent or delay approval in the United States and any other foreign country. Regulatory requirements ultimately imposed on our products could limit our ability to test, manufacture and, ultimately, commercialize our products and thereby could adversely affect our financial condition and results of operations.

As we continue to adapt and develop parts of our product line in the future, including tissue-based products in the field of regenerative medicine, the manufacture and marketing of our products will become subject to government regulation in the United States and other countries. In the United States and most foreign countries, we will be required to complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the

product. The steps required by the FDA before our proposed products may be marketed in the United States include performance of preclinical (animal and laboratory) tests; submissions to the FDA of an IDE (Investigational Device Exemption), NDA (New Drug Application), or BLA (Biologic License Application) which must become effective before human clinical trials may commence; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product in the intended target population; performance of a consistent and reproducible manufacturing process intended for commercial use; Pre-Market Approval Application (PMA); and FDA approval of the PMA before any commercial sale or shipment of the product.

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

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

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

If restrictions on reimbursements and health care reform limit our collaborators’ actual or potential financial returns on therapeutic products that they develop based on our platform technology, our collaborators may reduce or terminate their collaborations with us.

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

these products.

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

We are subject to various environmental, health and safety laws.

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

Risks Related to Our Intellectual Property

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

Our commercial success will depend to a significant extent on our ability to obtain patents and maintain adequate protection for our technologies, intellectual property and potential products in the United States and other countries. If we do not protect our intellectual property adequately, competitors may be able to use our technologies and gain competitive advantage.

To protect our products and technologies, we and our collaborators and licensors must prosecute and maintain existing patents, obtain new patents and pursue other intellectual property protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. Moreover, the patent positions of many biotechnology and pharmaceutical companies are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, we cannot guarantee that:

- any patent applications filed by us will issue as patents;
- third parties will not challenge our proprietary rights, and if challenged that a court or an administrative board of a patent office will hold that our patents are valid and enforceable;
- third parties will not independently develop similar or alternative technologies or duplicate any of our technologies by inventing around our claims;
- any patents issued to us will cover our technology and products as ultimately developed;
- we will develop additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our business; or
- as issued patents expire, we will not lose some competitive advantage.

We may not be able to protect our intellectual property rights throughout the world.

Certain foreign jurisdictions have an absolute requirement of novelty that renders any public disclosure of an invention immediately fatal to patentability in such jurisdictions. Therefore, there is a risk that we may not be able to protect some of our intellectual property in the United States or abroad due to disclosures, which we may not be aware of, by our collaborators or licensors. Some foreign jurisdictions prohibit certain types of patent claims, such as “method-of-treatment/use-type” claims; thus, the scope of protection available to us in such jurisdictions is limited.

Moreover, filing, prosecuting and defending patents on all of our potential products and technologies throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not sought or obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our future products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be involved in lawsuits or other proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our collaborators or licensors. Or, our licensors may breach or otherwise prematurely terminate the provisions of our license agreements and continue to improperly use our technology. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our collaborators or licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Additionally, our licensors may retain certain rights to use technologies licensed by us for research purposes. Patent disputes can take years to resolve, can be very costly and can result in loss of rights, injunctions and substantial penalties. Moreover, patent disputes and related proceedings can distract management's attention and interfere with running the business.

Furthermore, because of the potential for substantial discovery in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments which could harm our business.

As more companies engage in patenting relating to bioprinters, it is possible that patent claims relating to bioprinters or bioprinted human tissue may be asserted against us, and any such assertions could harm our business. Moreover, we may face claims from non-practicing entities, which have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. Any such claims, with or without merit, could be time-consuming to defend, result in costly litigation and diversion of resources, cause product shipment or delays or require us to enter into royalty or license agreements. These licenses may not be available on acceptable terms, or at all. Even if we are successful in defending such claims, infringement and other intellectual property litigation can be expensive and time-consuming to litigate and divert management's attention from our core business. Any of these events could harm our business significantly.

Our current and future research, development and commercialization activities also must satisfy the obligations under our license agreements. Any disputes arising under our license agreements could be costly and distract our management from the conduct of our business. Moreover, premature termination of a license agreement could have an adverse impact on our business.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office ("PTO") to determine the priority of invention. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party.

Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents or those of our collaborators or licensors in the PTO. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

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

In addition to seeking patents for some of our technology and potential products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with

parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for these breaches. Alternatively, if a third party alleges that any of our employees or consultants has breached confidentiality obligations to our benefit, we may have to defend against allegations of trade secret misappropriation.

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

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

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

Risks Related to Our Common Stock and Liquidity Risks

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

There is limited trading history in our common stock, and although our common stock is now traded on the NYSE MKT, there is no assurance that an active market in our common stock will continue at present levels or increase in the future. As a result, an investor may find it difficult to dispose of our common stock. This factor limits the liquidity of our common stock, and may have a material adverse effect on the market price of our common stock and on our ability to raise additional capital.

Compliance with the reporting requirements of federal securities laws can be expensive.

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including the compliance obligations of the Sarbanes-Oxley Act. The costs of complying with the reporting requirements of the federal securities laws, including preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders, can be substantial.

If we fail to comply with the rules of Section 404 of the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures, or, if we discover material weaknesses and deficiencies in our internal control and accounting procedures, we may be subject to sanctions by regulatory authorities and our stock price could decline.

Section 404 of the Sarbanes-Oxley Act (the “Act”) requires that we evaluate and determine the effectiveness of our internal control over financial reporting and requires an attestation and report by our external auditing firm on our internal control over financial reporting. We believe our system and process evaluation and testing comply with the management certification and auditor attestation requirements of Section 404. We cannot be certain, however, that we will be able to satisfy the requirements in Section 404 in all future periods, especially as we grow our business. If we are not able to continue to meet the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, such as the SEC or NYSE MKT. Any such action could adversely affect our financial results or investors’ confidence in us and could cause our stock price to fall. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, we may be required to incur significant additional financial and management resources to achieve compliance.

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

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

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

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

- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- regulatory actions regarding our products;
- reduced government funding for research and development activities;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market;
- degree of coverage of securities analysts and reports and recommendations issued by securities analysts regarding our business;
- volume fluctuations in the trading of our common stock; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such a company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our capital stock.

We are authorized to issue 150,000,000 shares of common stock and 25,000,000 shares of preferred stock. As of March 31, 2015, there were an aggregate of 92,712,297 shares of our common stock issued and outstanding on a fully diluted basis and no shares of preferred stock outstanding. That total for our common stock includes 9,997,464 shares of our common stock that may be issued upon the exercise of outstanding stock options or is available for issuance under our equity incentive plans, and 1,178,109 shares of our common stock that may be issued upon the exercise of outstanding warrants.

In the future, we may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders. We may also issue additional shares of our capital stock or other securities that are convertible into or exercisable for our capital stock in connection with presently outstanding warrants, hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of capital stock may create downward pressure on the trading price of our common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock is currently traded on the NYSE MKT.

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

Our common stock is widely traded and held by retail investors, and these investors are subject to the influence of information provided by third party investor websites and independent authors distributing information on the internet. This information has become influential because it is widely distributed and links to it appear as top company headlines on commonly used stock quote and finance websites, or through services such as Google alerts. These emerging information distribution models are a consequence of the emergence of the internet. Some information and

content distribution is by individuals through platforms that mainly serve as hosts seeking advertising revenue. As such, we believe an incentive exists for these sites to increase advertising revenue by increasing page views, and for them to post or allow to be posted inflammatory information to achieve this end. It has been our experience that a significant portion of the information on these websites or distributed by independent authors about our Company is false or misleading, and occasionally, we believe, purposefully misleading. These sites and internet distribution strategies also create opportunity for individuals to pursue both “pump and dump” and “short and distort” strategies. We believe that many of these

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

Our common stock is controlled by insiders.

Our current executive officers and directors beneficially own approximately 12.8% of our outstanding shares of common stock, as of March 31, 2015. Although we are not aware of any voting arrangements between our officers and directors, such concentrated control may adversely affect the price of our common stock. Investors who acquire our common stock may have no effective voice in the management of our operations.

We do not intend to pay dividends for the foreseeable future.

We have paid no dividends on our common stock to date and it is not anticipated that any dividends will be paid to holders of our common stock in the foreseeable future. While our future dividend policy will be based on the operating results and capital needs of our business, it is currently anticipated that any earnings will be retained to finance our future expansion and for the implementation of our business plan. As an investor, you should take note of the fact that a lack of a dividend can further affect the market value of our stock, and could significantly affect the value of any investment.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our Board of Directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by the Board of Directors without prior stockholder approval, with rights senior to those of the common stock;
- provide for a classified Board of Directors, with each director serving a staggered three-year term;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent; and
- require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our Board of Directors or initiate actions that are opposed by our then-current Board of Directors, including delaying or impeding a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our Board of Directors could cause the market price of our common stock to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

On February 27, 2012, the Company entered into a facilities lease at 6275 Nancy Ridge Drive (the "Original Lease"), San Diego, CA 92121, with occupancy as of July 15, 2012. The base rent under the lease was approximately $38,800 per month with 3% annual escalators. The lease term was 48 months with an option for the Company to extend the lease at the end of the lease term.

On December 5, 2013, the Company entered into a First Amendment (the "Amendment") to the Original Lease, together with the Amendment, (the "Amended Lease"). Pursuant to the Amendment, the Company expanded the size of its facility by approximately

15,268 square feet (the "Expansion Premises") from approximately 15,539 square feet (the "Original Premises") for a total of approximately 30,807 square feet. The Amended Lease provides for base rent (i) on the Original Premises to continue at approximately $38,800 per month, with annual escalators, until August 1, 2016, at which point the base rent shall be payable at the same rate per rentable square foot as the Expansion Premises and (ii) on the Expansion Premises of approximately $38,934 per month, with 3% annual escalators, not to commence until two months after the earlier of (A) the date that the landlord delivers possession of the Expansion Premises to the Company with the work in the Expansion Lab Premises (as defined in the Amendment) substantially complete and (B) the date the landlord could have delivered the Expansion Premises with the work in the Expansion Lab Premises (as defined in the Amendment) substantially complete but for certain delays of the Company. Additionally, the Company has a right of first refusal on adjacent additional premises of approximately 14,500 square feet. The term of the Amended Lease expires on the seven-year anniversary of the earlier of (A) the date that the landlord delivers possession of the Expansion Premises to the Company and (B) the date the landlord could have delivered the Expansion Premises but for certain delays of the Company (the "Expansion Premises Commencement Date"). The Expansion Premises Commencement Date was September 1, 2014. The Company also has the option to terminate the Amended Lease on the 5-year anniversary of the Expansion Premises Commencement Date. The Expansion Premises contains office, laboratory, and clean room areas.

On March 12, 2015, the Company entered into a Second Amendment to the Original Lease (the "Second Amendment), to adjust the square footage covered by Amended Lease and an additional portion of the building containing approximately 335 rentable square feet ("Second Expansion Premises"). This square footage adjustment was the result of the re-measurement of each suite and the building overall. The net adjustment to overall leased space was an increase of 88 square feet at the same per-square-foot rate as the Expansion Premises.

On January 9, 2015, the Company entered into an agreement to lease a second facility consisting of 5,803 rentable square feet of office and lab space located at 6310 Nancy Ridge Drive, San Diego, CA 92121. The term of the lease is 36 months, beginning on February 1, 2015 and ending on January 31, 2018, with monthly rental payments of approximately $12,000 commencing on April 1, 2015. In addition, there are annual rent escalations of 3% on each 12-month anniversary of the lease commencement date.

Item 3. Legal Proceedings.

See Note 8 of the Notes to the Consolidated Financial Statements contained within this Annual Report on Form 10-K for a further discussion of our legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information for Common Stock

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

The following table sets forth, on a per share basis, for the periods indicated, the high and low bid or sales prices of our common stock.

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

Year Ended March 31, 2014	High	Low
Fourth Quarter	$12.38	$7.12
Third Quarter	$13.65	$5.33
Second Quarter	$8.50	$3.69
First Quarter	$5.10	$3.27

As of March 31, 2015, we had 81,536,724 outstanding shares of common stock, with a closing price of $3.54 per share. On this date, there were 114 holders of record of the Company's common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Performance Graph

This performance graph is furnished and shall not be deemed “filed” with the SEC or subject to Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended.

The graph set forth below compares our total stockholder returns since we commenced trading on February 15, 2012 through March 31, 2015 to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. This graph assumes the investment of $100 on February 15, 2012 in our common stock, the NASDAQ Composite Index and the NASDAQ Biotech Index, and assumes the reinvestment of dividends. No cash dividends have been declared or paid on our common stock. The comparisons in the graph below are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock, and we do not make or endorse any predictions as to future stockholder returns.

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

Equity Compensation Plans

The following table summarizes information about the Company’s equity compensation plans by type as of March 31, 2015 (in thousands, except per share amounts):

Plan category	Number of securities to be issued upon exercise/vesting of outstanding options, warrants, units and rights (1)	Weighted average exercise price (1)	Number of securities available for future issuance
Equity compensation plans approved by security holders	7,422,418	$ 4.18	2,883,916
Equity compensation plans not approved by security holders	—	—	—

(1) Does not include outstanding restricted stock units.

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

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

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

The table below shows selected consolidated financial data. The consolidated statements of operations data for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, and the consolidated balance sheet data at March 31, 2015 and 2014 are derived from our consolidated financial statements included elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2011 and 2010 and the consolidated balance sheet data as of March 31, 2013, December 31, 2012, December 31, 2011 and December 31, 2010 are derived from our consolidated financial statements not included in this report. The historical results presented below are not necessarily indicative of financial results to be achieved in future periods.

	Year Ended March 31, 2015	Year Ended March 31, 2014	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012 (unaudited)	Year Ended December 31, 2012	Year Ended December 31, 2011	Year Ended December 31, 2010
Selected Consolidated Statement of Operations Data:							
Revenue	$571	$379	$215	$120	$1,197	$969	$603
Operating loss	$(30,297)	$(20,649)	$(4,025)	$(1,329)	$(9,319)	$(2,305)	$(1,178)
Net loss	$(30,082)	$(25,848)	$(16,120)	$(37,081)	$(43,553)	$(4,383)	$(1,339)
Loss per share, basic and diluted	$(0.38)	$(0.35)	$(0.26)	$(1.17)	$(1.01)	$(0.19)	$(0.09)
Weighted average shares outstanding, basic and diluted	79,650,087	73,139,618	61,750,157	31,591,663	43,149,657	22,925,694	14,620,140
	March 31,	March 31,	March 31,	March 31, 2012	December 31,	December 31,	December 31,

	2015	2014	2013	(unaudited)	2012	2011	2010
Selected Consolidated Balance Sheet Data:							
Working capital (deficit)	$46,501	$47,268	$7,762	$9,724	$(6,169)	$(946)	$(749)
Total assets	$53,489	$50,186	$17,375	$11,241	$16,749	$1,409	$760
Long-term liabilities	$32	$9	$24	$47,515	$17	$1,267	$1,888
Stockholders' equity (deficit)	$48,696	$48,284	$8,969	$(37,385)	$(5,303)	$(1,835)	$(2,300)

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

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

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

Overview

We are 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 believe we can introduce a paradigm shift in the approach to the generation of three-dimensional human tissues, by utilizing our proprietary platform technology to create human tissue constructs in 3D that mimic native human tissue composition and architecture. We believe we will improve the current industry standard cell-based 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.

Reverse Merger Transaction

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

Simultaneously with the Merger, on the Closing Date, all of the issued and outstanding shares of Organovo common stock converted, on a 1 for 1 basis, into shares of the Company's common stock, par value $0.001 per share ("Common Stock"). Also on the Closing Date, all of the issued and outstanding options to purchase shares of Organovo Common Stock, all of the issued and outstanding Bridge Warrants (as defined below) to purchase shares of Organovo Common Stock, and other outstanding warrants to purchase Organovo Common Stock converted, respectively, into options (the "New Options"), new bridge warrants (the "New Bridge Warrants") and new warrants (the "New Warrants") to purchase

shares of Common Stock on a 1 for 1 basis. The New Options are being administered under Organovo's 2008 Equity Incentive Plan (the "2008 Plan"), which the Company assumed and adopted on the Closing Date in connection with the Merger.

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

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

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

In connection with the Merger, Organovo Holdings, Inc.'s Board of Directors and stockholders adopted the 2012 Equity Incentive Plan (the "2012 Plan"). The 2012 Plan, as amended, provides for the issuance of up to 11,553,986 shares, or approximately 14% of our March 31, 2015 outstanding Common Stock, to executive officers, directors, advisory board members, consultants and employees. In addition, we assumed and adopted the 2008 Plan, and as described above option holders under that plan were granted New Options to purchase Common Stock. No further options will be granted under the 2008 Plan. The parties have taken all actions necessary to ensure that the Merger was treated as a tax free exchange under Section 368(a) of the Internal Revenue Code of 1986, as amended.

As of June 1, 2015, the Company had 81,580,538 total issued and outstanding shares of Common Stock, and five year warrants for the opportunity to purchase an additional 1,139,875 shares of Common Stock at exercise prices ranging from $0.85 to $7.62 per share. The Company had outstanding stock options to purchase an aggregate of 7,085,295 shares of Common Stock at exercise prices ranging from $0.08 to $9.92 and 258,750 outstanding restricted stock units, with each unit representing the right to receive one share of Common Stock.

Critical Accounting Policies

Our consolidated financial statements include the accounts of the Company as well as its wholly-owned subsidiaries, with all material intercompany accounts and transactions eliminated in consolidation, which appear under Item 8 of Part II, have been prepared in accordance with accounting principles generally accepted in the United States, which require that we make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 2 to our consolidated financial statements. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

Revenue Recognition

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

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

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met.

Revenue Arrangements with Multiple Deliverables

The Company may enter into revenue arrangements that contain multiple deliverables. Judgment is required to properly identify the accounting units of the multiple deliverable transactions and to determine the manner in which revenue should be allocated among the accounting units. Moreover, judgment is used in interpreting the commercial terms and determining when all criteria of revenue recognition have been met for each deliverable in order for revenue recognition to occur in the appropriate accounting period. For multiple deliverable agreements, consideration is allocated at the inception of the agreement to all deliverables based on their relative selling price. The relative selling price for each deliverable is determined using Vendor Specific Objective Evidence ("VSOE") of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable.

The Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance. While changes in the allocation of the arrangement consideration between the units of

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

Revenue from Research Service Agreements

For research service agreements, the Company defers any up-front fees collected from customers and recognizes revenue when earned, typically when services are rendered or deliverables are provided to the customer. When substantial customer acceptance terms exist, the Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance.

Research and Development Revenue under Collaborative Agreements

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

The Company recognizes revenue from research funding under collaboration agreements when earned on a "proportional performance" basis as research hours are incurred. The Company performs services as specified in each respective agreement on a best-efforts basis, and is reimbursed based on labor hours incurred on each contract. The Company initially defers revenue for any amounts billed, or payments received, in advance of the services being performed, and recognizes revenue pursuant to the related pattern of performance, based on total labor hours incurred relative to total labor hours estimated under the contract.

Product Revenue

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

Product Returns

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

Grant Revenues

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

Derivative Financial Instruments

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

The Company reviews the terms of convertible debt and equity instruments it issues to determine whether there are derivative instruments, including an embedded conversion option that is required to be bifurcated and accounted for separately as a derivative financial instrument. In circumstances where the convertible instrument contains more than one embedded derivative instrument, including the conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument. Also, in connection with the

sale of convertible debt and equity instruments, the Company may issue freestanding warrants that may, depending on their terms, be accounted for as derivative instrument liabilities, rather than as equity.

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

Fair Value Measurements

Financial assets and liabilities are measured at fair value, which is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of

observable inputs and minimize the use of unobservable inputs. The following is a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value:

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

The Company has issued warrants, of which some are classified as derivative liabilities as a result of the terms in the warrants that provide for down-round protection in the event of a dilutive issuance. The Company uses Level 3 inputs for its valuation methodology for the warrant derivative liabilities. The estimated fair values were determined using a Monte Carlo option pricing model based on various assumptions. The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to fair value of derivative liabilities. Various factors are considered in the pricing models we use to value the warrants, including the Company's current stock price, the remaining life of the warrants, the volatility of the Company's stock price, and the risk free interest rate. Future changes in these factors may have a significant impact on the computed fair value of the warrant liability. As such, changes in the fair value of the warrants have in the past and could continue in the future to vary significantly from period to period.

Stock-Based Compensation

For purposes of calculating stock-based compensation, we estimate the fair value of stock options using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of the stock options. The expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts. If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

Results of Operations

Overview

Organovo was founded in Delaware in April 2007. Activities since the Company's inception through March 31, 2015, were devoted primarily to developing a platform technology and functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs, raising capital and building infrastructure. In November 2014, the Company announced the full commercial release of its first product, the exVive3D™ Human Liver Tissue for use in toxicology and other preclinical drug testing. In December 2014, we established a wholly-owned subsidiary, Samsara Sciences, Inc., to focus on the acquisition of qualified cells in support of our commercial and research endeavors. As of March 31, 2015, the Company has not yet realized significant revenues from its planned principal operations. The Company's activities are subject to significant risks and uncertainties including failing to secure additional funding to fully

operationalize the Company's current technology and continue to implement its business plan.

Change in Fiscal Year End

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

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

Revenues

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

Operating Expenses

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

Research and Development Expenses

Research and development expense increased $4.9 million, or 61%, from approximately $8.0 million for the year ended March 31, 2014 to approximately $12.9 million for the year ended March 31, 2015 as the Company significantly increased its research staff to support its obligations under certain collaborative research agreements and grants, and to expand product development efforts in preparation for commercial revenues. Full-time research and development staffing increased from thirty-two full-time employees as of March 31, 2014 to fifty-four full-time employees as of March 31, 2015. In addition to the incremental payroll, benefits and stock-based compensation resulting from increased staffing levels, the Company increased its facility space to accommodate its growing research staff, and increased its spending on lab equipment and supplies in proportion to its increased research activities.

Selling, General and Administrative Expenses

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

Other Income (Expense)

Other income was approximately $0.2 million for the year ended March 31, 2015, and consisted primarily of interest income and a gain related to the revaluation of warrant derivative liabilities. This gain was caused by a declining stock price during the period that decreased the value of the derivative liability. For the year ended March 31, 2014, other

expense consisted primarily of a $5.1 million loss related to the revaluation of warrant derivative liabilities due to rising stock prices during the period that caused an increase in the value of the derivative liability. In addition, the majority of the underlying warrants to which the derivative relates were exercised or converted to equity instruments during fiscal 2014, significantly lessening the impact of subsequent changes in our stock price.

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

Comparison of the Years Ended March 31, 2014 and December 31, 2012

Revenues

Revenues of $0.4 million for the year ended March 31, 2014 decreased approximately $0.8 million, or 67%, over revenues of $1.2 million for the year ended December 31, 2012. This decrease reflects the completion or declining activity under two previous

collaborative research agreements since 2012, partially offset by increasing revenue contributions from three new collaborative research agreements.

Operating Expenses

Operating expenses increased approximately $10.5 million, or 100%, from $10.5 million for the year ended December 31, 2012 to $21.0 million for the year ended March 31, 2014. Of this increase, $5.9 million is related to increased selling, general and administrative expense, while the other $4.6 million relates to increased investment in research and development expense. Those increases are attributed to the Company's continued implementation of its business plan, including hiring additional staff to support its research and development initiatives, incremental investment associated with commercialization project initiatives, expenses related to operating as a publicly traded corporation, expansion to a larger facility, and increased stock compensation expense relative to employees and certain consulting services.

Research and Development Expenses

Research and development expense increased $4.6 million, or 135%, from approximately $3.4 million for the year ended December 31, 2012 to approximately $8.0 million for the year ended March 31, 2014 as the Company significantly increased its research staff to support its obligations under certain collaborative research agreements and grants, and to expand product development efforts in preparation for commercial revenues. Full-time research and development staffing increased from nineteen full-time employees as of December 31, 2012 to thirty-two full-time employees as of March 31, 2014. In addition to the incremental payroll, benefits and stock-based compensation resulting from increased staffing levels, the Company increased its facility space to accommodate its growing research staff, and increased its spending on lab equipment and supplies in proportion to its increased research activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased approximately $5.9 million, or 83%, from $7.1 million for the year ended December 31, 2012 to $13.0 million for the year ended March 31, 2014. Increased staffing expenses of approximately $1.5 million was due to the headcount increase from ten full-time employees as of December 31, 2012 to thirteen full-time employees as of March 31, 2014, to provide strategic infrastructure in developing collaborative relationships and preparing for commercialization of products and services, and to address the additional compliance requirements of operating as a publicly traded corporation. In addition, the year ended March 31, 2014 includes $1.2 million more in payroll taxes related to the vesting of restricted stock units the Company previously granted to certain of its executives. Stock-based compensation costs also increased approximately $2.9 million due to additional grants to employees and consultants as well as an overall increase in the Company's stock price. The remainder of the increase is primarily due to non-recurring external fees and expenses incurred during the year ended March 31, 2014 related to the Company's up-listing to the NYSE MKT and its completion of a secondary public offering during the year.

Other Income (Expense)

The $29.0 million decrease in other expenses as compared to the year ended December 31, 2012 was primarily due to the inclusion of one-time non-cash transaction costs associated with the Merger and 2012 Private Placements in other expense during 2012, including approximately $19.0 million of expense for the excess of the fair value of warrant liabilities over proceeds received, $2.1 million of financing costs in excess of proceeds received and $1.0 million in interest expense from the accretion of debt discount and amortization of deferred financing costs related to the 2011 Private Placement, the Merger and the 2012 Private Placement. In addition, $1.9 million of expense was recorded in 2012 for the loss on inducement to exercise warrants under a tender offer completed during the year. Finally, non-cash expense related to the change in fair value of warrant liabilities decreased by approximately $4.8 million, due to fewer warrants outstanding as of March 31, 2014.

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

Comparison of the Three Months Ended March 31, 2013 and 2012

Revenues

Revenues of $0.2 million for the three months ended March 31, 2013 increased approximately $0.1 million, or nearly 100%, over revenues of approximately $0.1 million for the three months ended March 31, 2012. That increase can be attributed to $0.1 million of

grant revenue during the three months ended March 31, 2013, while the Company had no active grants or grant revenue during the three months ended March 31, 2012.

Operating Expenses

Operating expenses increased approximately $2.8 million, or 200%, from $1.4 million for the three months ended March 31, 2012 to $4.2 million for the three months ended March 31, 2013. Of this increase, $1.9 million is related to increased selling, general and administrative expense while the other $0.9 million relates to increased investment in research and development. These increases are attributed to the Company's continued implementation of its business plan, including hiring additional staff to support research and development initiatives, incremental investment associated with strategic growth and commercialization project initiatives, expenses related to operating as a publicly traded corporation, relocation to a larger facility, and increased stock compensation expense relative to employees and certain consulting services.

Research and Development Expenses

Research and development expense increased $0.9 million, or 180%, from $0.5 million for the three months ended March 31, 2012 to $1.4 million for the three months ended March 31, 2013 as the Company more than doubled its research staff to support its obligations under certain collaborative research agreements and government grants, and to expand product development efforts in preparation for research-derived revenues. Full-time research and development staffing increased from ten full-time employees as of March 31, 2012 to twenty-one full-time employees as of March 31, 2013. In addition to the incremental payroll, benefits and stock-based compensation resulting from increased staffing levels, the Company relocated its facilities to accommodate its growing research staff, and increased its spending on lab equipment and supplies in proportion to its increased research activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $1.9 million, or 211%, from $0.9 million for the three months ended March 31, 2012 to $2.8 million for the three months ended March 31, 2013. Increased staffing expenses of approximately $0.6 million included full-time administrative headcount which was increased from five full-time employees to nine full-time employees, including the addition of two executives, to provide strategic infrastructure in developing collaborative relationships and preparation for commercialization of research based product introductions and to address the additional compliance requirements of becoming a publicly traded corporation. In addition, stock-based compensation costs increased due to approximately $0.4 million in additional grants to employees, and approximately $0.3 million for the revaluation of restricted common stock issued to consultants during the three months ended March 31, 2013. Finally, the Company incurred approximately $0.3 million more in external expenses related to becoming a publicly traded corporation, including SEC financial reporting, investor relations, corporate governance, and audit fees.

Other Income (Expense)

The $23.7 million decrease in other expenses as compared to the three months ended March 31, 2012 was primarily due to the inclusion of one-time non-cash transaction costs associated with the Merger and 2012 Private Placements in other expense during the first quarter of 2012, including approximately $19.0 million of expense for the excess of the fair value of warrant liabilities over proceeds received, $2.1 million of financing costs in excess of proceeds received and $1.0 million in interest expense from the accretion of debt discount and amortization of deferred financing costs related to the 2011 Private Placement, the Merger and the 2012 Private Placement. The non-cash expense related to the change in fair value of warrant liabilities decreased by approximately $1.5 million, due in part to fewer warrants outstanding as of March 31, 2013. Interest expense of less than $0.1 million for the three months ended March 31, 2013 is primarily related to the modification of certain warrant agreements during the period.

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

Financial Condition, Liquidity and Capital Resources

Since its inception, the Company has primarily devoted its efforts to technology and product development, raising capital and building infrastructure. The Company has not realized significant revenues from its planned principal operations.

Since inception, the Company has incurred negative cash flows from operations. Net cash used in operations is primarily driven by our operating results (net income adjusted for stock-based compensation, depreciation, amortization, changes in fair value, and other non-cash charges). As of March 31, 2015, the Company had cash and cash equivalents of $50.1 million and an accumulated deficit of $122.3 million. The Company also had negative cash flows from operations of $19.6 million, $15.6 million, $2.8 million, $3.6

million, and $9.7 million for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively.

At March 31, 2015, we had total current assets of $51.3 million and current liabilities of $4.8 million, resulting in working capital of $46.5 million. At March 31, 2014, we had total current assets of $49.2 million and current liabilities of $1.9 million, resulting in working capital of $47.3 million.

Net cash used in investing activities was approximately $1.5 million, $0.3 million, $0.2 million, less than $0.1 million, and $0.4 million for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively. The majority of net cash used in investing activities to date has been for the purchases of laboratory equipment, in particular in fiscal 2015 as the Company launched its first commercial product and expanded its research capabilities.

Net cash provided by financing activities was approximately $23.1 million, $48.4 million, $3.7 million, $13.6 million, and $24.6 million for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively.

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

During the year ended March 31, 2014, we raised net proceeds of approximately $43.4 million through the sale of 10,350,000 shares of our common stock in a public offering. In addition, we raised net proceeds of approximately $3.5 million from an at-the-market follow-on offering, $1.0 million from the exercise of warrants, and $0.4 million from stock option exercises during the year ended March 31, 2014.

On February 5, 2013, the Company provided a Notice of Redemption to affected warrant holders, of approximately 2.4 million warrant shares, that they would have until March 14, 2013 to exercise their outstanding warrants at $1.00 per share. Thereafter, any warrants that remained unexercised would have been automatically redeemed by the Company at a redemption price of $0.0001 per share of common stock then issuable upon exercise of the redeemed warrant. As of March 14, 2013, all redeemable warrants had been exercised for net proceeds of approximately $2.3 million. During the three months ended March 31, 2013, the Company also received approximately $1.4 million of additional proceeds from the exercise of other warrants unrelated to the Redemption Notification.

Cash provided by financing activities in 2012 was primarily related to proceeds received from the issuance of common stock and the exercise of warrants during the year. During February and March 2012, the Company received gross proceeds of $13.7 million from the private placement of equity securities. On February 8, February 29, and March 16, 2012, the Company completed the first, second and final closings, respectively, of the private placement offering. In these three closings, the Company issued 6,525,887 units, 1,806,100 units, and 6,916,000 units, respectively, to accredited investors at a price of $1.00 per unit, including the conversion of $1.5 million of principal and $25,379 of accrued interest under certain bridge promissory notes issued in 2011. The first closing was conducted simultaneously with the completion of the Company’s merger (the “Merger”) with Organovo, Inc. Each unit consisted of one share of common stock of the Company, $0.001 par value per share and a five-year warrant to purchase one share of common stock at $1.00 per share. Total net proceeds were $11.6 million (or $12.8 million, including the conversion of the bridge promissory notes referred to above). In addition, the Company consummated a tender offer in December 2012 to the holders of outstanding warrants to purchase approximately 14.5 million shares of the Company’s common stock. The warrant tender offer, which expired on December 21, 2012, resulted in approximately 9.6 million of the outstanding warrants being exercised by their holders for aggregate proceeds of approximately $7.7 million.

Through March 31, 2015, the Company has financed its operations primarily through the sale of convertible notes, the private placement of equity securities, the public offering of common stock, and through revenue derived from products and services, grants, and collaborative research agreements. Based on its current operating plan and available cash resources, the Company has sufficient resources to fund its business for at least the next twelve months.

The Company will need additional capital to further fund the development and commercialization of its human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. The Company intends to cover its future operating expenses through cash on hand, through revenue derived from research services agreements, product sales, grants, and collaborative research agreements, and through the issuance of additional equity or debt securities. Depending on market conditions, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders.

Having insufficient funds may require us to delay, scale back, or eliminate some or all of our development programs or relinquish rights to our technology on less favorable terms than we would otherwise choose. Failure to obtain adequate financing could

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

Contractual Obligations

In the normal course of business, we enter into contracts and commitments that obligate us to make payments in the future. The table below sets forth Organovo's significant contractual obligations and related scheduled payments as of March 31, 2015 (in thousands):

	Total	2016	2017 to 2018	2019 to 2020	2021 and Thereafter
Capital lease obligations (A)	5	5	—	—	—
Operating lease obligations (B)	7,072	1,138	2,282	2,094	1,558
Total	7,077	1,143	2,282	2,094	1,558

(A) Capital lease obligations include the remaining payments due under a laboratory equipment lease.
(B) Operating lease obligations include the remaining payments due under the Company's facility leases.

Recent Accounting Pronouncements

For information regarding recently adopted and issued accounting pronouncements, see Note 13 to the consolidated financial statements.

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

The primary objective of our investment activities is to preserve our capital for the purpose of funding our operations. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash, cash equivalents, and short-term investments in a variety of securities, including commercial paper and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are comprised of cash and cash equivalents. We currently do not hedge interest rate exposure. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure. We have limited foreign currency risk exposure as our business operates primarily in U.S. dollars. We do not have any foreign currency or other derivative financial instruments.

Item 8. Consolidated Financial Statements.

Organovo Holdings, Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Organovo Holdings, Inc.

San Diego, California

We have audited the accompanying consolidated balance sheets of Organovo Holdings, Inc. and Subsidiaries (the "Company") as of March 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013, and the year ended December 31, 2012. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Organovo Holdings, Inc. and Subsidiaries as of March 31, 2015 and 2014, and the results of their consolidated operations and their cash flows for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013, and the year ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Organovo Holdings, Inc. and Subsidiaries' internal control over financial reporting as of March 31, 2015, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated June 9, 2015 expressed an unqualified opinion.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

June 9, 2015

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Organovo Holdings, Inc.

San Diego, California

We have audited Organovo Holdings, Inc. and Subsidiaries' internal control over financial reporting as of March 31, 2015, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Organovo Holdings, Inc. and Subsidiaries' management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, Organovo Holdings, Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of March 31, 2015, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows of Organovo Holdings, Inc. and Subsidiaries, and our report dated June 9, 2015 expressed an

unqualified opinion.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

June 9, 2015

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ORGANOVO HOLDINGS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands except per share data)

	March 31, 2015	March 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$50,142	$48,167
Inventory, net	66	63
Prepaid expenses and other current assets	1,054	931
Total current assets	51,262	49,161
Fixed assets, net	2,042	857
Restricted cash	79	79
Other assets, net	106	89
Total assets	$53,489	$50,186
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$1,387	$326
Accrued expenses	2,257	822
Deferred rent	759	345
Deferred revenue	227	13
Capital lease obligation	5	10
Warrant liabilities	126	377
Total current liabilities	4,761	1,893
Deferred revenue, net of current portion	32	4
Capital lease obligation, net of current portion	—	5
Total liabilities	$4,793	$1,902
Commitments and Contingencies (Note 8)		
Stockholders' Equity		
Common stock, $0.001 par value; 150,000,000 shares authorized, 81,536,724 and 78,113,639 shares issued and outstanding at March 31, 2015 and March 31, 2014, respectively	82	78
Additional paid-in capital	170,909	140,419
Accumulated deficit	(122,295)	(92,213)
Total stockholders' equity	48,696	48,284
Total Liabilities and Stockholders' Equity	$53,489	$50,186

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

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands except per share data)

	Year Ended March 31, 2015	Year Ended March 31, 2014	Three Months Ended March 31, 2013	March 31, 2012 (Unaudited)	Year Ended December 31, 2012
Revenues					
Product and service	$314	$—	$—	$—	$—
Collaborations	134	248	98	120	1,035
Grants	123	131	117	—	162
Total Revenues	571	379	215	120	1,197
Selling, general, and administrative expenses	17,947	13,054	2,792	902	7,080
Research and development expenses	12,921	7,974	1,448	547	3,436
Loss from Operations	(30,297)	(20,649)	(4,025)	(1,329)	(9,319)
Other Income (Expense)					
Fair value of warrant liabilities in excess of proceeds received	—	—	—	(19,019)	(19,019)
Change in fair value of warrant liabilities	196	(5,120)	(12,034)	(13,506)	(9,931)
Financing transaction costs in excess of proceeds received	—	—	—	(2,130)	(2,130)
Loss on inducement to exercise warrants	—	—	—	—	(1,904)
Loss on disposal of fixed assets	(12)	(84)	—	—	(158)
Interest expense	(1)	(13)	(65)	(1,088)	(1,088)
Interest income	32	18	4	—	5
Other income (expense)	—	—	—	(9)	(9)
Total Other Income (Expense)	215	(5,199)	(12,095)	(35,752)	(34,234)
Net Loss	$(30,082)	$(25,848)	$(16,120)	$(37,081)	$(43,553)
Net loss per common share—basic and diluted	$(0.38)	$(0.35)	$(0.26)	$(1.17)	$(1.01)
Weighted average shares used in computing net loss per common share—basic and diluted	79,650,087	73,139,618	61,750,157	31,591,663	43,149,657

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

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (in thousands)

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2011	22,445	$ 22	$ 4,835	$ (6,692)	$ (1,835)
Issuance of common stock in connection with the merger	6,000	6	(6)	—	—
Issuance of common stock through private placements in connection with reverse merger	13,723	14	13,709	—	13,723
Cost associated with merger	—	—	(13,723)	—	(13,723)
Issuance of common stock through conversion of notes payable and accrued interest in connection with the merger	1,525	2	1,524	—	1,526
Issuance of warrant	—	—	890	—	890
Issuance of common stock from warrant exercises, net	13,424	14	10,977	—	10,991
Warrant liability removed due to exercises of warrants	—	—	23,321	—	23,321
Stock option exercises	224	—	18	—	18
Issuance of restricted common stock	1,380	1	(1)	—	—
Restricted stock forfeitures	(186)	—	—	—	—
Stock-based compensation expense	—	—	1,435	—	1,435
Loss on inducement to exercise warrants	—	—	1,904	—	1,904
Net loss	—	—	—	(43,553)	(43,553)
Balance at December 31, 2012	58,535	$ 59	$ 44,883	$ (50,245)	$ (5,303)
Issuance of common stock from warrant exercises, net	6,131	6	3,718	—	3,724
Issuance of restricted common stock	55	—	—	—	—
Restricted stock forfeitures	(34)	—	—	—	—
Stock-based compensation expense	—	—	848	—	848
Expense related to modification of warrants	—	—	65	—	65
Warrant liability removed due to exercises of warrants	—	—	23,869	—	23,869
Warrant liability reclassified to equity	—	—	1,886	—	1,886
Net loss	—	—	—	(16,120)	(16,120)
Balance at March 31, 2013	64,687	$ 65	$ 75,269	$ (66,365)	$ 8,969
Issuance of common stock from warrant exercises, net	2,713	3	1,098	—	1,101
Issuance of restricted common stock	60	—	—	—	—
Restricted stock forfeitures	(215)	—	—	—	—
Issuance of common stock from public offering, net	10,684	10	46,905	—	46,915
Stock-based compensation expense	—	—	4,600	—	4,600
Expense related to modification of warrants	—	—	12	—	12
Warrant liability removed due to exercises of warrants	—	—	10,874	—	10,874
Warrant liability reclassified to equity	—	—	767	—	767
Stock option exercises	184	—	402	—	402
Issuance of warrants to consultant	—	—	492	—	492
Net loss	—	—	—	(25,848)	(25,848)
Balance at March 31, 2014	78,113	$ 78	$ 140,419	$ (92,213)	$ 48,284
Issuance of common stock from warrant exercises, net	211	—	445	—	445

Restricted stock forfeitures	(190)	—	—	—	—
Issuance of common stock from public offering, net	3,198	4	22,303	—	22,307
Stock-based compensation expense	—	—	7,020	—	7,020
Warrant liability removed due to exercises of warrants	—	—	55	—	55
Stock option exercises	205	—	351	—	351
Issuance of warrants to consultant	—	—	316	—	316
Net loss	—	—	—	(30,082)	(30,082)
Balance at March 31, 2015	81,537	$ 82	$ 170,909	$ (122,295)	$48,696

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

ORGANOVO HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)

	Year Ended March 31, 2015	Year Ended March 31, 2014	Three Months Ended March 31, 2013	March 31, 2012 (Unaudited)	Year Ended December 31, 2012
Cash Flows From Operating Activities					
Net loss	$ (30,082)	$ (25,848)	$ (16,120)	$ (37,081)	$ (43,553)
Adjustments to reconcile net loss to net cash used in operating activities:					
Amortization of deferred financing costs	-	-	-	319	319
Amortization of warrants issued for services	557	323	261	-	556
Depreciation and amortization	472	387	80	17	195
Loss on disposal of fixed assets	12	84	-	-	158
Amortization of debt discount	-	-	-	896	896
Interest accrued on convertible notes payable	-	-	-	12	12
Fair value of warrant liabilities in excess of proceeds	-	-	-	19,019	19,019
Change in fair value of warrant liabilities	(196)	5,120	12,034	13,506	9,931
Loss on inducement to exercise warrants	-	-	-	-	1,904
Expense associated with warrant modification	-	12	65	-	-
Stock-based compensation	7,020	4,600	848	4	1,435
Increase (decrease) in cash resulting from changes in:					
Grants receivable	-	101	61	-	(162)
Inventory	(3)	25	-	(45)	(459)
Prepaid expenses and other assets	(389)	(392)	(61)	(65)	(101)
Accounts payable	1,061	(315)	216	(217)	(233)
Accrued expenses	1,435	312	(283)	(28)	384
Deferred rent	270	75	82	(9)	159
Deferred revenue	242	(45)	62	116	(153)
Net cash used in operating activities	(19,601)	(15,561)	(2,755)	(3,556)	(9,693)
Cash Flows From Investing Activities					
Deposits released from restriction (restricted cash deposits)	-	9	-	(38)	(88)
Purchases of fixed assets	(1,517)	(277)	(137)	(6)	(357)
Purchases of intangible assets	-	-	(19)	-	-
Net cash used in investing activities	(1,517)	(268)	(156)	(44)	(445)
Cash Flows From Financing Activities					
Proceeds from issuance of common stock and exercise of warrants, net	22,752	48,016	3,724	13,723	24,714
Proceeds from exercise of stock options	351	402	-	-	18

Principal payments on capital lease obligations	(10)	(10)	(2)	-	(7)
Repayment of convertible notes and interest payable	-	-	-	(110)	(110)
Deferred financing costs	-	(40)	-	-	-
Net cash provided by financing activities	23,093	48,368	3,722	13,613	24,615
Net Increase in Cash and Cash Equivalents	1,975	32,539	811	10,013	14,477
Cash and Cash Equivalents at Beginning of Period	48,167	15,628	14,817	340	340
Cash and Cash Equivalents at End of Period	$ 50,142	$ 48,167	$ 15,628	$ 10,353	$ 14,817
Supplemental Disclosure of Cash Flow Information:					
Interest	$ —	$ —	$ —	$ 10	$ 10
Income Taxes	$ 4	$ —	$ —	$ 1	$ 1

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

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

During 2012, the Company issued 1,525,387 shares of common stock to note holders for the conversion of Convertible Notes with a principal balance totaling $1,500 and accrued interest totaling $25.

During 2012, the Company issued warrants, valued at approximately $32,743, in connection with the Reverse Merger and the Private Placement. The warrants were recognized as a derivative liability.

During 2012, the Company purchased equipment valued at $34 through a capital lease.

During 2012, the Company transferred approximately $391 of bioprinter related inventory to fixed assets.

During 2012, the Company issued 650,000 warrants to purchase shares of our common stock for consulting services. The warrants were valued at approximately $890.

During 2012, the warrant liability was reduced by $23,321 as a result of settlements during the year.

During the three months ended March 31, 2013, the Company transferred approximately $272 of bioprinter related inventory to fixed assets.

During the three months ended March 31, 2013, the warrant liability was reduced by approximately $23,869 as a result of warrant exercises and $1,886 for warrants reclassified as equity instruments.

During the year ended March 31, 2014, the warrant liability was reduced by approximately $10,874 as a result of warrant exercises and $767 for warrants reclassified as equity instruments.

During the year ended March 31, 2014, the Company issued 75,000 warrants to purchase shares of our common stock for consulting services. The warrants were valued at approximately $404.

During the year ended March 31, 2015, the warrant liability was reduced by approximately $55 as a result of warrant exercises.

During the year ended March 31, 2015, approximately $144 of leasehold improvements were funded by the Company’s landlord as a lease incentive. The Company capitalized these costs as property, plant and equipment, with a corresponding increase in deferred rent that will be amortized over the remaining lease term.

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

Organovo Holdings, Inc.

Notes to Consolidated Financial Statements

1. Change in Fiscal Year End

On March 31, 2013, the Board of Directors of the Company (the "Board") approved a change in the Company's fiscal year end from December 31st to March 31st. As a result of this change, the Company filed a Transition Report on Form 10-KT for the three-month transition period ended March 31, 2013. References to any of the Company's pre-2013 fiscal years mean the fiscal year ending December 31 of that calendar year.

2. Description of Business and Summary of Significant Accounting Policies

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

Nature of operations and basis of presentation

References in these notes to the consolidated financial statements to "Organovo Holdings, Inc.," "Organovo Holdings," "we," "us," "our," "the Company" and "our Company" refer to Organovo Holdings, Inc. and its consolidated subsidiaries. Our consolidated financial statements include the accounts of the Company as well as its wholly-owned subsidiaries, with all material intercompany accounts and transactions eliminated in consolidation. In December 2014, we established a wholly-owned subsidiary, Samsara Sciences, Inc., to focus on the acquisition of qualified cells in support of our commercial and research endeavors.

Since its inception, the Company has devoted its efforts primarily to developing and commercializing a platform technology and functional human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs, raising capital and building infrastructure. In November 2014, the Company announced the full commercial release of its first product, the exVive3D ™ Human Liver Tissue for use in toxicology and other preclinical drug testing. As of March 31, 2015, the Company has not yet realized significant revenues from its planned principal operations. The Company's activities are subject to significant risks and uncertainties including failing to secure additional funding to fully operationalize the Company's current technology and continue to implement its business plan.

Reverse merger transaction

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

Simultaneously with the Merger, on February 8, 2012 (the "Closing Date"), all of the issued and outstanding shares of Organovo, Inc.'s common stock converted, on a 1 for 1 basis, into shares of the Company's common stock, par value $0.001 per share. Also, on the closing date, all of the issued and outstanding options to purchase shares of Organovo,

Inc.’s common stock and other outstanding warrants to purchase Organovo, Inc.’s common stock, and all of the issued and outstanding bridge warrants to purchase shares of Organovo, Inc.’s common stock, converted on a 1 for 1 basis, into options, warrants and new bridge warrants to purchase shares of the Company’s common stock.

Immediately following the consummation of the Merger: (i) the former security holders of Organovo, Inc. common stock had an approximate 75% voting interest in the Company and the Company stockholders retained an approximate 25% voting interest, (ii) the former executive management team of Organovo, Inc. remained as the only continuing executive management team for the Company, and (iii) the Company’s ongoing operations consisted solely of the ongoing operations of Organovo, Inc. Based primarily on these factors, the Merger was accounted for as a reverse merger and a recapitalization in accordance with U.S. generally accepted accounting principles (“GAAP”). As a result, these financial statements reflect the historical results of Organovo, Inc. prior to the Merger, and the combined results of the Company following the Merger. The par value of Organovo, Inc. common stock immediately prior to the Merger was $0.0001 per share. The par value subsequent to the Merger is $0.001 per share, and therefore the historical results of Organovo, Inc. prior to the Merger have been retroactively adjusted to affect the change in par value.

In connection with three separate closings of a private placement transaction completed in connection with the Merger (the “Private Placement”), the Company received gross proceeds of approximately $5.0 million, $1.8 million and $6.9 million on closings on February 8, 2012, February 29, 2012 and March 16, 2012, respectively. In 2011, the Company received $1.5 million from the purchase of 6% convertible notes which were automatically converted into 1,500,000 shares of common stock, plus 25,387 shares for accrued interest of $25,387 on the principal, on February 8, 2012.

The cash transaction costs related to the Merger were approximately $2.1 million.

Before the Merger, the Company's Board of Directors and stockholders adopted the 2012 Equity Incentive Plan (the "2012 Plan"). In addition, the Company assumed and adopted Organovo, Inc.'s 2008 Equity Incentive Plan.

NYSE MKT listing

On July 9, 2013, the Company announced that its common stock had been approved to list on the NYSE MKT. Shares began trading on the New York Stock Exchange on July 11, 2013 under the symbol "ONVO". Prior to that time, the Company's shares were quoted on the OTC QX.

Liquidity

As of March 31, 2015, the Company had an accumulated deficit of approximately $122.3 million. The Company also had negative cash flows from operations of approximately $19.6 million during the year ended March 31, 2015.

Through March 31, 2015, the Company has financed its operations primarily through the sale of convertible notes, the private placement of equity securities, the public offering of common stock, and through revenue derived from grants, collaborative research agreements, and product and service agreements. Based on its current operating plan and available cash resources, the Company believes it has sufficient resources to fund its business for at least the next twelve months.

The Company will need additional capital to further fund the development and commercialization of its human tissues that can be employed in drug discovery and development, biological research, and as therapeutic implants for the treatment of damaged or degenerating tissues and organs. The Company intends to cover its future operating expenses through cash on hand, through revenue derived from research service agreements, product sales, collaborative research agreements, grants, and through the issuance of additional equity or debt securities. Depending on market conditions, we cannot be sure that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or to our stockholders.

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

Use of estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Significant estimates used in preparing the consolidated financial statements include those assumed in computing the valuation of warrants and conversion features, revenue recognized under the proportional performance model, the valuation of stock-based compensation expense, and the valuation allowance on deferred tax assets.

Financial instruments

For certain of the Company's financial instruments, including cash and cash equivalents, inventory, prepaid expenses and other assets, accounts payable, accrued expenses, deferred revenue, and capital lease obligations, the carrying amounts are generally considered to be representative of their respective fair values because of the short-term nature

of those instruments.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less to be cash equivalents.

Derivative financial instruments

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

The Company reviews the terms of convertible debt and equity instruments it issues to determine whether there are derivative instruments, including an embedded conversion option that is required to be bifurcated and accounted for separately as a derivative

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

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

The discount from the face value of the convertible debt, together with the stated interest on the instrument, is amortized over the life of the instrument through periodic charges to interest expense, using the effective interest method.

Restricted cash

As of March 31, 2015 and 2014, the Company had approximately $78,800 of restricted cash deposited with a financial institution. The entire amount is held in certificates of deposit to support a letter of credit agreement related to the Company’s facility lease.

Inventory

Inventories are stated at the lower of the cost or market (first-in, first-out). Inventory consists of approximately $66,000, and $63,000 in raw materials as of March 31, 2015 and 2014, respectively, net of reserves.

Fixed assets and depreciation

Property and equipment are carried at cost. Expenditures that extend the life of the asset are capitalized and depreciated. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets or, in the case of leasehold improvements, over the lesser of the useful life of the related asset or the remaining lease term. The estimated useful lives of the fixed assets range between three and seven years.

Impairment of long-lived assets

In accordance with authoritative guidance the Company reviews its long-lived assets, including property and equipment and other assets, for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be fully recoverable. To determine recoverability of its long-lived assets, the Company evaluates whether future undiscounted net cash flows will be less than the carrying amount of the assets and adjusts the carrying amount of its assets to fair value. Management has determined that no impairment of long-lived assets occurred as of March 31, 2015.

Fair value measurement

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

and the last unobservable, that may be used to measure fair value:

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

The Company has issued warrants, of which some are classified as derivative liabilities as a result of the terms in the warrants that provide for down-round protection in the event of a dilutive issuance. The Company uses Level 3 inputs for its valuation methodology for the warrant derivative liabilities. The estimated fair values were determined using a Monte Carlo option pricing model based on various assumptions (see Note 5). The Company's derivative liabilities are adjusted to reflect estimated fair value at each period end, with any decrease or increase in the estimated fair value being recorded in other income or expense accordingly, as adjustments to the

fair value of derivative liabilities. Various factors are considered in the pricing models we use to value the warrants, including the Company's current stock price, the remaining life of the warrants, the volatility of the Company's stock price, and the risk free interest rate. Changes in these factors have had and may continue in the future to have a significant impact on the computed fair value of the warrant liability.

The estimated fair values of the liabilities measured on a recurring basis are as follows:

Fair Value Measurements at March 31, 2015 and 2014 (in thousands):

	Balance at March 31, 2015	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Warrant liability	$ 126	$ —	$ —	$ 126

	Balance at March 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Warrant liability	$ 377	$ —	$ —	$ 377

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the years ended March 31, 2015 and 2014:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)

	Warrant Derivative Liability (in thousands)
Balance at March 31, 2013	$ 6,898

Issuances	$ —
Adjustments to estimated fair value	$ 5,120
Warrant liability removal due to settlements	$ (10,874)
Warrant liability reclassified to equity	$ (767)
Balance at March 31, 2014	$ 377
Issuances	$ —
Adjustments to estimated fair value	$ (196)
Warrant liability removal due to settlements	$ (55)
Balance at March 31, 2015	$ 126

Research and development

Research and development expenses, including direct and allocated expenses, consist of independent research and development costs, as well as costs associated with sponsored research and development. Research and development costs are expensed as incurred.

Income taxes

Deferred income taxes are recognized for the tax consequences in future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is the combination of the tax payable for the year and the change during the year in deferred tax assets and liabilities.

Revenue recognition

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

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

Billings to customers or payments received from customers are included in deferred revenue on the balance sheet until all revenue recognition criteria are met. As of March 31, 2015 and 2014 the Company had approximately $259,000 and $17,000, respectively, in deferred revenue related to its grants, collaborative research programs and research service agreements.

Revenue arrangements with multiple deliverables

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

The Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance. While changes in the allocation of the arrangement consideration between the units of accounting will not affect the amount of total revenue recognized for a particular sales arrangement, any material changes in these allocations could impact the timing of revenue recognition, which could affect the Company’s results of operations.

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

Revenue from research service agreements

For research service agreements, the Company defers any up-front fees collected from customers and recognizes revenue when earned, typically when services are rendered or deliverables are provided to the customer. When substantial customer acceptance terms exist, the Company recognizes revenue for delivered elements only when it determines there are no uncertainties regarding customer acceptance.

Research and development revenue under collaborative agreements

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

The Company recognizes revenue from research funding under collaboration agreements when earned on a “proportional performance” basis as research hours are incurred. The Company performs services as specified in each respective agreement on a best-efforts basis, and is reimbursed based on labor hours incurred or achievement of

milestones or certain deliverables as specified in the contract. The Company initially defers revenue for any amounts billed or payments received in advance of the services being performed, and recognizes revenue pursuant to the related pattern of performance, based on total labor hours incurred relative to total labor hours estimated under the contract.

In December 2010, the Company entered into a 12 month research contract agreement with a third party, whereby the Company was engaged to perform research and development services on a fixed-fee basis for approximately $600,000. Based on the proportional performance criteria, the Company recognized approximately $150,000 in revenue related to the contract during the year ended December 31, 2012. Total revenue recognized on the contract as of March 31, 2015 was approximately $600,000.

In October 2011, the Company entered into a research contract agreement with a third party to perform research and development services for a fixed-fee of $1,365,000. The agreement included an initial payment to the Company of approximately $239,000 with remaining payments occurring over a twenty-one month period. On November 27, 2012, the agreement was amended to include

additional research and development services, for an additional $135,000, bringing the total contract value to $1,500,000. The third party ultimately elected to have only $40,000 of these additional research and development services performed by the Company, resulting in a total contract value of $1,405,000. The amendment extended the original contract (which ran concurrently) from twenty-one months to twenty-eight months. The Company recorded approximately $0, $184,000, $97,000, $120,000, and $885,000 for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively, in revenue related to the research contract in recognition of the proportional performance achieved.

In September 2013, the Company entered into a research contract agreement with a third party to perform research and development services for fixed fees ranging from approximately $7,000 to $83,000, depending on go/no-go decisions made along the way. The agreement included an initial payment to the Company of approximately $7,000 with remaining payments occurring at the completion of each phase of work. The third party ultimately elected to have $76,000 of work performed under the agreement, and as such the Company recorded approximately $69,000 and $7,000, for the years ended March 31, 2015 and 2014, respectively, in revenue related to the research contract in recognition of the proportional performance achieved.

In October 2013, the Company entered into a research contract agreement with a third party to perform research and development services for fixed fees ranging from approximately $59,000 to approximately $93,000, depending on go/no-go decisions made along the way. The agreement included an initial payment to the Company of approximately $29,000 with remaining payments occurring at the beginning of each phase of work. The third party elected to have all potential work performed under the agreement, and as such the Company recorded approximately $41,000 and $52,000, for the years ended March 31, 2015 and 2014, respectively, in revenue related to the research contract in recognition of the proportional performance achieved.

Product revenue

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

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

Grant revenues

During 2012, 2010 and 2009, the NIH awarded the Company three research grants totaling approximately $558,000. Revenues from these NIH grants were based upon internal and subcontractor costs incurred that were specifically covered by the grants, and where applicable, an additional facilities and administrative rate that provided funding for overhead expenses. These revenues were recognized when expenses had been incurred by subcontractors and as the Company incurred internal expenses that were related to the grants. Revenue recognized under these grants for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012 was approximately $0, $12,000, $117,000, $0, and $162,000, respectively.

During August of 2013, the Company was awarded a research grant by a private, not-for-profit organization for up to $251,700, contingent on go/no-go decisions made by the grantor at the completion of each stage of research as

outlined in the grant award. Revenues from the grant are based upon internal costs incurred that are specifically covered by the grant, plus an additional rate that provides funding for overhead expenses. Revenue is recognized when the Company incurs expenses that are related to the grant. Revenue recognized under this grant was approximately $49,000 and $119,000 for the years ended March 31, 2015 and 2014, respectively.

During September of 2014, the NIH awarded the Company a research grant totaling approximately $222,000. The grant provides for fixed payments based on the achievement of certain milestones. As such, revenue will be recognized upon completion of those milestones. Revenue recognized under this grant was approximately $74,000 for the year ended March 31, 2015.

Stock-based compensation

The Company accounts for stock-based compensation in accordance with the Financial Accounting Standards Board's ASC Topic 718, Compensation — Stock Compensation, which establishes accounting for equity instruments exchanged for employee services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant).

The Company accounts for equity instruments, including restricted stock or stock options, issued to non-employees in accordance with authoritative guidance for equity based payments to non-employees. Stock options issued to non-employees are accounted for at their estimated fair value determined using the Black-Scholes option-pricing model. The fair value of options granted to non-employees is

re-measured as they vest, and the resulting increase in value, if any, is recognized as expense during the period the related services are rendered. Restricted stock issued to non-employees is accounted for at its estimated fair value as it vests.

Comprehensive income (loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive income (loss) in the financial statements in the period in which they are recognized. Net income (loss) and other comprehensive income (loss), including unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income (loss). For the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012 the comprehensive loss was equal to the net loss.

Net loss per share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, and the assumed issuance of common stock under restricted stock units, shares subject to repurchase and warrants as the effect would be anti-dilutive. No dilutive effect was calculated for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 or 2012, or the year ended December 31, 2012 as the Company reported a net loss for each respective period and the effect would have been anti-dilutive. Total common stock equivalents that were excluded from computing diluted net loss per share were approximately 8.6 million, 7.7 million, 8.9 million, 25.8 million, and 15.2 million for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012 and the year ended December 31, 2012, respectively.

Reclassifications

Certain reclassifications were made to the Consolidated Balance Sheet as of March 31, 2014 in order to conform to the presentation of the Consolidated Balance Sheet as of March 31, 2015. The reclassifications did not have any effect on previously reported financial position.

3. Fixed Assets

Fixed assets consisted of the following (in thousands):

	March 31, 2015	March 31, 2014
Laboratory equipment	$1,951	$1,207
Construction in process	529	—
Computer software and equipment	274	191
Furniture and fixtures	135	33
Leasehold improvements	155	—
	3,044	1,431
Less accumulated depreciation and amortization	(1,002)	(574)

	$2,042	$857

Depreciation and amortization expense for the years end March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012 was approximately $464,000, $380,000, $78,000, $15,000, and $188,000, respectively.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2015	March 31, 2014
Accrued compensation	$1,917	$ 505
Accrued legal and professional fees	195	283
Other accrued expenses	145	34
	$2,257	$ 822

5. Derivative Liability

During 2012, in relation to the reverse Merger and the three offerings under the Private Placement, the Company issued 21,347,182 five-year warrants to purchase the Company's common stock. In October and November of 2011, the Company issued 1,500,000 five-year warrants in connection with Convertible Notes. The exercise price of the warrants is protected against down-round financing throughout the term of the warrant, as described below. Pursuant to ASC 815-15 and ASC 815-40, the fair value of the warrants of approximately $32.7 million and $1.3 million in 2012 and 2011, respectively, was recorded as a derivative liability on the issuance dates.

The Company revalued the warrants as of the end of each reporting period, and the estimated fair value of the outstanding warrant liabilities was $0.1 million, $0.4 million, $6.9 million, and $20.6 million as of March 31, 2015, March 31, 2014, March 31, 2013, and December 31, 2012, respectively. The change in fair value of the derivative liabilities for the year ended March 31, 2015 was a decrease of $0.2 million. The changes in fair value of the derivative liabilities for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012 were increases of $5.1 million, $12.0 million, $13.5 million, and $9.9 million, respectively. These changes are included in other income (expense) in the statements of operations.

During the years ended March 31, 2015 and 2014, 8,647 and 1,920,874 warrants that were classified as derivative liabilities were exercised. The warrants were revalued as of the settlement date, and the change in fair value was recognized to earnings. In addition, in the year ended March 31, 2014 the Company entered into amendment agreements with certain of the warrant holders, which removed the down-round pricing protection provision, resulting in 269,657 of these warrants being reclassified from liability instruments to equity instruments. The Company also recognized a reduction in the warrant liability based on the fair value as of the settlement date for the warrants exercised and as of the modification date for the warrants that were amended, with a corresponding increase in additional paid-in capital.

The derivative liabilities were valued at the closing dates of the Private Placement and the end of each reporting period using a Monte Carlo valuation model with the following assumptions:

	March 31, 2015	March 31, 2014
Closing price per share of common stock	$3.54	$7.64
Exercise price per share	$1.00	$1.00
Expected volatility	76.80%	76.50%
Risk-free interest rate	0.56 %	0.90 %
Dividend yield	—	—
Remaining expected term of underlying securities (years)	1.96	2.96

In addition, as of the valuation dates, management assessed the probabilities of future financings assumptions in the Monte Carlo valuation models. Management also applied a discount for lack of marketability to the valuation of the derivative liabilities based on such trading restrictions due to certain of the shares not being registered.

In accordance with the terms of the warrant agreements, if, prior to the expiration date of the warrants, the Company issues additional shares of common stock, as defined below, without consideration or for a consideration per share less than the exercise price of the warrants in effect immediately prior to such issue, then the exercise price shall be reduced, concurrently with such issue, to a price (calculated to the nearest cent) determined by multiplying such exercise price by a fraction, (A) the numerator of which shall be (1) the number of shares of common stock outstanding immediately prior to such issue plus (2) the number of shares of common stock which the aggregate

consideration received or to be received by the Company for the total number of additional shares of common stock so issued would purchase at such exercise price; and (B) the denominator of which shall be the number of shares of common stock outstanding immediately prior to such issue plus the number of such additional shares of common stock so issued; provided that (i) all shares of common stock issuable upon conversion or exchange of convertible securities outstanding immediately prior to such issue shall be deemed to be outstanding, and (ii) the number of shares of common stock deemed issuable upon conversion or exchange of such outstanding convertible securities shall be determined without giving effect to any adjustments to the conversion or exchange price or conversion or exchange rate of such convertible securities resulting from the issuance of additional shares of common stock that is the subject of this calculation. For purposes of the warrants, "additional shares of common stock" shall mean all shares of common stock issued by the Company after the effective date (including without limitation any shares of common stock issuable upon conversion or exchange of any convertible securities or upon exercise of any option or warrant, on an as-converted basis), other than: (i) shares of common stock (and/or warrants for any class of equity securities of the Company) issued or issuable upon conversion or exchange of any convertible securities or exercise of any options or warrants outstanding on the effective date; (ii) shares of common stock issued or issuable by reason of a dividend, stock split, split-up or other distribution on shares of common stock; (iii) shares of common stock (or options with respect thereto) issued or issuable to employees or directors of, or consultants to, the Company or any of its subsidiaries pursuant to a plan, agreement or arrangement approved by the Board of Directors of the Company; (iv) any

securities issued or issuable by the Company pursuant to (A) the Private Placement; or (B) the Merger; (v) securities issued pursuant to acquisitions or strategic transactions approved by a majority of disinterested directors of the Company, provided that any such issuance shall only be to a person which is, itself or through its subsidiaries, an operating company in a business synergistic with the business of the Company and in which the Company receives benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities and (vi) securities issued to financial institutions, institutional investors or lessors in connection with credit arrangements, equipment financings or similar transactions approved by a majority of disinterested directors of the Company, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities.

Upon each adjustment of the exercise price pursuant to the provisions stated above, the number of warrant shares issuable upon exercise of the warrants shall be adjusted by multiplying a number equal to the exercise price in effect immediately prior to such adjustment by the number of warrant shares issuable upon exercise of the warrant immediately prior to such adjustment and dividing the product so obtained by the adjusted exercise price.

6. Convertible Notes Payable

Local bridge

During July and August 2011, $740,000 of Convertible Notes bearing interest at 20% per annum, and warrants to purchase shares of common stock were issued to investors. The Convertible Notes were due at the earlier of 1) one year from the issuance date or 2) one week after the consummation of a Merger transaction. The number of warrants to be issued was equal to the note principal divided by the exercise price. The exercise price was the per-share or per-unit fair market value received in the Merger. The notes were convertible at a price per share equal to seventy-five percent (75%) of the per-share fair market value of the total consideration received for a share of a public company’s common stock to be determined to be identified upon consummation of a merger.

The Company determined that the beneficial conversion feature and the warrants did not represent embedded derivative instruments. Additionally, at issuance of the Convertible Notes, the Company did not record the discount for the beneficial conversion feature due to the contingencies surrounding conversion. The beneficial conversion feature was recorded when the contingencies were resolved. In accordance with ASC 470-20, Debt with Conversion and Other Options, the Company recorded a discount of approximately $583,700 for the warrants in 2011. The discount was amortized to interest expense over the term of the Convertible Notes using the effective interest method.

Exchange Agreement and Release

In October 2011, the Company’s Board of Directors and stockholders approved an Exchange Agreement and Release, whereby the note holders could exchange their Convertible Notes and accrued interest for shares of the Company’s common stock and warrants to purchase the Company’s common stock. A total of $3,030,000 of principal and approximately $459,800 of accrued interest converted, at prices ranging from $0.27 to $0.75, into 7,676,828 shares of the Company’s common stock, plus five-year warrants to purchase 1,309,750 common shares at an exercise price of $1.00 per share. For the holders that elected to participate, the Exchange Agreement and Release resulted in the cancellation of the Convertible Notes and release from the note holders for any claims related to the Convertible Notes.

The Company determined that the warrants issued in connection with the Exchange Agreement and Release did not represent derivative instruments. The warrants, valued at approximately $527,600, were classified as equity instruments and recorded as interest expense on the date of issuance in 2011. The Company calculated the fair value of the warrants using the Black-Scholes Model, using a volatility of 110.13%, an interest rate of 1.11% and a dividend yield of zero.

At December 31, 2011, an unsecured $100,000 Convertible Note, with interest at 10% and a maturity date of April 2014, remained outstanding. In February 2012, at the close of the Merger, the convertible note and accrued interest in the aggregate of approximately $110,000 were repaid.

2011 Private Placement

On September 18, 2011, Organovo, Inc.’s Board of Directors authorized a Private Placement offering of up to 30 units of its securities at a price of $50,000 per unit for an aggregate purchase price of $1,500,000. Each unit consisted of a convertible note in the principal amount of $50,000 accruing simple interest at the rate of 6% per annum (the “Convertible Notes”), plus five-year warrants to purchase 50,000 shares of the next Qualified Round of Equity Securities, at an exercise price of $1.00 per share. The principal plus accrued interest was convertible into the Company’s common stock upon consummation of a Merger transaction.

During October and November 2011, $1,500,000 of Convertible Notes bearing interest at 6% per annum with a maturity date of March 30, 2012, and five-year warrants to purchase 1,500,000 shares of the Company's common stock were issued to investors under the Private Placement. The warrants are exercisable at $1.00 per share, expire in five years, and contain down-round price protection. The Convertible Notes were outstanding at December 31, 2011, and were converted into 1,525,387 units during February 2012, in connection with the Merger.

The Company determined that the warrants represent a derivative instrument due to the down-round price protection, and accordingly, the Company recorded a derivative liability related to the warrants, with a corresponding debt discount of approximately $1,260,300. See Note 5. Additionally, upon issuance of the notes during 2011, the Company recorded the discount for the beneficial conversion feature of $239,700. The debt discount associated with the warrants and beneficial conversion feature were amortized to interest expense over the life of the Convertible Notes, and fully amortized upon conversion of the Convertible Notes in 2012. The Company recorded approximately $896,200 of interest expense for the amortization of the debt discount during the year ended December 31, 2012.

As consideration for locating investors to participate in the Private Placement, the placement agent earned a cash payment of $195,000 in 2011. Additionally, upon closing of the Merger transaction in 2012, the placement agent earned five-year warrants to purchase 610,155 shares of the Company's common stock at $1.00 per share. These warrants contain down round protection and were classified as derivative liabilities upon issuance. See Note 5.

2012 Private Placement

During 2012, concurrently with the closing of the Merger and in contemplation of the Merger, the Company completed the initial closing of the Private Placement of up to 8,000,000 units of its securities, at a price of $1.00 per unit, with the ability to increase the offering to an aggregate of up to 16,000,000 units. Each unit consisted of one share of common stock and a warrant to purchase one share of common stock. The Company completed three closings under the Private Placement during 2012, and raised total gross proceeds of $13,722,600 and total net proceeds of $11,593,066. The Company issued 13,722,600 shares of its common stock and warrants to purchase 15,247,987 shares of its common stock (including warrants to purchase 1,525,387 shares to former holders of the Convertible Notes) exercisable at $1.00 to investors in the offering. The placement agent and its selected dealers were paid total cash commissions of $1,372,260 and the placement agent was paid an expense allowance of $411,678 and was issued placement agent warrants to purchase 6,099,195 shares of the Company's common stock at an exercise price of $1.00 per share.

The warrants issued to the investors and the placement agent, as described above, contain down round protection, and accordingly, were classified as derivative liabilities upon issuance. On the closing date, the derivative liabilities were recorded at an estimated fair value of approximately $32,742,000. Given that the fair value of the derivative liabilities exceeded the total proceeds of the private placement of $13,722,600, no net amounts were allocated to the common stock. The amount by which the recorded liabilities exceeded the proceeds of approximately $19,019,400 was charged to other expense at the closing dates. The Company has revalued the derivative liability as of each reporting period, and will continue to do so on each subsequent balance sheet date until the securities to which the derivative liabilities relate are exercised or expire, with any changes in the fair value recognized through earnings in the statement of operations. See Note 5.

Interest expense, including amortization of the note discounts and other interest expense was approximately $1,000, $13,000, $65,000, $1,088,000, and $1,088,000 for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively.

7. Stockholders' Equity

Common stock

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

On August 2, 2013, the Company, entered into an Underwriting Agreement (the “Underwriting Agreement”) with Lazard Capital Markets LLC, acting as representative of the underwriters named in the Underwriting Agreement (the “Underwriters”) and joint book-runner with Oppenheimer & Co. Inc., relating to the issuance and sale of 10,350,000 shares of the Company’s common stock, which includes the issuance and sale of 1,350,000 shares pursuant to an overallotment option exercised by the Underwriters on August 5, 2013. JMP Securities LLC and Maxim Group LLC each acted as co-managers for the offering. The price to the public in the offering was $4.50 per share, and the Underwriters purchased the shares from the Company pursuant to the Underwriting Agreement at a price of $4.23 per share. The net proceeds to the Company from the offering were approximately $43.4 million, after deducting

underwriting discounts and commissions and other offering expenses of $3.2 million payable by the Company, including the Underwriters' exercise of the overallotment option. The transactions contemplated by the Underwriting Agreement closed on August 7, 2013.

In November 2013, the Company entered into an equity distribution agreement with an investment banking firm. Under the terms of the distribution agreement, the Company may offer and sell up to 4,000,000 shares of its common stock, from time to time, through the investment bank in at-the-market ("ATM") offerings, as defined by the SEC, and pursuant to the Company's effective shelf registration statement previously filed with the SEC. During the years ended March 31, 2015 and 2014, the Company issued 2,197,768 and 334,412 shares of common stock in ATM offerings under the distribution agreement with net proceeds of $16.1 and $3.5 million, respectively.

In December 2014, the Company entered into an equity offering sales agreement with another investment banking firm. Under the terms of the sales agreement, the Company may offer and sell shares of its common stock, from time to time, through the investment bank in ATM offerings, as defined by the SEC, and pursuant to the Company's effective shelf registration statement previously filed with the SEC. During the year ended March 31, 2015, the Company sold 1,000,000 shares of common stock in ATM offerings under the sales agreement with net proceeds of $6.2 million. The Company intends to use the net proceeds raised through any ATM sales for general corporate purposes, including research and development, the commercialization of the Company's products, general administrative expenses, and working capital and capital expenditures.

The Company will limit future sales under the 2013 distribution agreement and the 2014 sales agreement to ensure that it does not exceed the maximum amount available for sale under its effective shelf registration statement previously filed with the SEC. Based on its use of the shelf registration statement through March 31, 2015, the Company cannot sell more than an aggregate of $26,777,785 in shares of common stock under the 2013 distribution agreement and the 2014 sales agreement.

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

In addition, during the years ended March 31, 2015 and 2014, the Company issued 210,600 and 2,713,207 shares of common stock upon exercise of 211,647 and 3,201,633 warrants, respectively.

During the years ended March 31, 2015 and 2014, the Company issued 205,033 and 183,796 shares of common stock upon exercise of 205,684 and 183,796 options, respectively.

Restricted stock awards

In May of 2008, the Board of Directors of the Company approved the 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan authorized the issuance of up to 1,521,584 common shares for awards of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock award units, and stock appreciation rights. The 2008 Plan terminates on July 1, 2018. No shares have been issued under the 2008 Plan since 2011, and the Company does not intend to issue any additional shares from the 2008 Plan in the future.

In January 2012, the Board of Directors of the Company approved the 2012 Equity Incentive Plan (the "2012 Plan"). The 2012 Plan authorized the issuance of up to 6,553,986 shares of common stock for awards of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, performance shares, and other stock or cash awards. The Board of Directors and stockholders of the Company approved an amendment to the 2012 Plan in August 2013 to increase the number of shares of common stock that may

be issued under the 2012 Plan by 5,000,000 shares, for an aggregate of 11,553,986 shares issuable under the 2012 Plan. The 2012 Plan terminates ten years after its adoption.

On August 6, 2012, 200,000 restricted stock awards were issued to a member of senior management, the vesting of which was performance based with achievement to be measured at December 31, 2014 or earlier if the metric was achieved. As of December 31, 2014, the Company had determined that three of the four target metrics had been achieved with the fourth performance metric criterion not met resulting in 150,000 shares of restricted stock vested and the remaining 50,000 restricted stock awards surrendered back to the Company unvested. The Company recognized the related stock-based compensation expense over the requisite service period ending on March 31, 2015.

During the year ended December 31, 2012, the Company issued an aggregate 950,000 of restricted stock awards to certain members of senior management and 130,000 restricted stock awards to non-executive employees. The vesting schedule is 25% on each

anniversary of the vesting start date over four years. Additionally, the Company issued 100,000 restricted stock awards to a consultant. The vesting schedule is 100% after 6 months.

During the year ended December 31, 2012, there were 95,842 restricted stock awards forfeited by staff members upon termination of their employment with the Company. Additionally, 89,674 restricted stock awards were surrendered related to shares of common stock returned to the Company, at the option of the holders, to cover the tax liability related to the vesting of 211,250 restricted stock awards. Upon the return of the common stock, 89,674 stock option grants with immediate vesting were granted to the individuals at the vesting date market value strike price.

During the three months ended March 31, 2013, the Company issued an aggregate of 55,000 restricted stock awards with immediate vesting to a consultant.

During the three months ended March 31, 2013, there were 10,000 restricted stock awards forfeited by one staff member upon termination of their employment with the Company. Additionally, 24,690 restricted stock awards were surrendered related to shares of common stock returned to the Company, at the option of the holder, to cover the tax liability related to the vesting of 50,000 restricted stock awards. Upon the return of the common stock, 24,690 stock option grants with immediate vesting were granted to the individual at the vesting date market value strike price.

During the year ended March 31, 2014, 218,655 restricted stock awards were surrendered related to shares of common stock returned to the Company, at the option of the holder, to cover the tax liability related to the vesting of 405,000 restricted stock awards. Upon the return of the common stock, 218,655 stock option grants with immediate vesting were granted to the individual at the vesting date market value strike price.

During the year ended March 31, 2014, the Company issued an aggregate of 60,000 restricted stock units with immediate vesting to a consultant.

During the year ended March 31, 2015, 137,816 restricted stock awards were surrendered related to shares of common stock returned to the Company, at the option of the holder, to cover the tax liability related to the vesting of 255,000 restricted stock awards. Upon the return of the common stock, 137,816 stock option grants with immediate vesting were granted to the individual at the vesting date market value strike price.

A summary of the Company’s restricted stock award activity is as follows:

	Number of Shares
Unvested at December 31, 2011	1,111,295
Granted	1,380,000
Vested	(1,233,409)
Canceled / forfeited	(95,842)
Unvested at December 31, 2012	1,162,044
Granted	55,000
Vested	(221,302)
Canceled / forfeited	(10,000)
Unvested at March 31, 2013	985,742
Granted	60,000
Vested	(472,247)
Canceled / forfeited	—
Unvested at March 31, 2014	573,495

Granted	—
Vested	(262,245)
Canceled / forfeited	(52,500)
Unvested at March 31, 2015	258,750

The fair value of each restricted common stock award is recognized as stock-based compensation expense over the vesting term of the award. The Company recorded restricted stock-based compensation expense in operating expenses for employees and non-employees of approximately $421,000, $817,000, $478,000, $0, and $835,000, during the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively. Expense for each of the periods included approximately $15,000, $16,000, $4,000, $0, and $23,000, for research and development during the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively.

General and administrative expense for the years ended March 31, 2015 and March 31, 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012 were approximately $406,000, $801,000, $474,000, $0, and $812,000, respectively.

As of March 31, 2015, total unrecognized restricted stock-based compensation expense was approximately $222,000, which will be recognized over a weighted average period of 0.62 years.

Stock options

During the years ended March 31, 2015 and 2014, under the 2012 Equity Incentive Plan, 1,429,191 and 2,519,572 incentive stock options were issued, respectively, at various exercise prices. The stock options generally vest on the one year anniversary of the grant date, quarterly over a three year period, or over a four-year period, with a quarter vesting on either the one year anniversary of employment or the one year anniversary of the vesting commencement date, and the remainder vesting ratably over the remaining 36 month terms with the exception of 139,316 and 218,655 of the incentive stock option grants during the years ended March 31, 2015 and 2014, respectively, that have immediate vesting at the grant date, 56,500 and 99,500 of the incentive stock option grants in the years ended March 31, 2015 and 2014, respectively, that vest quarterly over three years, and 128,500 and 122,500 of the incentive stock option grants in the years ended March 31, 2015 and 2014, respectively, that vest after one full year.

The following table summarizes stock option activity for the years ended March 31, 2014 and 2015:

	Options Outstanding	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at March 31, 2013	3,618,567	$ 2.11	$5,909,154
Options granted	2,519,572	$ 8.63	
Options canceled	(18,455)	$ 3.31	
Options exercised	(183,796)	$ 2.19	$1,002,419
Outstanding at March 31, 2014	5,935,888	$ 4.87	$20,482,823
Options granted	1,429,191	$ 6.18	
Options canceled	(45,847)	$ 7.17	
Options exercised	(205,684)	$ 1.73	$883,795
Outstanding at March 31, 2015	7,113,548	$ 5.21	$4,969,499
Vested and Exercisable at March 31, 2015	3,113,164	$ 4.05	$3,264,723

The weighted-average remaining contractual term of options exercisable and outstanding at March 31, 2015 was approximately 7.82 years and 8.28 years, respectively.

The Company uses the Black-Scholes valuation model to calculate the fair value of stock options. Stock-based compensation expense is recognized over the vesting period using the straight-line method. The fair value of stock options was estimated at the grant date using the following weighted average assumptions:

	Year Ended	Year Ended

	March 31, 2015	March 31, 2014
Dividend yield	—	—
Volatility	76.90%	78.22%
Risk-free interest rate	1.60 %	1.32 %
Expected life of options	6.00 years	6.00 years
Weighted average grant date fair value	$4.14	$5.92

The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. Due to the Company's limited historical data, the estimated volatility incorporates the historical and implied volatility of comparable companies whose share prices are publicly available. The risk-free interest rate assumption was based on the U.S. Treasury rates. The weighted average expected life of options was estimated using the average of the contractual term and the weighted average vesting term of the options. Certain options granted to consultants are subject to variable accounting treatment and are required to be revalued until vested.

The total stock option based compensation recorded as operating expense was approximately $6,599,000, $3,783,000, $370,000, $4,000, and $600,000, for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively. Expense included approximately $1,175,000, $462,000, $58,000 and $81,000 for research and development during the years ended March 31, 2015 and 2014, the three months ended March 31, 2013, and the year ended

December 31, 2012, respectively. General and administrative expense for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and year ended December 31, 2012, were approximately $5,424,000, $3,321,000, $312,000, $4,000, and $519,000, respectively.

The total unrecognized compensation cost related to unvested stock option grants as of March 31, 2015 was approximately $15,115,000 and the weighted average period over which these grants are expected to vest is 2.77 years.

Warrants

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

During the years ended March 31, 2015 and 2014, 203,000 and 225,000 of these warrants were exercised for cash proceeds of approximately $445,000 and $210,000, respectively, and 8,647 and 2,628,003 of these warrants were exercised through a cashless exercise for issuance of 7,600 and 2,139,577 shares of common stock, respectively.

In December 2012, the Company consummated a warrant tender offer to the holders of outstanding warrants to purchase approximately 14.5 million shares of the Company’s common stock. In accordance with the tender offer, for those warrant holders that elected to participate, this resulted in a reduction of the exercise price of the warrants from $1.00 per share to $0.80 per share of common stock in cash, shortened the exercise period of the warrants so that they expired concurrently with the tender offer, and removed the price-based anti-dilution provisions contained in the warrants. The Company completed the tender offer on December 21, 2012, resulting in approximately 9.6 million warrants being exercised for gross proceeds of approximately $7,700,000. In connection with the transaction, the Company recognized an expense for the inducement to exercise the warrants of approximately $1,900,000. The Company also incurred approximately $400,000 in placement agent fees, legal costs, and other related fees, which have been recognized as an offset to the proceeds received from the warrant exercises.

During the year ended March 31, 2014, derivative liability warrants of 1,920,874 were exercised and 6,990,556 of the warrants exercised during the three months ended March 31, 2013 and 13,010,237 of the warrants exercised in 2012 were derivative liabilities and were valued at the settlement date. The warrant liability was reduced to equity at the fair value on the settlement date. See Note 5.

During the twelve months ended March 31, 2014, the Company entered into amendment agreements for 269,657 warrants to purchase common stock which reduced the exercise price of the warrants from $1.00 to $0.85, which removed the down-round price protection provision of the warrant agreement related to the adjustment of exercise price upon issuance of additional shares of common stock. As a result of the removal of the down-round price protection provision, the warrants were reclassified from liability to equity instruments at their fair value. The Company determined the incremental expense associated with the modification based on the fair value of the awards prior to and subsequent to the modification. The fair value of the awards subsequent to modification was calculated using the Black-Scholes model. The incremental expense associated with the modification of approximately $12,000 was recognized as interest expense for the year ended March 31, 2014.

During the year ended December 31, 2012 the Company entered into four agreements with consultants for services. In connection with the agreements, the Company issued a total of 650,000 warrants to purchase common stock, at prices ranging from $1.70 to $3.24, with lives ranging from two to five years, to be earned over service periods of up to six months. The fair value of the warrants was estimated to be approximately $890,000, which was recognized as a prepaid asset and is being amortized over the term of the consulting agreements. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using volatility rates ranging from 79.8% to 103.8% and risk free interest rate factors ranging from 0.24% to 0.63%, were used to determine the value. The value is being amortized over the term of the agreements. During the years ended March 31,

2015 and 2014, the Company recognized approximately $0 and $72,000, respectively, of expense related to these services. During the year ended March 31, 2015, no warrants held by consultants were exercised. During the year ended March 31, 2014, 348,630 warrants held by consultants were exercised resulting in proceeds to the Company of approximately $891,000.

During November 2013 the Company entered into an agreement with a consultant for services. In connection with the agreement, the Company issued 75,000 warrants to purchase common stock, at a price of $7.36, with a life of five years, to be earned over a twelve month service period. The fair value of the warrants was estimated to be approximately $404,000, which was recognized as a prepaid asset and is being amortized over the term of the consulting agreement. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using a volatility rate of 96.90% and a risk-free interest rate factor of 0.60%, was used to determine the value. The Company recognized approximately $43,000 and $163,000 during the years ended March 31, 2015 and 2014, respectively, related to these services.

Additionally, during September 2014, the Company issued 50,000 warrants to a consultant in recognition of services previously provided. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Company recognized approximately $237,000 during the year ended March 31, 2015 related to these services.

During November 2014 the Company entered into an agreement with a consultant for services. In connection with the agreement, the Company issued 145,000 warrants to purchase common stock, at a price of $6.84, with a life of five years, to be earned over a seventeen month service period ending on March 31, 2016. The final number of vested warrant shares will be determined, at the discretion of management, based on management's judgment of the satisfaction of specific performance metrics prior to the earliest to occur of March 31, 2016 or the termination of the consulting arrangement with the Company. The initial fair value of the warrants was estimated to be approximately $309,000, which is being revalued and amortized over the term of the consulting agreement. These warrants were classified as equity instruments because they do not contain any anti-dilution provisions. The Black-Scholes model, using a volatility rate of 76.78% and a risk-free interest rate factor of 1.37%, was used to determine the value. The Company recognized approximately $36,000 during the year ended March 31, 2015 related to these services.

The following table summarizes warrant activity for the years ended March 31, 2015 and 2014:

	Warrants	Weighted-Average Exercise Price
Balance at March 31, 2013	4,283,889	$ 1.17
Granted	112,500	$ 7.36
Expired / Canceled	—	—
Exercised	(3,201,633)	$ 1.16
Balance at March 31, 2014	1,194,756	$ 1.79
Granted	195,000	$ 7.04
Expired / Canceled	—	—
Exercised	(211,647)	$ 2.14
Balance at March 31, 2015	1,178,109	$ 2.59

The warrants outstanding at March 31, 2015 are immediately exercisable at prices between $0.85 and $7.36 per share, and have a weighted average remaining term of approximately 2.38 years.

Common stock reserved for future issuance

Common stock reserved for future issuance consisted of the following at March 31, 2015:

Common stock warrants outstanding	1,178,109
Common stock options outstanding under the 2008 Plan	622,192
Common stock options outstanding and reserved under the 2012 Plan	9,375,272
Total	11,175,573

Preferred stock

The Company is authorized to issue 25,000,000 shares of preferred stock. There are no shares of preferred stock currently outstanding, and the Company has no present plans to issue shares of preferred stock.

8. Commitments and Contingencies

Operating leases

The Company leases office and laboratory space under a non-cancelable operating lease entered into in February 2012 and amended in December 2013 and March 2015, and a non-cancelable operating lease entered into on January 9, 2015 with the future minimum lease payments from the leases included below. The Company records rent expense on a straight-line basis over the life of the leases and records the excess of expense over the amounts paid as deferred rent. In addition, one of the leases provides for certain improvements made for the Company's benefit to be funded by the landlord. Such costs, totaling approximately $144,000 to date, have been capitalized as fixed assets and included in deferred rent.

Rent expense was approximately $968,000, $561,500, $105,500, $60,200, and $325,600 for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, and the year ended December 31, 2012, respectively.

On February 27, 2012, the Company entered into a facilities lease at 6275 Nancy Ridge Drive (the "Original Lease"), San Diego, CA 92121, with occupancy as of July 15, 2012. The base rent under the lease was approximately $38,800 per month with 3% annual escalators. The lease term was 48 months with an option for the Company to extend the lease at the end of the lease term.

On December 5, 2013, the Company entered into a First Amendment (the "First Amendment") to the Original Lease, together with the First Amendment, (the "Amended Lease"). Pursuant to the First Amendment, the Company expanded the size of its facility by approximately 15,268 square feet (the "Expansion Premises") from approximately 15,539 square feet (the "Original Premises") for a total of approximately 30,807 square feet. The Amended Lease provides for base rent (i) on the Original Premises to continue at approximately $38,800 per month, with annual escalators, until August 1, 2016, at which point the base rent shall be payable at the same rate per rentable square foot as the Expansion Premises and (ii) on the Expansion Premises of approximately $38,934 per month, with 3% annual escalators, not to commence until two months after the earlier of (A) the date that the landlord delivers possession of the Expansion Premises to the Company with the work in the Expansion Lab Premises (as defined in the First Amendment) substantially complete and (B) the date the landlord could have delivered the Expansion Premises with the work in the Expansion Lab Premises (as defined in the First Amendment) substantially complete but for certain delays of the Company. Additionally, the Company has a right of first refusal on adjacent additional premises of approximately 14,500 square feet. The term of the Amended Lease expires on the seven-year anniversary of the earlier of (A) the date that the landlord delivers possession of the Expansion Premises to the Company and (B) the date the landlord could have delivered the Expansion Premises but for certain delays of the Company (the "Expansion Premises Commencement Date"). The Expansion Premises Commencement Date was September 1, 2014. The Company also has the option to terminate the Amended Lease on the 5-year anniversary of the Expansion Premises Commencement Date. The Expansion Premises contains office, laboratory, and clean room areas.

On March 12, 2015, the Company entered into a Second Amendment to the Original Lease (the "Second Amendment), to adjust the square footage covered by Amended Lease and an additional portion of the building containing approximately 335 rentable square feet ("Second Expansion Premises"). This square footage adjustment was the result of the re-measurement of each suite and the building overall. The net adjustment to overall leased space was an increase of 88 square feet with a corresponding increase in monthly rental payments at the same rate per square foot as the Expansion Premises.

On January 9, 2015, the Company entered into an agreement to lease a second facility consisting of 5,803 rentable square feet of office and lab space located at 6310 Nancy Ridge Drive, San Diego, CA 92121. The term of the lease is 36 months, beginning on February 1, 2015 and ending on January 31, 2018, with monthly rental payments of approximately $12,000 commencing on April 1, 2015. In addition, there are annual rent escalations of 3.0% on each 12-month anniversary of the lease commencement date.

Future minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year as of March 31, 2015, are as follows (in thousands):

Fiscal year ended March 31, 2016	$1,138
Fiscal year ended March 31, 2017	1,148
Fiscal year ended March 31, 2018	1,134
Fiscal year ended March 31, 2019	1,032
Fiscal year ended March 31, 2020	1,062
Thereafter	1,558
Total	$7,072

Legal matters

In addition to commitments and obligations in the ordinary course of business, the Company is subject to various claims and pending and potential legal actions arising out of the normal conduct of its business. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its financial statements. Because litigation is inherently unpredictable and unfavorable resolutions could occur, assessing litigation contingencies is highly subjective and requires judgments about future events. When evaluating contingencies, the Company may be unable to provide a meaningful estimate due to a number of factors, including the procedural status of the matter in question, the presence of complex or novel legal theories, and/or the ongoing discovery and development of information important to the matters. In addition, damage amounts claimed in litigation against it may be unsupported, exaggerated or unrelated to possible outcomes, and as such are not meaningful indicators of its potential liability.

The Company regularly reviews contingencies to determine the adequacy of its accruals and related disclosures. During the period presented, the Company has not recorded any accrual for loss contingencies associated with such claims or legal proceedings; determined that an unfavorable outcome is probable or reasonably possible; or determined that the amount or range of any possible loss is reasonably estimable. However, the outcome of legal proceedings and claims brought against the Company is subject to significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, if one or more of

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

Spencer Trask Matter. In June 2013, the Company filed a declaratory relief action against Spencer Trask Ventures ("STV") in the Supreme Court of New York (case #652305/2013) following claims by STV that it was entitled to additional compensation arising from a warrant tender offer the Company completed in December 2012. The Company is seeking a declaration that a Warrant Solicitation Agency Agreement (the "WSAA") between the parties is a valid and enforceable agreement; the Company believes that under the terms of this agreement and the Placement Agent Agreement (the "PAA") it entered into with STV in connection with the private placement financings the Company completed in February and March 2012, STV is not entitled to the additional compensation it is seeking.

Also in June, 2013, STV initiated an arbitration in which it is alleging (1) breach of contract, and (2) breach of confidentiality obligations under the terms of the PAA. STV is seeking compensation (including a cash fee and warrants to purchase common stock) as a result of the Company's warrant tender offer in December 2012 and its warrant redemption in 2013, and damages for breach of confidentiality provisions in relation to the contacting of warrant holders who participated in the warrant tender offer. The Company believes there was no breach of confidentiality, as the Company's tender offer was made to warrant holders of record relating to warrants already owned by them and whose identity was public information via a Registration Statement on Form S-1 the Company was required to file to register the resale of the shares underlying their warrants.

In January 2014, the Supreme Court of New York stayed the New York litigation, finding that the arbitrator should determine in the first instance which disputes between the Company and STV should proceed in the Arbitration and which disputes between the Company and STV should proceed in the New York Court. The parties are proceeding in the Arbitration and the Company has reserved its right to file a summary disposition motion with regard to the proper venue for its claims under the WSAA. The date for the Arbitration (previously scheduled for July, 2015) has been taken off the calendar but may be rescheduled for the fall of 2015. The Company believes that the assertions made against it by STV are without merit and the Company intends to continue to vigorously defend against the claims made by STV.

9. Licensing Agreements and Research Contracts

University of Missouri

On March 24, 2009, the Company entered into a license agreement with the Curators of the University of Missouri to in-license certain technology and intellectual property relating to self-assembling cell aggregates and to intermediate cellular units. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company paid to the University of Missouri a nonrefundable license fee of $25,000 and has committed to reimburse the University of Missouri for certain prior and future patent costs. Each year the Company is required to pay the University of Missouri royalties ranging from 1% to 3% of net sales depending on the level of net sales achieved by the Company each year. A minimum annual royalty of $25,000 is due beginning two years after the calendar year of the first commercial sale and is credited to sales royalties. The license agreement terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement, which are expected to expire after 2029. The $25,000 license fee is included in Other Assets in the accompanying balance sheets and is being amortized over the life of the related patent.

On March 12, 2010, the Company entered into a license agreement with the Curators of the University of Missouri to in-license certain technology and intellectual property relating to engineered biological nerve grafts. The Company

received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company paid to the University of Missouri a nonrefundable license fee of $5,000 and has committed to reimburse the University of Missouri for certain prior and future patent costs. In 2012, the Company paid the University of Missouri approximately $193,500 for prior patent costs relating to the license agreements with the University of Missouri. No payments were made during the years ended March 31, 2015, March 31, 2014 or the three months ended March 31, 2013. Each year the Company is required to pay the University of Missouri royalties ranging from 1% to 3% of net sales depending on the level of net sales achieved by the Company each year. A minimum annual royalty of $5,000 is due beginning two years after the calendar year of the first commercial sale and is credited to sales royalties. The license agreement terminates upon expiration of the patents licensed and is subject to certain conditions as defined in the license agreement. The $5,000 license fee is included in Other Assets and is being amortized over the life of the related patent.

Clemson University

On May 2, 2011, the Company entered into a license agreement with Clemson University Research Foundation to in-license certain technology and intellectual property relating to ink-jet printing of viable cells. The Company received the exclusive worldwide rights to commercialize products comprising this technology for all fields of use. The Company agreed to pay Clemson University a nonrefundable license fee of $32,500, as well as an additional $32,500 to reimburse Clemson University for certain prior and future

patent costs. These fees, totaling $65,000, are included in Other Assets and are being amortized over the life of the related patent. Each year the Company is required to pay the University royalties ranging from 1.5% to 3% of net sales depending on the level of net sales reached each year and minimum annual fees ranging from $20,000 to $40,000. Specific terms of the royalty and license agreements are confidential. The license agreement terminates upon expiration of the patents licensed, which is expected to expire in May 2024, and is subject to certain conditions as defined in the license agreement. Annual royalty payments of $20,000 were due beginning in calendar 2014, and as of March 31, 2015, the Company has made $40,000 of royalty payments under this license agreement.

Becton Dickinson

In February of 2013, the Company purchased the exclusive rights to intellectual property relating to perfusion bioreactors for culturing cells from Becton Dickinson and Company for $18,500. This fee is included in Other Assets and is being amortized over the life of the related patent. This patent represents the acquisition of bioreactor technology for the support of our 3D tissues for use in drug discovery and development. No future royalties or milestone payments are owed to Becton Dickinson and Company for this patent.

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

	March 31, 2015	March 31, 2014
License fees	$ 114	$ 114
Less accumulated amortization	(34)	(25)
License fees, net	$ 80	$ 89

Amortization expense of licenses was approximately $8,500, $8,500, $2,000, $1,700, and $7,000 for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012, the year ended December 31, 2012. At March 31, 2015, the weighted average remaining amortization period for all licenses was approximately 10 years. The annual amortization expense of licenses for the next five years is estimated to be approximately $8,500 per year.

10. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company’s net deferred tax assets are as follows as of March 31, 2015 and 2014 (in thousands):

	March 31, 2015	March 31, 2014
Deferred tax assets:		
Net operating loss carry forwards	$—	$—
Research and development credits	—	—

Depreciation and amortization	(48)	22
Accrued expenses and reserves	826	280
Stock compensation	3,462	1,941
Other, net	6	1
Total deferred tax assets	4,246	2,244
Valuation allowance	(4,246)	(2,244)
	$—	$—

A full valuation allowance has been established to offset the deferred tax assets as management cannot conclude that realization of such assets is more likely than not. Under the Internal Revenue Code ("IRC") Sections 382 and 383, annual use of our net operating loss and research tax credit carryforwards to offset taxable income may be limited based on cumulative changes in ownership. We have not completed an analysis to determine whether any such limitations have been triggered as of March 31, 2015. Until this analysis is completed, we have removed the deferred tax assets related to net operating losses and research credits from our deferred tax asset schedule. Further, until a study is completed and any limitation known, no amounts are being considered as an uncertain tax position or disclosed as an unrecognized tax benefit. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact its effective tax rate. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. The valuation allowance increased by approximately $2,002,000 and $1,277,000 for the years ended March 31, 2015 and 2014, respectively.

The Company had federal and state net operating loss carryforwards of approximately $59,334,000 and $58,850,000 at March 31, 2015, respectively. The federal and state net operating loss carryforwards will begin expiring in 2028, unless previously utilized. The

net operating loss carryforwards included approximately $6,236,000 of windfall tax benefits related to stock compensation that will be recorded as an increase to additional paid in capital.

The Company had federal and state research tax credit carry forwards of approximately $790,000 and $987,000 at March 31, 2015, respectively. The federal research tax credit carryforwards begin expiring in 2028. The state research tax credit carryforwards do not expire.

In 2009 the Company adopted the accounting guidance for uncertainty in income taxes pursuant to ASC 740-10. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. The Company did not record any accruals for income tax accounting uncertainties for the year ended March 31, 2015.

The Company's policy is to recognize interest and penalties that would be assessed in relation to the settlement value of unrecognized tax benefits as a component of income tax expense. The Company did not accrue either interest or penalties from inception through March 31, 2015.

The Company does not have any unrecognized tax benefits that will significantly decrease or increase within 12 months of March 31, 2015.

The Company is subject to tax in the United States and in the state of California. As of March 31, 2015, the Company's tax years from inception are subject to examination by the tax authorities. The Company is not currently under examination by any U.S. federal or state jurisdictions.

11. Concentrations

Credit risk

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

12. Defined Benefit Plan

The Company has a defined contribution 401(k) plan covering substantially all employees. During the year ended March 31, 2015, the 401(k) plan was amended ("the Amended Plan") to include an employer matching provision. Under the terms of the Amended Plan, the Company will make matching contributions on up to the first 6 % of compensation contributed by its employees. Amounts expensed under the Company's 401(k) plan for the years ended March 31, 2015 and 2014 were approximately $57,000 and $0, respectively.

13. Recent Accounting Pronouncements

In May 2014, the Financial Accountings Standards Board issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers, or ASU 2014-09, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for us on April 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures. We have not yet selected a transition method nor have we determined the effect of the standard on our ongoing financial reporting.

In June 2014, the FASB issued ASU 2014-10, Development Stage Entities, which eliminated certain financial reporting requirements under Topic 915 for entities considered to be in the development stage. This standard becomes effective for annual reporting periods beginning after December 15, 2014 and interim reporting periods beginning after December 15, 2015, with earlier application permitted. The Company adopted this standard prospectively as of April 1, 2014. This adoption had no effect on current or previously reported amounts, but eliminated the need to present inception-to-date financial information that was previously required under Topic 915.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements—Going Concern—Disclosures of Uncertainties about an entity's Ability to Continue as a Going Concern ("ASU 2014-15"). ASU 2014-15 provides new guidance

related to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards and to provide related footnote disclosures. This new guidance is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The requirements of ASU 2014-15 are not expected to have a significant impact on our consolidated financial statements.

14. Subsequent Events

On April 17, 2015, the Company entered into a multi-year research collaboration agreement with Merck Sharp & Dohme Corp. ("Merck"). The Agreement will give Merck access to Organovo's commercial exVive3D™ Human Liver Tissue service, and will also involve a collaboration to develop multiple custom tissue models utilizing the Company's proprietary NovoGen Bioprinting Platform™ for use in drug development.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

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

Under the supervision of our Chief Executive Officer and our Chief Financial Officer, and with the participation of all members of management, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were designed and operating effectively as of the end of the period covered by this Annual Form 10-K.

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management's annual report on internal control over financial reporting is set forth below and the report of our independent registered public accounting firm is included on page F-3 of this Annual Report on Form 10-K.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our system of internal control over financial reporting is designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of our consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, under the supervision of our Chief Executive Officer and the Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of March 31, 2015. In making this assessment, we used the framework included in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the criteria set forth in Internal Control — Integrated Framework (2013), our management concluded that our internal control over financial reporting was effective as of March 31, 2015.

Auditor's Attestation Report on Internal Control Over Financial Reporting

Mayer Hoffman McCann P.C., our independent registered public accounting firm, has audited our consolidated financial statements included in this Annual Report on Form 10-K and has issued an attestation report, included herein, on the effectiveness of our internal control over financial reporting as of March 31, 2015.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of the fiscal year ended March 31, 2015 to which this report relates that

has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can

occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information relating to our directors, executive officers and corporate governance, including our Code of Business Conduct, will be included in the proxy statement for the 2015 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference. The full text of our Code of Business Conduct, which is the code of ethics that applies to all of our officers, directors and employees, can be found in the "Investors" section of our website accessible to the public at www.organovo.com.

Item 11. Executive Compensation.

Information relating to executive compensation will be included in the proxy statement for the 2015 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information relating to the beneficial ownership of our common stock will be included in the proxy statement for the 2015 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information relating to certain relationships and related transactions and director independence will be included in the proxy statement for the 2015 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

Information relating to principal accountant fees and services will be included in the proxy statement for the 2015 annual meeting of the Company's stockholders, expected to be filed within 120 days of the end of our fiscal year, which is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a).The following documents have been filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements: The information required by this item is included in Item 8 of Part II of this report.
2. Financial Statement Schedules: Financial statement schedules required under the related instructions are not applicable for the years ended March 31, 2015 and 2014, the three months ended March 31, 2013 and 2012 and the year ended December 31, 2012, and have therefore been omitted.
3. Exhibits: The exhibits listed in the Exhibit Index attached to this report are filed or incorporated by reference as part of this Annual Report.

(b).The exhibits listed in the accompanying Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ORGANOVO HOLDINGS, INC.

By: /s/ Keith Murphy
Keith Murphy,
Chief Executive Officer and President

Date: June 9, 2015

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Keith Murphy and Barry Michaels, and each of them individually, as the undersigned's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for the undersigned and in the undersigned's name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their respective substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Keith Murphy Keith Murphy	Chief Executive Officer and President (Principal Executive Officer)	June 9, 2015
/s/ Barry Michaels Barry Michaels	Chief Financial Officer and Corporate Secretary (Principal Financial Officer)	June 9, 2015
/s/ Robert Baltera, Jr. Robert Baltera, Jr.	Director	June 9, 2015
/s/ James Glover James Glover	Director	June 9, 2015
/s/ Tamar Howson Tamar Howson	Director	June 9, 2015
/s/ Richard Heyman Richard Heyman	Director	June 9, 2015
/s/ Kirk Malloy	Director	June 9, 2015

Kirk Malloy

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of February 8, 2012, by and among Organovo Holdings, Inc. a Delaware corporation, Organovo Acquisition Corp., a Delaware corporation and Organovo, Inc., a Delaware corporation (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
2.2	Certificate of Merger as filed with the Delaware Secretary of State effective February 8, 2012 (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
2.3	Articles of Merger as filed with the Nevada Secretary of State effective December 28, 2011 (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 3, 2012 (the "February 2012 Form 8-K")
2.4	Agreement and Plan of Merger, dated as of December 28, 2011, by and between Real Estate Restoration and Rental, Inc. and Organovo Holdings, Inc. (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on January 4, 2012)
2.5	Certificate of Merger as filed with the Delaware Secretary of State effective January 30, 2012 (incorporated by reference from Exhibit 2.3 to the February 2012 Form 8-K)
2.6	Agreement and Plan of Merger, dated as of January 30, 2012, by and between Organovo Holdings, Inc. (Nevada) and Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 2.2 to the February 2012 Form 8-K)
2.7	Articles of Merger as filed with the Nevada Secretary of State effective January 30, 2012 (incorporated by reference from Exhibit 2.4 to the February 2012 Form 8-K)
3.1	Certificate of Incorporation of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.1 to the February 2012 Form 8-K)
3.2	Bylaws of Organovo Holdings, Inc. (Delaware) (incorporated by reference from Exhibit 3.2 to the February 2012 Form 8-K)
4.1	Form of Bridge Warrant of Organovo, Inc. (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
4.2	Form of Warrant of Organovo, Inc. issued to former holders of Organovo, Inc. promissory notes (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
4.3	Form of Warrant of Organovo Holdings, Inc. ($1.00 exercise price) issued to Placement Agent (incorporated by reference from Exhibit 4.2(i) to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012)
4.4	

	Form of Warrant of Organovo Holdings, Inc. ($1.00 exercise price) issued to Placement Agent in exchange for Organovo, Inc. warrant issued to Selling Agent (incorporated by reference from Exhibit 4.2(iii) to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012)
10.1	Form of Securities Purchase Agreement between Organovo, Inc. and the Bridge Investors (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.2	Selling Agent Agreement between Organovo, Inc. and the Selling Agent (incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012)
10.3	Form of Subscription Agreement, by and between Organovo Holdings, Inc. and the investors in the offering (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012 Form 8-K)
10.4	Joinder by Organovo Holdings, Inc. to Placement Agency Agreement (incorporated by reference from Exhibit 10.4(ii) to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012)
10.5	Placement Agent Agreement between Organovo, Inc. and the Placement Agent (incorporated by reference from Exhibit 10.4(i) to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012)
10.6	Extension to Placement Agent Agreement (incorporated by reference from Exhibit 10.4(iii) to the Company's Current Report on Form 8-K, as filed with the SEC on March 19, 2012)

Exhibit No.	Description
10.7	Split-Off Agreement, by and among Organovo Holdings, Inc., Organovo Split Corp., Deborah Lovig and James Coker (incorporated by reference from Exhibit 10.9 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.8	General Release Agreement by and among Organovo Holdings, Inc., Organovo Split Corp., Deborah Lovig and James Coker (incorporated by reference from Exhibit 10.10 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.9	Form of Share Cancellation Agreement and Release (incorporated by reference from Exhibit 10.11 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.10+	Offer Letter between Barry D. Michaels and Organovo, Inc. (incorporated by reference from Exhibit 10.12 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.11+	Offer Letter between Sharon Collins Presnell and Organovo, Inc. (incorporated by reference from Exhibit 10.13 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.12+	Organovo, Inc. 2008 Equity Incentive Plan (incorporated by reference from Exhibit 10.14 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.13+	Organovo Holdings, Inc. 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.15 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.14+	Form of Stock Option Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.16 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.15+	Form of Indemnification Agreement (incorporated by reference from Exhibit 10.17 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.16+	Scientific Advisory Board Consulting Agreement, dated as of March 17, 2008, by and between Organovo, Inc. and Glenn Prestwich, Ph.D. (incorporated by reference from Exhibit 10.19 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.17+	Scientific Advisory Board Consulting Agreement, dated as of March 17, 2008, by and between Organovo, Inc. and David Mooney, Ph.D. (incorporated by reference from Exhibit 10.20 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.18+	Scientific Advisory Board Consulting Agreement, dated as of April 14, 2008, by and between Organovo, Inc. and Gordana Vunjak-Novakovic (incorporated by reference from Exhibit 10.21 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.19+	Scientific Advisory Board Consulting Agreement, dated as of June 30, 2008, by and between Organovo, Inc. and K. Craig Kent, M.D. (incorporated by reference from Exhibit 10.22 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
10.20†	License Agreement dated as of March 24, 2009, by and between Organovo, Inc. and the Curators of the University of Missouri, **** (incorporated by reference from Exhibit 10.23 to the Company's Current

	Report on Form 8-K, as filed with the SEC on May 11, 2012)
10.21†	License Agreement dated as of March 12, 2010 by and between the Company and the University of Missouri, **** (incorporated by reference from Exhibit 10.24 to the Company's Current Report on Form 8-K, as filed with the SEC on May 11, 2012)
10.22†	License Agreement dated as of May 2, 2011, by and between the Company and Clemson University Research Foundation, **** (incorporated by reference from Exhibit 10.25 to the Company's Current Report on Form 8-K, as filed with the SEC on May 11, 2012)
10.23+	Executive Employment Agreement, dated February 28, 2012, by and between Keith Murphy and Organovo, Inc. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 1, 2012)
10.24+	Form of Executive Restricted Stock Unit Grant Notice under the 2012 Equity Incentive Plan. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 9, 2012)
10.25+	Forms of Performance Based Restricted Stock Grant Notice and Performance Based Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on August 9, 2012)
10.26+	Form of Executive Incentive Award Agreement under the 2012 Equity Incentive Plan (incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on August 9, 2012)

Exhibit No.	Description
10.27+	Amendment to 2012 Equity Incentive Plan, dated August 21, 2013. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 23, 2013)
10.28	Equity Distribution Agreement, dated November 27, 2013, between Organovo Holdings, Inc. and JMP Securities LLC. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 27, 2013)
10.29	First Amendment to Lease, dated December 4, 2013, by and between Organovo, Inc. and ARE-SD Region No. 25, LLC. (incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on February 6, 2014)
10.30+	Amendment No. 2 to the 2012 Equity Incentive Plan, effective as of February 3, 2014. (incorporated by reference from Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on February 6, 2014)
10.31+	Form of Executive Incentive Award Agreement under the 2012 Equity Incentive Plan. (incorporated by reference from Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on February 6, 2014)
10.32+	Forms of Executive Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan. (incorporated by reference from Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on February 6, 2014)
10.33+	Forms of Performance Based Restricted Stock Grant Notice and Performance Based Restricted Stock Unit Agreement under the 2012 Equity Incentive Plan. (incorporated by reference from Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q, as filed with the SEC on February 6, 2014)
10.34	Controlled Equity Offering^{SM} Sales Agreement, dated December 30, 2014, by and between Organovo Holdings, Inc. and Cantor Fitzgerald & Co. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 30, 2014)
10.35+	Form of Non-employee Director Stock Option Award Agreement under the 2012 Equity Incentive Plan*
10.36+	Form of Executive Stock Option Award Agreement under the 2012 Equity Incentive Plan*
10.37†	Research Collaboration Agreement, dated March 31, 2015, by and between Organovo Holdings, Inc. and L'Oreal USA Products, Inc.*
21.1	Subsidiaries of Organovo Holdings, Inc. (incorporated by reference from Exhibit 21.1 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
23.1	Consent of Independent Registered Public Accounting Firm*
24.1	Power of Attorney (included on signature page hereto)*
31.1	Certification of Chief Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchanges Act of 1934, as amended.*

31.2	Certification of Chief Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.*
32.1	Certifications Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and to 18 U.S.C. Section 1350.*
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase*
101.DEF	XBRL Taxonomy Extension Definition Linkbase*
101.LAB	XBRL Taxonomy Extension Label Linkbase*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase*

*Filed herewith.

+Designates management contracts and compensation plans.

¶This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the redaction pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

¶This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the redaction pursuant to a Confidential Treatment Request under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.