

ORGANOVO HOLDINGS, INC.

Form 10-K

June 10, 2014

Table of Contents

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Fiscal Year Ended March 31, 2014**

**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**  
**(State of incorporation)**

**27-1488943**  
**(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:**

<b>Title of Each Class</b>	<b>Name of Each Exchange on which Registered</b>
<b>Common Stock, par value \$0.001 per share</b>	<b>NYSE MKT</b>

**Securities registered pursuant to section 12(g) of the Act: None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

Large accelerated filer  Accelerated filer   
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

The aggregate market value of the voting common stock held by non-affiliates based on the closing stock price on September 30, 2013, the last trading day of the registrant's second fiscal quarter, was \$394,475,790. 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 6, 2014 was 78,276,250.

### **Documents Incorporated by Reference**

Certain information required for Part III of this report is incorporated herein by reference to the proxy statement for the 2014 annual meeting of the registrant's stockholders, expected to be filed within 120 days of the end of the registrant's fiscal year.

**Table of Contents**

**Organovo Holdings, Inc.**  
**Annual Report on Form 10-K**  
**For the Year Ended March 31, 2014**  
**Table of Contents**

	<b>Page</b>
<u>Important Information Regarding Forward-Looking Statements</u>	1
<b><u>PART I</u></b>	
Item 1. <u>Business</u>	2
Item 1A. <u>Risk Factors</u>	12
Item 1B. <u>Unresolved Staff Comments</u>	27
Item 2. <u>Properties</u>	27
Item 3. <u>Legal Proceedings</u>	27
Item 4. <u>Mine Safety Disclosures</u>	27
<b><u>PART II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	28
Item 6. <u>Selected Financial Data</u>	31
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	32
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	42
Item 8. <u>Consolidated Financial Statements</u>	F-1
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	43
Item 9A. <u>Controls and Procedures</u>	43
Item 9B. <u>Other Information</u>	45
<b><u>PART III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	46
Item 11. <u>Executive Compensation</u>	46
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	46
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	46
Item 14. <u>Principal Accountant Fees and Services</u>	46
<b><u>PART IV</u></b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	47

**Table of Contents**

**Important Information Regarding Forward-Looking Statements**

Portions of this Annual Report on Form 10-K (including information incorporated by reference) include forward-looking statements 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.

**Table of Contents**

**PART I**

**Item 1. Business.**

**Overview**

We are a development-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 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.

Our foundational proprietary technology 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. We were selected by MIT's Technology Review magazine among the Most Innovative Companies of 2012 and by Inc. Magazine as one of the Most Audacious Companies in 2013. We believe these corporate achievements provide strong validation for the commercial potential of our 3D bioprinting technology.

**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 combinations of cellular bio-ink (building blocks comprised of cells), and hydrogel. A key distinguishing feature of our bioprinting platform is the ability to generate three-dimensional constructs 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 three-dimensional 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 the cellularity and architecture of 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.

## Table of Contents

We are focused on developing the following products:

A suite of standardized, three-dimensional 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<sup>®</sup> 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 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 assessments of absorption, distribution, metabolism, excretion (ADME), drug metabolism and pharmacokinetics (DMPK), and toxicology studies. ADME testing is used to determine which factors enhance or inhibit how a potential drug compound reaches the blood stream. Distribution of a compound can be affected by binding to plasma proteins; age, genetics, and other factors can influence metabolism of a compound; and the presence of certain disease states can have effects on excretion of a compound. Many companies perform ADME studies utilizing various cell-based assays or automated bioanalytical techniques. 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. Toxicology testing is a further requirement to determine the detrimental effects of a particular drug on specific tissues. Products in the ADME, DMPK, and toxicology space 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

---

**Table of Contents**

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, lung tissues, and breast 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, and kidney disease. 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<sup>®</sup> 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.

## **Table of Contents**

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 three-dimensional (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 at least two 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.

The NovoGen MMX Bioprinter™ has won the following awards and accolades:

2010 International Society for Biofabrication Meeting Special Award

2010 TIME Magazine 50 Best Inventions of 2010

2011 Australian Engineering Innovation Award, sponsored by the Australian government  
In 2011 to 2014, 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

## **Table of Contents**

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.

In October 2011, we entered into a Research Agreement with United Therapeutics Corporation ( **Unither** ) to establish and conduct a research program to discover treatments for pulmonary hypertension using our NovoGen Bioprinter technology, which remains in effect until the later of 30 months from its commencement or our completion of the contracted research. We have progressed the work on this agreement according to the research plan. We are currently finalizing the research results to be presented in a final technical report, after which we and Unither will select a path forward on the research plan. We currently anticipate that further research on the project will be conducted; though we can give no assurance that future agreements will be secured or the timing of any such agreements.

In January 2013, we entered into a collaboration agreement with the Knight Cancer Institute at Oregon Health & Science University ( **OHSU** ), a national leader in translational oncology research, to develop more clinically predictive in vitro three dimensional cancer models with the goal to advance discovery of novel cancer therapeutics. We and OHSU have subsequently publicly presented results from ongoing research in oncology at scientific forums.

In August 2013, we entered into an agreement with the Michael J. Fox Foundation for Parkinson's Research to develop tissues for drug discovery. This research program has proceeded according to plan, and met interim milestones.

In September 2013, we entered into an agreement with Hoffman La Roche ( **Roche** ) exploring the use of 3D liver tissue in toxicology. This research program has proceeded according to plan, and we believe that during this research program we have demonstrated valuable function of the 3D Liver tissues. We anticipate that research from this collaboration will be published and be informative to those considering the commercial use of our 3D Liver tissues in a research setting, although we can give no assurance that this will be the case. We currently anticipate that an additional agreement or agreements will be arrived at to utilize our 3D Liver tissues in Roche's future research efforts, although we can give no assurance that future agreements will be secured or the timing of any such agreements. Any agreement or agreements that are best classified as contract research services under our standard 3D Liver commercial business model subsequent to commercial launch may result in us recording and reporting revenue along with that of additional customers in the normal course of business.

In October 2013, we entered into an agreement with L'Oréal exploring the use of 3D skin for testing skin care products. This research program has proceeded according to plan, and we anticipate that an additional agreement or agreements will be signed, although we can give no assurance that future agreements will be secured or the timing of any such agreements.

---

## Table of Contents

### **Our Product Candidates**

We 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. We expect that our first commercial tissue offered will be our 3D Human Liver Tissue, which is designed to be used for the toxicological 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. We expect to offer 3D Human Liver services more broadly, and also intend to offer our 3D Human Liver Tissue directly to end user customers in a kit for toxicological testing, after our full commercial launch scheduled to occur before the end of the calendar 2014.

### **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 expenses 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.

- 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

---

## **Table of Contents**

model enables 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.

- 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, Tengion, Aastrom Biosciences and Cytograft Tissue Engineering. 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 \$8.0 million, \$3.4 million and \$1.4 million for the fiscal years ended March 31, 2014, December 31, 2012 and December 31, 2011, 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 obtain and enforce patents, maintain protection of trade secrets, and operate without infringing the proprietary rights of third parties. We hold exclusive licenses to five U.S. patents, three U.S. patent applications and multiple corresponding international patent applications. We have filed nine U.S. patent applications and corresponding international patent applications regarding our technology and its various uses in areas of tissue creation and utilization in drug discovery, including filings for specific tissue types.

In March 2009, we obtained a world-wide exclusive license to a suite of intellectual property owned by the University of Missouri-Columbia ( **MU** ) and the Medical University of South Carolina covering the following two patents:

Self-Assembling Cell Aggregates and Methods of Making Engineered Tissue Using the Same U.S. Pat. No. 8,241,905.

## Table of Contents

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.

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 the University of Missouri-Columbia 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.

Under our agreements we also hold exclusive licenses to the following two patents as well as future child patents derived from the same applications:

Self-Assembling Multicellular Bodies and Methods of Producing a Three-Dimensional Biological Structure Using the Same (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.

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. 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 May 2012, the Intellectual Property Office of the United Kingdom issued us a patent (GB2478801), titled Multilayered Vascular Tubes. This is our first issued patent and represents the issuance of a patent from our first patent application, which was submitted in May 2010. The original patent application continues to be under review at the U.S. Patent and Trademark Office and multiple other jurisdictions.

In November 2012, Hong Kong patent HK1159682 was issued to us for a similar matter.

In February 2013, another patent, with additional claims directed to our vascular tube inventions, was issued in the United Kingdom as patent GB2489081.

In January 2014, a fourth patent directed to our vascular tube inventions was issued in Australia as patent AU2011227282.

## **Table of Contents**

Also in February 2013, we purchased the exclusive rights to a patent titled Perfusion Bioreactors for Culturing Cells (U.S. Pat. No. 7,767,446 as well as related foreign patents) from Becton Dickinson and Company. This patent represents the acquisition of bioreactor technology for the support of our 3D tissues for use in drug discovery and development. No future royalties or milestone payments are owed to Becton Dickinson and Company for these patents.

We currently have U.S. patent applications pending to protect our proprietary methods processes and compositions across the bioprinting platform, tissue configurations, and specific tissue types. We have also filed, and intend to file, corresponding foreign patent applications. 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.

## **Table of Contents**

### **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 30, 2014, we have fifty-two employees, of whom forty-eight 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>).



---

**Table of Contents****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, with the full commercial launch of our 3D Human Liver Tissue product scheduled to occur before the end of the calendar 2014. As a result, as of March 31, 2014, we had not generated revenues from our planned principal operation and continue to be considered a development-stage company. 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 \$20.6 million, \$9.3 million and \$2.3 million for the years ended March 31, 2014, December 31, 2012 and December 31, 2011, 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, 2014, we had incurred cumulative operating losses of \$38.3 million and cumulative net losses totaling \$92.2 million. We expect to incur substantial additional operating losses over the next several years as our research, development, and commercial activities increase. The amount of future losses and when, if ever, we will achieve profitability are uncertain. Our ability to generate revenue and achieve profitability will depend on, among other things, successfully developing drug discovery, biological research and therapeutic tools and products 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 and therapeutic tools and products; entering into successful manufacturing, sales and marketing arrangements with third parties or developing an effective sales and marketing infrastructure to commercialize any future tools and products; 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 and therapeutic tools and products can be successfully developed with our platform technology. Our success will also depend on our ability to obtain any necessary regulatory approvals for our tools and products, to

enter into additional collaboration agreements on favorable terms and to select an appropriate commercialization strategy for the tools and products we or our collaborators choose to pursue. If we are not successful in implementing our development and commercialization strategies, which are new and unproven, we may never achieve profitability, or if we achieve profitability, be able to maintain or increase our profitability.

**Table of Contents**

*We may not be able to correctly estimate our future revenues and operating expenses, which could lead to cash shortfalls, and we may need to secure additional financing.*

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 tools and products and from collaborations with third parties;

the time and resources required to develop our drug discovery, biological research and therapeutic tools and products;

the time and cost of obtaining any necessary regulatory approvals;

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 tools and products 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. As a result, a significant shortfall in our planned revenues 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, or at all. 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 on our planned timeline, or at all, 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 avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or products. In such event, our business, prospects, financial condition and results of operations would be adversely affected.

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

Our platform technology, as well as our drug discovery, biological research and therapeutic tools and products, involve new and unproven models and approaches. We have not proven that our platform technology will enable us or our collaborators to develop effective or competitive drug discovery and biological research tools and products. Nor have we proven that any of our existing or planned tools or products 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 and products. 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 and products. If our drug discovery and biological research products and tools 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 and products. Our

**Table of Contents**

inability to successfully develop effective and competitive drug discovery, biological research and therapeutic tools and products and achieve and maintain commercial acceptance for those tools and products would materially adversely affect our business, financial condition and results of operations.

***Our technology, tools and products 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 and therapeutic tools and products 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 and products. These complications could materially delay or limit the use of those tools and products, substantially increase the anticipated cost of manufacturing them 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, tools and products is complex, and if we are unable to develop enhancements to, and new features for, our existing tools and products or acceptable new tools and products that keep pace with technological developments or industry standards, our tools and products may become obsolete, less marketable and less competitive.

***Our ability to successfully commercialize any drug discovery, biological research or therapeutic tools or products 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 tools or products that are effective and competitive;

failing to demonstrate the commercial and technical viability of any tools or products that we successfully develop or otherwise failing to achieve market acceptance of such tools or products;

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 tools and products before the successful marketing of similar tools and products 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 and products 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

## **Table of Contents**

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, 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



**Table of Contents**

opportunities in fields that could conflict with those of our collaborators. Developing products that compete with our collaborators or potential collaborators' products 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 research tools and products.***

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 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.

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. Given our operations to date, we currently do not maintain any product liability insurance coverage. At such

point that we determine it is prudent to obtain this insurance, we may not be able to obtain or maintain insurance at a reasonable cost. There can be no assurance that existing insurance coverage will extend to other products in the future. Any 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

---

**Table of Contents**

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 may rely on third-party suppliers for some of our materials.***

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 tool businesses as well as for the manufacture of any therapeutic product candidates that we may develop in the future. 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 could negatively affect our operations.

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

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

The timing and amount of revenues from customers that rely on government funding of research may vary significantly due to factors that can be difficult to forecast. Research funding for life science research has increased

more slowly during the past several years compared to the previous years and has declined in some countries, and some grants have been frozen for extended periods of time or otherwise become unavailable to

## **Table of Contents**

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.

## **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

## **Table of Contents**

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



## **Table of Contents**

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**

***We will depend on our patent portfolio and our licensed technology in the conduct of our business.***

Our commercial success will depend 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. To do so, 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;

**Table of Contents**

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; or

the patents of others will not have an adverse effect on our business.

***We may not be able to protect our intellectual property rights in the United States.***

There are numerous recent changes to the patent laws and proposed changes to the rules of the United States Patent and Trademark Office ( PTO ) which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, on September 16, 2011, President Obama signed the Leahy-Smith America Invents Act ( AIA ) which codifies several significant changes to the U.S. patent laws, including, among other things, changing from a first-to-invent to a first-inventor-to-file system, limiting where a patentee may file a patent suit, eventually eliminating interference proceedings while maintaining derivation actions, and creating a new set of procedures to challenge patents in the PTO after they have issued. The effects of these changes are currently uncertain as the PTO has recently implemented regulations related to these changes and the courts have yet to address many of these provisions in the context of a dispute. Further, we have not assessed the applicability of the act and new regulations to the specific patents discussed in this document.

In addition, the PTO, like many foreign governmental patent agencies, requires compliance with a number of procedural, documentary, fee payment and other provisions during the patent process and/or post-grant. There are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Our patent protection could be reduced or eliminated for non-compliance with these requirements, for example, competitors might be able to enter the market earlier than would otherwise have been the case.

***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

## **Table of Contents**

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.

We cannot assure you that our technology or any of our current or future product candidates will not infringe existing or future patents. Because we have not conducted a formal freedom to operate analysis for patents related to our technology, we may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future product candidates. Nevertheless, we are not aware of any issued patents that will prevent us from using our technology or marketing our product candidates. Because patent applications can take many years to issue and may be confidential for eighteen months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that we may infringe by commercializing any of our current or future product candidates. In addition, third parties may obtain patents in the future and claim that use of our technology infringes upon these patents. 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.

***We must operate without infringing the proprietary rights of third parties and without breaching our patent license agreements.***

Our current and future research, development and commercialization activities, including any tools or products resulting from these activities, may infringe or be claimed to infringe patents owned by third parties and as to which we do not hold licenses or other rights. As a result, we may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. If a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product that is the subject of the suit. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or

both. These licenses may not be available on

## **Table of Contents**

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 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.



## **Table of Contents**

### **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, beginning with this annual report for the fiscal year ending March 31, 2014, the Act 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.

**Table of Contents**

*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, 2014, there were an aggregate of 89,515,576 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 10,207,181 shares of our common stock that may be issued upon the exercise of outstanding stock options, and 1,194,756 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

## **Table of Contents**

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 14% of our outstanding shares of common stock, as of March 31, 2014. 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.

## **Table of Contents**

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.**

In February 2012, we entered into a lease for our new corporate headquarters at 6275 Nancy Ridge Drive, Suite 110, San Diego, CA 92121. The leased facility includes approximately 15,539 square feet, including approximately 6,400 square feet of laboratory space. The base rent under the lease is approximately \$38,800 per month with 3% annual escalators. The lease term is 48 months with an option for the Company to extend the lease at the end of the lease term for an additional 36 months. On December 5, 2013, we entered into a First Amendment to that lease agreement that expanded the size of our facility by approximately 15,268 square feet 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 substantially complete and (B) the date the landlord could have delivered the expansion premises with the work in the expansion lab premises 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 us and (B) the date the landlord could have delivered the expansion premises but for certain delays we created. We have the option to terminate the amended lease on the 5-year anniversary of the expansion premises commencement date. We intend for the expansion premises to contain office, laboratory, and clean room areas.

### **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.

**Table of Contents****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.

<b><i>Year Ended March 31, 2014</i></b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$ 12.38	\$ 7.12
Third Quarter	\$ 13.65	\$ 5.33
Second Quarter	\$ 8.50	\$ 3.69
First Quarter	\$ 5.10	\$ 3.27
<b><i>2013</i></b>	<b>High</b>	<b>Low</b>
Three Months Ended March 31, 2013	\$ 6.35	\$ 2.35
<b><i>Year Ended December 31, 2012</i></b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$ 3.39	\$ 1.80
Third Quarter	\$ 4.43	\$ 1.49
Second Quarter	\$ 10.90	\$ 2.00
First Quarter (commencing February 15, 2012)	\$ 2.65	\$ 1.24

As of March 31, 2014, we had 78,113,639 outstanding shares of common stock, with a closing price of \$7.64 per share. On this date, there were 146 holders of record and approximately 61,161 non-objecting beneficial owners 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.



**Table of Contents****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, 2014 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
Organovo Holdings, Inc.	ONVO	100.00	149.70	223.03	463.03
NASDAQ Composite	IXIC	100.00	106.03	112.06	144.01
NASDAQ Biotechnology	NBI	100.00	102.25	133.23	197.05

**Table of Contents****Equity Compensation Plans**

The following table summarizes information about the Company's equity compensation plans by type as of March 31, 2014 (in thousands, except per share amounts):

<u>Plan category</u>	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	6,249,758	\$ 4.83	4,271,293
Equity compensation plans not approved by security holders			

(1) Does not include outstanding restricted stock units.

**Table of Contents****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 year ended March 31, 2014, the three months ended March 31, 2013 and 2012, and the years ended December 31, 2012 and 2011 and the consolidated balance sheet data at March 31, 2014, March 31, 2013, and December 31, 2012 are derived from our consolidated financial statements included elsewhere in this report. The consolidated statements of operations data for the years ended December 31, 2010 and 2009 and the consolidated balance sheet data as of December 31, 2011, 2010 and 2009 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, 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	Year Ended December 31, 2009
<b>Selected Consolidated Statement of Operations Data:</b>							
Revenue	\$ 379	\$ 215	\$ 120	\$ 1,197	\$ 969	\$ 603	\$ 79
Operating loss	\$ (20,649)	\$ (4,025)	\$ (1,329)	\$ (9,319)	\$ (2,305)	\$ (1,178)	\$ (791)
Net loss	\$ (25,848)	\$ (16,120)	\$ (37,081)	\$ (43,553)	\$ (4,383)	\$ (1,339)	\$ (872)
Loss per share, basic and diluted	\$ (0.35)	\$ (0.26)	\$ (1.17)	\$ (1.01)	\$ (0.19)	\$ (0.09)	\$ (0.06)
Weighted average shares outstanding, basic and diluted	73,139,618	61,750,157	31,591,663	43,149,657	22,925,694	14,620,140	14,426,251
	March 31, 2014	March 31, 2013	March 31, 2012	December 31, 2012	December 31, 2011	December 31, 2010	December 31, 2009

(unaudited)

**Selected  
Consolidated  
Balance  
Sheet Data:**

Working capital (deficit)	\$	47,268	\$	7,762	\$	9,724	\$	(6,169)	\$	(946)	\$	(749)	\$	(217)
Total assets	\$	50,186	\$	17,375	\$	11,241	\$	16,749	\$	1,409	\$	760	\$	496
Long-term liabilities	\$	9	\$	24	\$	47,515	\$	17	\$	1,267	\$	1,888	\$	1,095
Stockholders equity (deficit)	\$	48,284	\$	8,969	\$	(37,385)	\$	(5,303)	\$	(1,835)	\$	(2,300)	\$	(966)

---

**Table of Contents****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 a development-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 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.

## **Table of Contents**

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 15% of our March 31, 2014 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 May 30, 2014, the Company had 78,276,250 total issued and outstanding shares of Common Stock, and five year warrants for the opportunity to purchase an additional 1,086,109 shares of Common Stock at exercise prices ranging from \$0.85 to \$7.36 per share. The Company had outstanding stock options to purchase an aggregate of 6,126,652 shares of Common Stock at exercise prices ranging from \$0.08 to \$11.90 and 573,475 outstanding restricted stock units, with each unit representing the right to receive one share of Common Stock.

## **Critical Accounting Policies**

Our consolidated financial statements, 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**

Through March 31, 2014, the Company's revenues have been derived from collaborative research agreements, grants from the National Institute of Health (NIH), U.S. Treasury Department and private not-for-profit organizations, as well as the sale of bioprinter related products and services, and license agreements.

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.



## **Table of Contents**

### *Product Revenue*

The Company recognizes product revenue at the time of shipment to the customer, provided all other revenue recognition criteria have been met. The Company recognizes product revenues upon shipment to customers, provided that (i) the price is substantially fixed or determinable at the time of sale; (ii) the customer's obligation to pay the Company is not contingent upon resale of the products; (iii) title and risk of loss passes to the customer at time of shipment; (iv) the customer has economic substance apart from that provided by the Company; (v) the Company has no significant obligation to the customer to bring about resale of the products; and (vi) future returns can be reasonably estimated. For any sales that do not meet all of the above criteria, revenue is deferred until all such criteria have been met.

### *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 upfront 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.

### *Revenue Arrangements with Multiple Deliverables*

The Company occasionally 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.

### *Grant Revenues*

Revenues from grants 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.

## **Table of Contents**

### **Allowance for Doubtful Accounts**

When we begin to sell commercial product 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.

### **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,

## **Table of Contents**

and the risk free interest rate. Future changes in these factors will 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 to continue to vary significantly from quarter to quarter.

## **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, 2014 were devoted primarily to developing a platform technology for the generation of 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. The Company has not realized significant revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

### **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, 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

---

**Table of Contents**

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 to continue to vary significantly from quarter to quarter.





## **Table of Contents**

### ***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

## **Table of Contents**

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 to continue to vary significantly from quarter to quarter.

### *Comparison of the years ended December 31, 2012 and 2011*

#### **Revenues**

2012 total revenues of \$1.2 million increased \$0.2 million, or 20%, over 2011 revenues of \$1.0 million. That increase was due to a \$0.3 million increase in collaborative agreement revenues, and a \$0.1 million increase in grant revenues, partially offset by a \$0.2 million reduction in product revenues.

#### **Operating Expenses**

Operating expenses increased approximately \$7.2 million, or 218%, in 2012 over 2011, from \$3.3 million in 2011 to \$10.5 million in 2012. Most significantly, relative to the prior year, the Company invested in infrastructure and outside services to support its transition from private ownership to a publicly owned and traded corporation. As expected in such transition, incremental initiatives were established in investor outreach, corporate governance, and SEC financial reporting. Non-payroll related incremental public company expenses incurred in 2012 were approximately \$3.2 million. Moreover, the Company invested in building its executive, research and development staff, increasing payroll related expenses by \$2.0 million or 154% over 2011, from \$1.3 million to \$3.3 million. The increase in payroll-related expenses accounted for approximately 28% of total year-to-year increase in operating expenses. Stock-based compensation expense increased by approximately \$1.4 million compared to the prior year under the 2012 Equity Incentive Plan with awards granted related to increased headcount in line with expanded operations. Additionally, the Company consolidated and relocated its facilities to a larger space to accommodate its growing research operations staff at an incremental cost over 2011 of approximately \$0.3 million.

#### **Research and Development Expenses**

2012 research and development expenses of \$3.4 million increased by approximately \$2.0 million, or 143%, over 2011 expenses of \$1.4 million as the Company increased its research staff to support its obligations under certain collaborative research agreements and to expand product development efforts in preparation for research-derived revenues. Full-time research and development staffing increased from seven scientists and engineers as of December 31, 2011 to nineteen as of December 31, 2012.

#### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses grew from \$1.7 million in 2011 to \$7.1 million in 2012, an increase of \$5.4 million or 318%. Expense increases were driven by non-recurring charges associated with the financing, increased payroll and facilities expenses and our transition from operating in a private company environment to operating in a publicly traded corporation. As expected in such transition, incremental initiatives were established in

investor outreach, corporate governance, and SEC financial reporting. Non-payroll related incremental public company expenses incurred in 2012 were approximately \$3.2 million including non-recurring charges associated with the Merger and the Private Placements completed during the year. In addition, expanded staff increased payroll and facilities expenses in 2012 over 2011 levels with general and administrative staff increasing from four full-time employees as of December 31, 2011 to ten full-time employees as of

## **Table of Contents**

December 31, 2012. This increase was primarily due to the addition of two executive positions and a small number of accounting and administrative staff. In addition, existing executive officers received salary increases as approved by the Board of Directors, reflecting the increased responsibilities assumed as a result of becoming a publicly traded company and success on growth initiatives.

### **Other Income (Expense)**

The \$32.2 million increase in other expenses as compared to 2011 was primarily related to the non-cash transaction costs associated with the Merger, the 2012 Private Placement, and the tender offer loss on the inducement to exercise warrants we completed in December 2012. We issued warrants to purchase 6,099,195 shares of our common stock to the placement agent and warrants to purchase 15,247,987 of our common stock to investors in the Private Placement. The warrants issued to the placement agent and Private Placement investors were determined to be derivative liabilities as a result of the anti-dilution provisions in the warrant agreements that may result in an adjustment to the warrant exercise price. We revalue the derivative liability on each subsequent balance sheet date until the securities to which the derivatives liabilities relate are exercised or expire. The fair value of warrant liabilities in excess of proceeds received was \$19.0 million, while the change in fair value of warrant liabilities was \$9.9 million. Financing transaction costs in excess of proceeds received was \$2.1 million, the loss on inducement to exercise warrants under the Tender Offer was \$1.9 million, and our interest expense was \$1.1 million. 2012 interest expense was primarily comprised of non-cash components including accretion of debt discounts and amortization of deferred financing costs. The \$2.1 million of interest expense in 2011 was primarily comprised of non-cash components including \$1.2 million in amortization of debt discounts, \$0.6 million fair value of warrants issued in connection with the 2011 Exchange Agreement (see Note 6) and amortization of deferred financing costs of \$0.1 million.

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 to continue to vary significantly from quarter to quarter.

### **Financial Condition, Liquidity and Capital Resources**

Since its inception, the Company has devoted its efforts primarily to developing a platform technology for the generation of 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. The Company has not realized significant revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

Since inception, the Company has incurred negative cash flows from operations. As of March 31, 2014, the Company had cash and cash equivalents of \$48.2 million and an accumulated deficit of \$92.2 million. The Company also had negative cash flows from operations of \$15.6 million, \$2.8 million, \$3.6 million, \$9.7 million and \$1.9 million for the year ended March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and the years ended December 31, 2012 and December 31, 2011, respectively.

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. At March 31, 2013, we had total current assets of \$16.1 million and current liabilities of \$8.4 million, resulting in working capital of \$7.7 million. At December 31, 2012, we had total current assets of \$15.9 million and current liabilities of \$22.0 million, resulting in a working capital deficit of \$6.1 million.

Net cash used in investing activities was approximately \$0.3 million, \$0.2 million, less than \$0.1 million, \$0.4 million, and \$0.1 million for the year ended March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and the years ended December 31, 2012 and December 31, 2011, respectively. The majority of net cash used in investing activities from inception to date has been for the purchases of equipment for the research lab.

---

**Table of Contents**

Net cash provided by financing activities was approximately \$48.4 million, \$3.7 million, \$13.6 million, \$24.6 million and \$2.1 million for the year ended March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and the years ended December 31, 2012 and December 31, 2011, respectively.

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.

The increase in cash provided by financing activities in 2012 was primarily due 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.

Cash provided by financing activities for the Company during 2011 included raising proceeds of \$2.5 million which came from several transactions including a September 2011, private placement offering of convertible note securities for an aggregate purchase price of \$1.5 million. The principal plus accrued interest was convertible into the common stock of the public shell company to be identified upon consummation of the merger transaction. In addition, during October and November 2011, \$1.5 million 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 Convertible Notes were outstanding at December 31, 2011, and were converted into common stock in connection with the Merger. The warrants are exercisable at \$1.00 per share, expire in five years, and contained down-round price protection.

Through March 31, 2014, 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 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 product 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



**Table of Contents**

future operating expenses through cash on hand, through additional financing from existing and prospective investors, and from revenue derived from grants, collaborative research agreements and revenue from the commercialization of products and services. However, we may not be successful in obtaining funding from new or existing collaborative research agreements. In addition, 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. Further, we cannot assure you that we will receive 100% of the potential funding under existing grants, and we may not be successful in securing additional grants in the future.

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.

**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.

**Table of Contents**

**Item 8. Consolidated Financial Statements and Supplementary Data**

**Organovo Holdings, Inc.**

**(A development stage company)**

**Index to Consolidated Financial Statements**

	<b>Page Number</b>
<u>Reports of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of March 31, 2014, March 31, 2013, and December 31, 2012</u>	F-4
<u>Consolidated Statements of Operations for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012, the years ended December 31, 2012, 2011 and from April 19, 2007 (Inception) through March 31, 2014</u>	F-5
<u>Consolidated Statements of Stockholders' Equity (Deficit) from April 19, 2007 (Inception) through March 31, 2014</u>	F-6
<u>Consolidated Statements of Cash Flows for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012 and the years ended December 31, 2012, 2011 and from April 19, 2007 (Inception) through March 31, 2014</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-9

**Table of Contents**

**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 Subsidiary** (the Company ) as of March 31, 2014 and 2013 and December 31, 2012, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the year ended March 31, 2014, the three months ended March 31, 2013, the years ended December 31, 2012 and 2011, and for the period from April 19, 2007 (Inception) through March 31, 2014. 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 Subsidiary** as of March 31, 2014 and 2013 and December 31, 2012, and the results of their consolidated operations and their cash flows for the year ended March 31, 2014, the three months ended March 31, 2013, the years ended December 31, 2012, and 2011, and for the period from April 19, 2007 (Inception) through March 31, 2014, 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 Subsidiary's** internal control over financial reporting as of March 31, 2014, based on criteria established in *Internal Control – Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated June 10, 2014 expressed an unqualified opinion.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

June 10, 2014

**Table of Contents**

**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 Subsidiary** s internal control over financial reporting as of March 31, 2014, based on criteria established in *Internal Control – Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). **Organovo Holdings, Inc. and Subsidiary** s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying **Management s Report on Internal Control over Financial Reporting**. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We 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 Subsidiary** maintained, in all material respects, effective internal control over financial reporting as of March 31, 2014, based on criteria established in *Internal Control – Integrated Framework (1992)* 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 balance sheets and the related statements of operations, stockholders equity (deficit), and cash flows of **Organovo Holdings, Inc. and Subsidiary**, and our report dated June 10, 2014 expressed an unqualified opinion.

/s/ Mayer Hoffman McCann P.C.

San Diego, CA

June 10, 2014

F-3

**Table of Contents****ORGANOVO HOLDINGS, INC.****(A development stage company)****CONSOLIDATED BALANCE SHEETS**

(in thousands except per share data)

	March 31, 2014	March 31, 2013	December 31, 2012
<b>Assets</b>			
<b>Current Assets</b>			
Cash and cash equivalents	\$ 48,167	\$ 15,628	\$ 14,817
Grant receivable		101	162
Inventory	63	88	360
Deferred financing costs	40		
Prepaid expenses and other current assets	891	327	527
Total current assets	49,161	16,144	15,866
Fixed assets, net	857	1,045	714
Restricted cash	79	88	88
Other assets, net	89	98	81
Total assets	\$ 50,186	\$ 17,375	\$ 16,749
<b>Liabilities and Stockholders Equity (Deficit)</b>			
<b>Current Liabilities</b>			
Accounts payable	\$ 326	\$ 641	\$ 425
Accrued expenses	1,167	780	981
Deferred revenue	13	53	
Current portion of capital lease obligation	10	10	10
Warrant liabilities	377	6,898	20,619
Total current liabilities	1,893	8,382	22,035
Deferred revenue, net of current portion	4	9	
Capital lease obligation, net of current portion	5	15	17
Total liabilities	\$ 1,902	\$ 8,406	\$ 22,052
<b>Commitments and Contingencies (Note 8)</b>			
<b>Stockholders Equity (Deficit)</b>			
Common stock, \$0.001 par value; 150,000,000 shares authorized, 78,113,639, 64,686,919 and 58,535,411 shares issued and outstanding at March 31, 2014, March 31, 2013, and December 31, 2012, respectively	78	65	59
Additional paid-in capital	140,419	75,269	44,883

Deficit accumulated during the development stage	(92,213)	(66,365)	(50,245)
<b>Total stockholders equity (deficit)</b>	<b>48,284</b>	<b>8,969</b>	<b>(5,303)</b>
<b>Total Liabilities and Stockholders Equity (Deficit)</b>	<b>\$ 50,186</b>	<b>\$ 17,375</b>	<b>\$ 16,749</b>

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

Table of Contents**ORGANOVO HOLDINGS, INC.****(A development stage company)****CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands except per share data)

	Year ended March 31, 2014	Three Months Ended March 31,		Year ended December 31, 2012	Year ended December 31, 2011	<i>Period from April 19, 2007 Inception Through March 31, 2014</i>
		2013	2012 (Unaudited)			
<b>Revenues</b>						
Product	\$	\$	\$	\$	\$	224
Collaborations	248	98	120	1,035	688	2,144
Grants	131	117		162	57	1,074
<b>Total Revenues</b>	<b>379</b>	<b>215</b>	<b>120</b>	<b>1,197</b>	<b>969</b>	<b>3,442</b>
Cost of product revenue					121	134
Selling, general, and administrative expenses	13,054	2,792	902	7,080	1,733	25,593
Research and development expenses	7,974	1,448	547	3,436	1,420	16,056
<b>Loss from Operations</b>	<b>(20,649)</b>	<b>(4,025)</b>	<b>(1,329)</b>	<b>(9,319)</b>	<b>(2,305)</b>	<b>(38,341)</b>
<b>Other Income (Expense)</b>						
Fair value of warrant liabilities in excess of proceeds received			(19,019)	(19,019)		(19,019)
Change in fair value of warrant liabilities	(5,120)	(12,034)	(13,506)	(9,931)	(7)	(27,092)
Financing transaction costs in excess of proceeds received			(2,130)	(2,130)		(2,130)
Loss on inducement to exercise warrants				(1,904)		(1,904)
	(84)			(158)		(242)



Loss on disposal of fixed assets							
Interest expense	(13)	(65)	(1,088)	(1,088)	(2,067)	(3,484)	
Interest income	18	4		5		29	
Other expense			(9)	(9)	(4)	(30)	
<b>Total Other Income (Expense)</b>	(5,199)	(12,095)	(35,752)	(34,234)	(2,078)	(53,872)	
<b>Net Loss</b>	\$ (25,848)	\$ (16,120)	\$ (37,081)	\$ (43,553)	\$ (4,383)	\$ (92,213)	
Net loss per common share basic and diluted	\$ (0.35)	\$ (0.26)	\$ (1.17)	\$ (1.01)	\$ (0.19)		
Weighted average shares used in computing net loss per common share basic and diluted	73,139,618	61,750,157	31,591,663	43,149,657	22,925,694		

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

Table of Contents

## ORGANOVO HOLDINGS, INC.

(A development stage company)

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

Period from April 19, 2007 (Inception) through March 31, 2014

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
<b>Balance at inception (April 19, 2007)</b>		\$	\$	\$	\$
Issuance of common stock					
Stock-based compensation expense					
Net loss					
<b>Balance at December 31, 2007</b>		\$	\$	\$	\$
Issuance of common stock to founders	1,730	2	(2)		
Issuance of restricted common stock	12,628	12	(12)		
Stock-based compensation expense			2		2
Net loss				(98)	(98)
<b>Balance at December 31, 2008</b>	<b>14,358</b>	<b>\$ 14</b>	<b>\$ (12)</b>	<b>\$ (98)</b>	<b>\$ (96)</b>
Issuance of restricted common stock	130				
Stock-based compensation expense			2		2
Net loss				(872)	(872)
<b>Balance at December 31, 2009</b>	<b>14,488</b>	<b>\$ 14</b>	<b>\$ (10)</b>	<b>\$ (970)</b>	<b>\$ (966)</b>
Issuance of restricted common stock	219				
Stock-based compensation expense			4		4
Net loss				(1,339)	(1,339)
<b>Balance at December 31, 2010</b>	<b>14,707</b>	<b>\$ 14</b>	<b>\$ (6)</b>	<b>\$ (2,309)</b>	<b>\$ (2,301)</b>
Issuance of common stock through conversion of notes payable	7,677	8	3,482		3,490
Issuance of restricted common stock	61				
Warrants issued with convertible notes and conversion of notes			1,111		1,111
Beneficial conversion feature of convertible notes payable			239		239
Stock-based compensation expense			9		9
Net loss				(4,383)	(4,383)
<b>Balance at December 31, 2011</b>	<b>22,445</b>	<b>\$ 22</b>	<b>\$ 4,835</b>	<b>\$ (6,692)</b>	<b>\$ (1,835)</b>

Edgar Filing: ORGANOVO HOLDINGS, INC. - Form 10-K

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
Costs associated with the 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 exercise 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)
<b>Balance at December 31, 2012</b>	<b>58,535</b>	<b>\$ 59</b>	<b>\$ 44,883</b>	<b>\$ (50,245)</b>	<b>\$ (5,303)</b>
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)
<b>Balance at March 31, 2013</b>	<b>64,687</b>	<b>\$ 65</b>	<b>\$ 75,269</b>	<b>\$ (66,365)</b>	<b>\$ 8,969</b>
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)
<b>Balance at March 31, 2014</b>	<b>78,113</b>	<b>\$ 78</b>	<b>\$ 140,419</b>	<b>\$ (92,213)</b>	<b>\$ 48,284</b>

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



**Table of Contents****ORGANOVO HOLDINGS, INC.****(A development stage company)****CONSOLIDATED STATEMENTS OF CASH FLOWS (in thousands)**

	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	Period from April 19, 2007 (Inception) Through March 31, 2014
<b>Cash Flows From Operating Activities</b>						
Net loss	\$ (25,848)	\$ (16,120)	\$ (37,081)	\$ (43,553)	\$ (4,383)	\$ (92,213)
Adjustments to reconcile net loss to net cash used in operating activities:						
Amortization of deferred financing costs			319	319	119	438
Amortization of warrants issued for services	323	261		556		1,140
Depreciation and amortization	387	80	17	195	68	818
Loss on disposal of fixed assets	84			158		242
Amortization of debt discount			896	896	1,188	2,084
Interest accrued on convertible notes payable			12	12	232	495
Fair value of warrant liabilities in excess of proceeds			19,019	19,019		19,019
Change in fair value of warrant liabilities	5,120	12,034	13,506	9,931	7	27,092
Loss on inducement to exercise warrants				1,904		1,904
Expense associated with warrant modification	12	65				77
Stock-based compensation	4,600	848	4	1,435	9	6,900
Warrants issued in connection with exchange agreement					528	528
Increase (decrease) in cash resulting from changes in:						
Grants receivable	101	61		(162)	60	
Inventory	25		(45)	(459)	(224)	(726)
Prepaid expenses and other assets	(392)	(61)	(65)	(101)	(69)	(647)

Edgar Filing: ORGANOVO HOLDINGS, INC. - Form 10-K

Accounts payable	(315)	216	(217)	(233)	373	326
Accrued expenses	387	(201)	(37)	543	132	1,167
Deferred revenue	(45)	62	116	(153)	46	17

<b>Net cash used in operating activities</b>	(15,561)	(2,755)	(3,556)	(9,693)	(1,914)	(31,339)
--	----------	---------	---------	---------	---------	----------

**Cash Flows From Investing Activities**

Deposits released from restriction (restricted cash deposits)	9		(38)	(88)		(79)
Purchases of fixed assets	(277)	(137)	(6)	(357)	(46)	(1,198)
Purchases of intangible assets		(19)			(65)	(114)

<b>Net cash used in investing activities</b>	(268)	(156)	(44)	(445)	(111)	(1,391)
--	-------	-------	------	-------	-------	---------

**Cash Flows From Financing Activities**

Proceeds from issuance of convertible notes payable					2,543	4,630
Proceeds from issuance of common stock and exercise of warrants, net	48,016	3,724	13,723	24,714		76,454
Proceeds from exercise of stock options	402			18		420
Proceeds from issuance of related party notes payable					225	250
Principal payments on capital lease obligations	(10)	(2)		(7)		(19)
Repayment of related party notes payable					(250)	(250)
Repayment of convertible notes and interest payable			(110)	(110)		(110)
Deferred financing costs	(40)				(438)	(478)

<b>Net cash provided by financing activities</b>	48,368	3,722	13,613	24,615	2,080	80,897
--	--------	-------	--------	--------	-------	--------

<b>Net Increase in Cash and Cash Equivalents</b>	32,539	811	10,013	14,477	55	48,167
--	--------	-----	--------	--------	----	--------

<b>Cash and Cash Equivalents at Beginning of Period</b>	15,628	14,817	340	340	285	
---	--------	--------	-----	-----	-----	--

<b>Cash and Cash Equivalents at End of Period</b>	\$ 48,167	\$ 15,628	\$ 10,353	\$ 14,817	\$ 340	\$ 48,167
---	-----------	-----------	-----------	-----------	--------	-----------

**Supplemental Disclosure of Cash Flow Information:**

Interest	\$	\$	\$	10	\$	10	\$	\$	10
----------	----	----	----	----	----	----	----	----	----

Income Taxes	\$	\$	\$	1	\$	1	\$	1	\$	3
--------------	----	----	----	---	----	---	----	---	----	---

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

**Table of Contents**

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

During 2010, the Company issued 219,369 shares of restricted common stock to certain employees, advisors and consultants of the Company.

During 2011, the Company issued certain convertible notes payable that included warrants. The related beneficial conversion feature, valued at \$823 was classified as an equity instrument and recorded as a discount to the carrying value of the related debt. The warrants, valued at approximately \$1,260, were recorded as a warrant liability and recorded as a discount to the carrying value related to debt.

During 2011, the Company issued 7,676,828 shares of common stock to note holders for the conversion of Convertible Notes with a principal balance totaling \$3,030 and accrued interest totaling \$460.

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.

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



## **Table of Contents**

### **Organovo Holdings, Inc.**

#### **(A development stage company)**

### **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 31<sup>st</sup> to March 31<sup>st</sup>. 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 subsidiary Organovo, Inc. The Company is developing and commercializing functional three-dimensional (3D) 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.

As of March 31, 2014, the Company has devoted its efforts primarily to developing a platform technology for the generation of 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. The Company has not realized significant revenues from its planned principal operations. Accordingly, the Company is considered to be in the development stage.

##### *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.

## **Table of Contents**

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, 2014, the Company had an accumulated deficit of approximately \$92.2 million. The Company also had negative cash flows from operations of approximately \$15.6 million during the year ended March 31, 2014.

In August of 2013, the Company raised net proceeds of approximately \$43.4 million through the sale of 10,350,000 shares of its common stock in a public offering (see Note 7).

In addition, 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 offerings, as defined by the SEC, and pursuant to the Company's effective shelf registration statement previously filed with the SEC. As of March 31, 2014, the Company has raised approximately \$3.5 million through the sale of 334,412 shares of its common stock under the distribution agreement.

Through March 31, 2014, 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 or 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 product 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 additional financing from existing and prospective investors, from revenue derived from grants and collaborative research agreements, and revenue from the commercialization of products and services. However, we may not be successful in obtaining funding from new or existing collaborative research agreements. In addition, 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. Further, we cannot assure you that we will receive 100% of the potential funding under existing grants, and we may not be successful in securing additional grants in the future.

F-10

## **Table of Contents**

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, grants receivable, 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.

F-11

---

**Table of Contents***Restricted cash*

As of March 31, 2014, March 31, 2013, and December 31, 2012, the Company had approximately \$78,800, \$88,300, and \$88,300, respectively, of restricted cash deposited with a financial institution. The entire \$78,800 as of March 31, 2014 and \$38,300 of the balance as of March 31, 2013 and December 31, 2012 was held in certificates of deposit to support a letter of credit agreement related to the facility lease entered into during 2012. In December 2013, the lease was amended to increase the rented area by 15,268 square feet, and as such, the Company was required to increase the amount held in certificates of deposit to support the increased letter of credit as required by the lease amendment. The additional \$50,000 included in the balance as of March 31, 2013 and December 31, 2012 represents funds held by a financial institution as a guarantee for the Company's commercial credit cards. These funds were released from restriction during the year ended March 31, 2014 as a result of the Company transferring its credit card program to a different financial institution.

*Grant receivable*

Grant receivable as of March 31, 2013 and December 31, 2012 represents the amount due from the National Institutes of Health ( NIH ) under a research grant that concluded in April 2013. The Company considers the grants receivable to be fully collectible; and accordingly, no allowance for doubtful amounts has been established. If amounts become uncollectible, they are charged to operations.

*Inventory*

Inventories are stated at the lower of the cost or market (first-in, first-out). Inventory consists of approximately \$63,000, and \$88,000 in raw materials as of March 31, 2014 and 2013, respectively, net of reserves. Inventory consists of approximately \$196,000 in finished goods, \$60,000 work-in-process and \$104,000 in raw materials as of December 31, 2012.

The Company provides inventory allowances based on excess or obsolete inventories determined based on anticipated use in the final product. The reserve for obsolete inventory at March 31, 2014 was approximately \$31,000. There was no reserve for obsolete inventory as of March 31, 2013 or December 31, 2012.

*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 lease term. The estimated useful lives of the fixed assets range between two and five 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 in the period from inception through March 31, 2014.

*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

F-12



**Table of Contents**

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. Future changes in these factors will 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 to continue to vary significantly from quarter to quarter.

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

**Fair Value Measurements at March 31, 2014, March 31, 2013, and December 31, 2012**  
(in thousands):

	<b>Balance at March 31, 2014</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Other Unobservable Inputs (Level 3)</b>
Warrant liability	\$ 377	\$	\$	\$ 377
	<b>Balance at March 31, 2013</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Other Unobservable Inputs (Level 3)</b>
Warrant liability	\$ 6,898	\$	\$	\$ 6,898

	<b>Balance at December 31, 2012</b>	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Other Unobservable Inputs (Level 3)</b>
Warrant liability	\$ 20,619	\$	\$	\$ 20,619

F-13

**Table of Contents**

The following table presents the activity for liabilities measured at estimated fair value using unobservable inputs for the year ended December 2012, the three months ended March 31, 2013, and the year ended March 31, 2014:

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3)**

	<b>Warrant Derivative Liability (in thousands)</b>
Balance at December 31, 2011	\$ 1,267
Issuances	\$ 32,742
Adjustments to estimated fair value	\$ 9,931
Warrant liability removal due to settlements	\$ (23,321)
<b>Balance at December 31, 2012</b>	<b>\$ 20,619</b>
Issuances	\$
Adjustments to estimated fair value	\$ 12,034
Warrant liability removal due to settlements	\$ (23,869)
Warrant liability reclassified to equity	\$ (1,886)
<b>Balance at March 31, 2013</b>	<b>\$ 6,898</b>
Issuances	\$
Adjustments to estimated fair value	\$ 5,120
Warrant liability removal due to settlements	\$ (10,874)
Warrant liability reclassified to equity	\$ (767)
<b>Balance at March 31, 2014</b>	<b>\$ 377</b>

*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 collaborative research agreements, grants from the NIH, U.S. Treasury Department and private not-for-profit organizations, as well as the sale of bioprinter related products and services, and license agreements.

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, 2014, March 31, 2013, and December 31, 2012, the Company had approximately \$17,000, \$62,000, and \$0, respectively, in deferred revenue related to its collaborative research programs.

## **Table of Contents**

### Product Revenue

The Company recognizes product revenue at the time of shipment to the customer, provided all other revenue recognition criteria have been met. The Company recognizes product revenues upon shipment to distributors, provided that (i) the price is substantially fixed or determinable at the time of sale; (ii) the distributor's obligation to pay the Company is not contingent upon resale of the products; (iii) title and risk of loss passes to the distributor at time of shipment; (iv) the distributor has economic substance apart from that provided by the Company; (v) the Company has no significant obligation to the distributor to bring about resale of the products; and (vi) future returns can be reasonably estimated. For any sales that do not meet all of the above criteria, revenue is deferred until all such criteria have been met.

### 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 upfront 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.

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 and \$450,000 in revenue related to the contract during the years ended December 31, 2012 and 2011, respectively. Total revenue recognized on the contract from inception through March 31, 2014 was approximately \$600,000.

In October 2011, the Company entered into a research contract agreement with a third party, whereby the Company is performing research and development services on a fixed-fee basis for \$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 \$184,000, \$97,000, \$120,000, \$885,000 and \$239,000 for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012, and the years ended December 31, 2012 and 2011, respectively, in revenue related to the research contract in recognition of the proportional performance achieved. Total revenue recognized on the contract from inception through March 31, 2014 was \$1,405,000.

### Revenue Arrangements with Multiple Deliverables

The Company occasionally 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

F-15

**Table of Contents**

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 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.

#### NIH and U.S. Treasury Grant Revenues

During 2010, the U.S. Treasury awarded the Company two one-time grants totaling approximately \$397,000 for investments in qualifying therapeutic discovery projects under section 48D of the Internal Revenue Code. The grants covered reimbursement for qualifying expenses incurred by the Company in 2010 and 2009. The proceeds from these grants are classified in Revenues - Grants for the period from inception through March 31, 2014.

During 2012, 2010 and 2009, the NIH awarded the Company three research grants totaling approximately \$558,000. Revenues from the NIH grants 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 when expenses have been incurred by subcontractors and as the Company incurs internal expenses that are related to the grants. Revenue recognized under these grants for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012, and the years ended December 31, 2012, and 2011 was approximately \$12,000, \$117,000, \$0, \$162,000, and \$57,000, respectively. Total revenue recorded under these grants from inception through March 31, 2014 was approximately \$558,000.

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 reimbursable expenses that are related to the grant. The Company recognized revenue from this grant of approximately \$119,000 for the year ended March 31, 2014 and from inception to date.

#### *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).





**Table of Contents**

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 their estimated fair value as they vest.

*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 year ended March 31, 2014, the three months ended March 31, 2013 and 2012, and the years ended December 31, 2012 and 2011, and for the period April 19, 2007 (inception) through March 31, 2014, 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 year ended March 31, 2014, the three months ended March 31, 2013 or 2012, or the years ended December 31, 2012 or 2011 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 7.7 million, 8.9 million, 25.8 million, 15.2 million, and 6.4 million for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012 and the years ended December 31, 2012 and 2011, respectively.

*Reclassifications*

Certain reclassifications were made to the 2011 financial statements in order to conform to the presentation of the financial statements for 2012. The reclassifications did not have any effect on previously reported net loss or stockholders' equity (deficit).

**3. Fixed Assets**

Fixed assets consisted of the following (in thousands):

	March 31, 2014	March 31, 2013	December 31, 2012
Laboratory equipment	\$ 1,207	\$ 1,168	\$ 759
Computer software and equipment	191	114	114
Furniture and fixtures	33	33	33
	1,431	1,315	906

Less accumulated depreciation and amortization	(574)	(270)	(192)
	\$ 857	\$ 1,045	\$ 714

Depreciation and amortization expense for the year end March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and the years ended December 31, 2012 and December 31, 2011 was approximately \$380,000, \$78,000, \$15,000, \$188,000 and \$63,000, respectively. Depreciation and amortization expense was approximately \$794,000 for the period from April 19, 2007 (inception) through March 31, 2014.

F-17

**Table of Contents****4. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	March 31, 2014	March 31, 2013	December 31, 2012
Accrued compensation	\$ 505	\$ 386	\$ 720
Deferred rent	345	270	188
Accrued legal and professional fees	283	53	
Other accrued expenses	34	71	73
	\$ 1,167	\$ 780	\$ 981

**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 \$0.4 million, \$6.9 million, \$20.6 million and \$1.3 million as of March 31, 2014, March 31, 2013, and December 31, 2012 and December 31, 2011, respectively. 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 years ended December 31, 2012 and 2011 were increases of \$5.1 million, \$12.0 million, \$13.5 million, \$9.9 million and less than \$0.1 million, respectively, and are included in other income (expense) in the statements of operations.

During the year ended March 31, 2014, the three months ended March 31, 2013 and the year ended December 31, 2012, 1,920,874, 6,990,556 and 13,010,237 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 and the three months ended March 31, 2013 the Company entered into amendment agreements with certain of the warrant holders, which removed the down-round pricing protection provision, resulting in 269,657 and 601,735, respectively, 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, 2014	March 31, 2013	December 31, 2012
-------------------	-------------------	----------------------

Edgar Filing: ORGANOVO HOLDINGS, INC. - Form 10-K

Closing price per share of common stock	\$ 7.64	\$ 3.68	\$ 2.60
Exercise price per share	\$ 1.00	\$ 1.00	\$ 1.00
Expected volatility	76.50%	88.80%	92.90%
Risk-free interest rate	0.90%	0.57%	0.54%
Dividend yield			
Remaining expected term of underlying securities (years)	2.96	3.88	4.16

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.

F-18

---

**Table of Contents**

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***Convertible notes*

From February 9, 2008 through December 31, 2011, the Company raised an aggregate of \$2,390,000 in funds through loans consisting of convertible notes ( Convertible Notes ) to certain stockholders, management, vendors, and investors. The notes bore interest at rates ranging from 8% to 10% per annum and had maturity dates ranging from 2011 to 2018. The Convertible Notes were unsecured and subordinated to certain senior indebtedness of the Company, and for all Convertible Notes the principal plus accrued interest was convertible into the Company's common stock. During

October 2011, in connection with the Exchange Agreement and Release, the Convertible Notes and accrued interest converted into the Company's common stock.

F-19

---

**Table of Contents***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.

The Company calculated the fair value of the warrants using the Black-Scholes Model using a volatility of 109.84%, an interest rate of 1.12% and a dividend yield of zero. Certain of these Convertible Notes and accrued interest were converted into the Company's common stock in October 2011, in connection with the Exchange Agreement and Release, as discussed below. Upon conversion the Company recognized the unamortized debt discount related to these notes to interest expense. The Company recognized approximately \$583,700 of interest expense for the amortization of the note discount during the year ended December 31, 2011.

*Exchange Agreement and Release*

In October 2011, the Company's Board of Directors and stockholders approved an Exchange Agreement, 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.



---

**Table of Contents**

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 and \$603,800 of interest expense for the amortization of the debt discount during the years ended December 31, 2012 and 2011, respectively, and approximately \$1,500,000 for the period from inception through March 31, 2014.

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 \$13,000, \$65,000, \$1,088,000, \$1,088,000, and \$2,067,000 for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012, and the years ended December 31, 2012, and 2011, respectively. Interest expense,

including amortization of the note discounts and other interest expense, for the period from April 19, 2007 (inception) through March 31, 2014 was approximately \$3,484,000.

---

**Table of Contents***Registration rights agreement*

The Company entered into a registration rights agreement ( *Registration Rights Agreement* ) with the investors in the Offering. Under the terms of the Registration Rights Agreement, the Company agreed to file a registration statement covering the resale of the common stock underlying the Units and the common stock that is issuable on exercise of the Investor Warrants (but not the common stock that is issuable upon exercise of the warrants issued as compensation to the placement agent in connection with the Offering) within 90 days from the final closing date of the Offering (the *Filing Deadline* ). The Company filed the registration statement on June 13, 2012. The registration statement became effective during July 2012.

The Company agreed to use reasonable efforts to maintain the effectiveness of the registration statement through the one year anniversary from the date the registration statement was declared effective by the Securities and Exchange Commission (the *SEC* ), or until Rule 144 of the 1933 Act is available to investors in the Offering with respect to all of their shares, whichever is earlier. If the Company had not met the Effectiveness Deadline, the Company would have been liable for monetary penalties equal to one-half of one percent (0.5%) of each investor's investment in the offering at the end of every 30 day period following such Effectiveness Deadline failure until such failure was cured. No payments shall be owed with respect to any period during which all of the investor's registrable securities may be sold by such investor under Rule 144 or pursuant to another exemption from registration.

**7. Stockholders' Equity***Common stock*

In October 2011, the Company issued 7,676,828 shares of common stock to note holders for the conversion of Convertible Notes with a principal balance totaling \$3,030,000 and accrued interest totaling approximately \$459,800.

During February and March 2012, the Company issued 21,247,987 shares of common stock related to the Merger. See Note 2. During the year ended December 31, 2012, the Company issued 13,423,622 shares of common stock upon exercise of 13,532,487 warrants.

During the year ended December 31, 2012, a total of 224,064 stock options were exercised for 224,064 shares of common stock.

During the three months ended March 31, 2013, the Company issued 6,131,198 shares of common stock upon exercise of 7,090,556 warrants.

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.

F-22

## Table of Contents

The Underwriting Agreement contained customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

The representations, warranties and covenants contained in the Underwriting Agreement were made only for purposes of the Underwriting Agreement as of specific dates indicated therein, were solely for the benefit of the parties to the Underwriting Agreement, and may be subject to limitations agreed upon by the parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the Underwriting Agreement.

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 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, 2014, the Company issued 334,412 shares of common stock in at-the-market offerings under the distribution agreement with net proceeds of \$3.5 million.

In addition, during the year ended March 31, 2014, the Company issued 2,713,207 shares of common stock upon exercise of 3,201,633 warrants.

During the year ended March 31, 2014, the Company issued 183,796 shares of common stock upon exercise of 183,796 options.

### *Restricted stock awards*

In February 2008, four founders, including the Chief Executive Officer ( CEO ) and three directors of the Company received 11,779,960 shares of restricted common stock, 25% vesting after the first year and the remaining 75% vesting in equal quarterly portions over the following three years. These shares are fully vested as of March 31, 2014.

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 were issued under the 2008 Plan during the year ended December 31, 2012, the three months ended March 31, 2013, or the year ended March 31, 2014, and the Company does not intend to issue any additional shares from the 2008 Plan in the future.

From 2008 through December 31, 2011, the Company issued a total of 1,258,934 shares of restricted common stock to various employees, advisors, and consultants of the Company. Of those shares, 1,086,662 were issued under the 2008 Plan and the remaining 172,272 shares were issued outside the plan.

In January of 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. In August 2013, the Board of Directors of the Company approved an amendment to the 2012 Plan 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.

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.

F-23

**Table of Contents**

During the year ended December 31, 2012, the Company issued an aggregate 200,000 restricted stock awards to a member of senior management, the vesting of which is performance based. As of March 31, 2014, the Company believed the financial targets would be met, and accordingly is recognizing the related stock based compensation expense over the requisite service period.

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.

**Table of Contents**

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

	Number of Shares
Unvested at December 31, 2007	
Granted	12,627,697
Vested	(65,211)
Canceled / forfeited	
Unvested at December 31, 2008	12,562,486
Granted	130,422
Vested	(5,373,004)
Canceled / forfeited	
Unvested at December 31, 2009	7,319,904
Granted	219,369
Vested	(3,256,191)
Canceled / forfeited	
Unvested at December 31, 2010	4,283,082
Granted	61,406
Vested	(3,233,193)
Canceled / forfeited	
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

The fair value of each restricted common stock award is recognized as stock-based 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 \$817,000, \$478,000, \$0, \$835,000, and \$3,000 during the year ended March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and the years ended December 31, 2012, and 2011, respectively. The Company recorded restricted stock-based compensation expense of approximately \$2,141,000



for the period from April 19, 2007 (inception) through March 31, 2014. Expense for each of the periods included approximately \$16,000, \$4,000, \$0, \$23,000, and \$0 for research and development during the year ended March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and the years ended December 31, 2012, and 2011, respectively. General and administrative expense for the year ended March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and the years ended December 31, 2012, and 2011 were approximately \$801,000, \$474,000, \$0, \$812,000, and \$3,000, respectively.

As of March 31, 2014, total unrecognized restricted stock-based compensation expense was approximately \$747,000, which will be recognized over a weighted average period of 1.46 years.

**Table of Contents***Stock options*

Under the 2008 Equity Incentive Plan, on October 12, 2011, the Company granted an officer incentive stock options to purchase 896,256 shares of common stock at an exercise price of \$0.08 per share, a quarter of which vested on the one year anniversary of employment, in May 2012, and the remaining options are vesting ratably over the remaining 36 month term. Other than this grant, the Company does not intend to issue any additional shares under the 2008 Plan.

During the year ended March 31, 2014, the three months ended March 31, 2013, and the year ended December 31, 2012, under the 2012 Equity Incentive Plan, 2,519,572, 927,981 and 2,023,394 incentive stock options were issued, respectively, at various exercise prices, a quarter of which will vest on either the one year anniversary of employment or one year anniversary of the vesting commencement date. The remaining options will vest ratably over the remaining 36 month terms, with the exception of 218,655, 24,690 and 83,986 of the incentive stock option grants during the year ended March 31, 2014, the three month period ended March 31, 2013, and the year ended December 31, 2012, respectively, that have immediate vesting at the grant date, 99,500 and 126,000 of the incentive stock option grants in the years ended March 31, 2014 and December 31, 2012, respectively, that vest quarterly over three years, and 122,500 and 70,750 of the incentive stock option grants in the years ended March 31, 2014 and December 31, 2012, respectively, that vest after one full year.

The following table summarizes stock option activity for 2010 through March 31, 2014:

	Options Outstanding	Weighted- Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2010			
Options granted	896,256	\$ 0.08	
Options canceled			
Options exercised			
Outstanding at December 31, 2011	896,256	\$ 0.08	
Options granted	2,023,394	\$ 1.95	
Options canceled	(5,000)	\$ 2.25	
Options exercised	(224,064)	\$ 0.08	\$ 564,641
Outstanding at December 31, 2012	2,690,586	\$ 1.48	\$ 3,041,476
Options granted	927,981	\$ 3.93	
Options canceled			
Options exercised			
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
Vested and Exercisable at March 31, 2014	1,546,377	\$ 2.73	\$ 7,733,041

The weighted-average remaining contractual term of options exercisable and outstanding at March 31, 2014 was approximately 8.5 years and 8.92 years, respectively.

F-26

**Table of Contents**

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

	Year Ended March 31, 2014	Three Months Ended March 31, 2013	Year Ended December 31, 2012
Dividend yield			
Volatility	78.22%	96.83%	96.22%
Risk-free interest rate	1.32%	1.19%	0.89%
Expected life of options	6.00 years	6.07 years	6.05 years
Weighted average grant date fair value	\$ 5.92	\$ 3.04	\$ 1.5

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 \$3,783,000, \$370,000, \$4,000, \$600,000, and \$6,000 for the year ended March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and the years ended December 31, 2012, and 2011, respectively. The Company recorded stock-based compensation expense of approximately \$4,761,000 for the period from April 19, 2007 (inception) through March 31, 2014. Expense for each of the periods included approximately \$462,000, \$58,000 and \$81,000 for research and development during the year ended March 31, 2014, the three months ended March 31, 2013, and the year ended December 31, 2012, respectively. General and administrative expense for the year ended March 31, 2014, the three months ended March 31, 2013 and March 31, 2012, and years ended December 31, 2012, and 2011 were approximately \$3,321,000, \$312,000, \$4,000, \$519,000, and \$6,000 respectively.

The total unrecognized compensation cost related to unvested stock option grants as of March 31, 2014 was approximately \$16,045,500 and the weighted average period over which these grants are expected to vest is 3.5 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 year ended March 31, 2014, the three months ended March 31, 2013 and the year ended December 31, 2012, 225,000, 3,852,214, and 13,259,987 of these warrants were exercised for cash proceeds of approximately \$210,000, \$3,850,000 and \$11,356,000, respectively, and 2,628,003, 3,138,342, and 272,500 of these warrants were exercised through a cashless exercise for issuance of 2,139,577, 2,220,764, and 163,635 shares of common stock, respectively. No warrants were exercised during 2011.

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

F-27

---

**Table of Contents**

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 and the three months ended March 31, 2013, the Company entered into amendment agreements for 269,657 and 601,735, warrants respectively, to purchase common stock which reduced the exercise price of the warrants from \$1.00 to between \$0.85 and \$0.90, 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 and \$65,000 was recognized as interest expense for the twelve months ended March 31, 2014 and the three months ended March 31, 2013, respectively.

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 year ended March 31, 2014, three months ended March 31, 2013 and the year ended December 31, 2012, the Company recognized approximately \$72,000, \$261,000, and \$556,000, respectively, of expense related to these services. 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 the three months ended March 31, 2013, 58,220 shares of common stock were issued through a cashless exercise of 100,000 of these warrants.

Additionally, 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 \$163,000 during the year ended March 31, 2014 and for the period from April 19, 2007 (inception) through March 31, 2014, related to these services.

**Table of Contents**

The following table summarizes warrant activity for the year ended March 31, 2014, the three months ended March 31, 2013, and the years ended December 31, 2012, 2011, and 2010:

	Warrants	Weighted-Average Exercise Price
Balance at December 31, 2010		
Granted	2,909,750	\$ 1.00
Expired / Canceled		
Exercised		
Balance at December 31, 2011	2,909,750	\$ 1.00
Granted	21,997,182	\$ 1.04
Exercised	(13,532,487)	\$ 0.84
Balance at December 31, 2012	11,374,445	\$ 1.08
Granted		
Exercised	(7,090,556)	\$ 1.01
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

The warrants outstanding at March 31, 2014 are immediately exercisable at prices between \$0.85 and \$7.36 per share, and have a weighted average remaining term of approximately 2.55 years.

*Common stock reserved for future issuance*

Common stock reserved for future issuance consisted of the following at March 31, 2014:

Common stock warrants outstanding	1,194,756
Common stock options outstanding under the 2008 Plan	672,192
Common stock options outstanding and reserved under the 2012 Plan	9,534,989
Total	11,401,937

*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 which was entered into in February 2012 and amended in December 2013, with the future minimum lease payments from the lease included below. The Company records rent expense on a straight-line basis over the life of the lease and records the excess of expense over the amounts paid as deferred rent. Deferred rent is included in accrued expenses in the consolidated balance sheets.

Rent expense was approximately \$561,500, \$105,500, \$60,200, \$325,600, and \$145,200 for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012, and the years ended December 31, 2012, and 2011, respectively. Rent expense was approximately \$1,317,200 for the period from April 19, 2007 (inception) through March 31, 2014.



**Table of Contents**

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 target Expansion Premises Commencement Date is 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 Company intends for the Expansion Premises to contain office, laboratory, and clean room areas.

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, 2014, are as follows (in thousands):

Fiscal year ended March 31, 2015	\$ 766
Fiscal year ended March 31, 2016	981
Fiscal year ended March 31, 2017	986
Fiscal year ended March 31, 2018	1,004
Fiscal year ended March 31, 2019	1,034
Thereafter	2,439
<b>Total</b>	<b>\$ 7,210</b>

*Capital leases*

During 2012, the Company entered into an agreement to lease certain laboratory equipment under a non-cancelable capital lease, which is included in fixed assets as follows (in thousands):

March 31, 2014	
Lab equipment	\$ 34
Less accumulated depreciation	(11)

Net book value	\$ 23
----------------	-------

Depreciation expense related to the capital lease obligation was approximately \$6,800, \$1,700 and \$2,900 for the year ended March 31, 2014, the three months ended March 31, 2013 and the year ended December 31, 2012, respectively.

F-30

**Table of Contents**

Future minimum capital lease payments at March 31, 2014 are as follows (in thousands):

Fiscal year ended March 31, 2015	\$ 11
Fiscal year ended March 31, 2016	4
<b>Total minimum lease payments</b>	<b>15</b>
Amount representing interest	
Present value of minimum lease payments	15
Less current portion	(10)
<b>Long term portion</b>	<b>\$ 5</b>

*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. An estimated loss contingency is accrued in its financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. 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. The amount of ultimate loss may differ from these estimates. It is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies. Whether any losses finally determined in any claim, action, investigation or proceeding could reasonably have a material effect on the Company's business, financial condition, results of operations or cash flows will depend on a number of variables, including: the timing and amount of such losses; the structure and type of any remedies; the monetary significance of any such losses, damages or remedies may have on our consolidated financial statements; and the unique facts and circumstances of the particular matter that may give rise to additional factors.

**Spencer Trask Matter.** On June 28, 2013, the Company filed a lawsuit for declaratory relief in the Supreme Court for the State of New York (case # 652305/2013) against Spencer Trask Ventures, Inc. ( STV or Spencer Trask ) in connection with a Warrant Solicitation Agency Agreement (the WSAA ) that the Company entered into with STV in February 2013 (the New York Action ). In the New York Action, the Company is seeking a declaration that the WSAA remains a valid and enforceable agreement. Over the course of several weeks in February 2013, Organovo and STV, through their respective attorneys, negotiated the WSAA pursuant to which the Company engaged STV as the Company's warrant solicitation agent in connection with the Company's efforts to solicit the exercise of outstanding Organovo warrants during the first quarter of 2013. STV's President signed the WSAA on behalf of STV, and the Company's CEO executed the agreement on behalf of Organovo. Spencer Trask provided services to the Company pursuant to the WSAA, and the Company has paid STV for those services.

The Company's dispute with Spencer Trask arose in March 2013 after the Company approached Spencer Trask about exercising its outstanding warrants to help the Company qualify for up-listing its common stock on the NYSE MKT. Previously, Spencer Trask had not asserted any claims for additional compensation as a result of the warrant tender offer the Company completed in December 2012. In March 2013, the Company received two demand letters from STV, and a demand for arbitration notice in June 2013. In the first demand letter, STV alleges that it is entitled to compensation (including a cash fee and warrants to purchase common stock) as a

F-31

---

**Table of Contents**

result of the warrant tender offer the Company completed in December 2012 and as a result of the notice of warrant redemption the Company completed in March 2013. In the second letter, STV alleges it is entitled to damages because the Company allegedly violated confidentiality provisions in the Placement Agency Agreement (the PAA ) the Company had previously entered into with STV in December 2012 in connection with the private placement financings the Company completed in February and March 2012 (the Private Placements ), by contacting the warrant holders who participated in the warrant tender offer. In response, on June 28, 2013, the Company filed a lawsuit for declaratory relief in the Supreme Court for the State of New York against STV. 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. For these and other reasons, including applicability of the WSAA, the Company believes STV is not entitled to compensation under the PAA and there was no violation of confidentiality. The Company received notice on August 5, 2013 that STV had filed its arbitration demand with the arbitrator (the Arbitration ). In July, 2013, the Company filed a motion to stay the arbitration pending determination of the New York Action. In January 2014, the New York Court stayed the New York Action, finding that the arbitrator should determine in the first instance which disputes between the Company and Spencer Trask should proceed in the Arbitration and which disputes between the Company and Spencer Trask 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 Arbitration is scheduled to commence on March 2, 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. The Company has not established a loss contingency accrual for these claims because any potential liability is not probable or estimable. Nonetheless, an unfavorable resolution of these claims could have a material adverse effect on the Company's business, liquidity or financial condition in the reporting period in which such resolution occurs.

**Other Legal Matters.** In addition to the matter described above, the Company is subject to normal and routine litigation in the ordinary course of business. The Company has not accrued any loss contingencies for such matters. The Company intends to defend itself in any such matters and does not currently believe that the outcome of such matters will have a material adverse effect on its business, liquidity or financial position.

**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 University of Missouri a nonrefundable license fee of \$5,000 and has

F-32

**Table of Contents**

committed to reimburse the University of Missouri for certain prior and future patent costs. In 2012 and 2011, the Company paid the University of Missouri approximately \$193,500 and \$23,800, respectively, for prior patent costs relating to the license agreements with the University of Missouri. No payments were made during the year ended 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. An additional royalty of \$12,500 is due if there are no net sales within five years from the effective date of the license. 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.

No royalty payments have been made under the above license agreements as of March 31, 2014. Approximately \$4,000 is due to the University of Missouri relating to the first commercial sale. Annual royalty payments of \$30,000 and \$20,000 will be due to the University of Missouri and Clemson University, respectively, in calendar 2014 per the terms of the respective license agreements.

*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, 2014	March 31, 2013	December 31, 2012
License fees	\$ 114	\$ 114	\$ 95
Less accumulated amortization	(25)	(17)	(15)
License fees, net	\$ 89	\$ 97	\$ 80

Amortization expense of licenses was approximately \$8,500, \$2,000, \$1,700, \$7,000, \$5,200, and \$25,200 for the year ended March 31, 2014, the three months ended March 31, 2013 and 2012, the years ended December 31, 2012 and 2011, and the period from April 19, 2007 (inception) through March 31, 2014, respectively. At March 31, 2014, the weighted average remaining amortization period for all licenses was approximately 11 years. The annual amortization expense of licenses for the next five years is estimated to be approximately \$8,500 per year.

F-33



**Table of Contents****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, 2014, March 31, 2013, and December 31, 2012 (in thousands):

	March 31, 2014	March 31, 2013	December 31, 2012
Deferred tax assets:			
Net operating loss carry forwards	\$	\$	\$
Research and development credits			
Depreciation and amortization	22	(1)	(2)
Accrued expenses and reserves	280	224	290
Stock compensation	1,941	743	562
Other, net	1	1	
Total deferred tax assets	2,244	967	850
Valuation allowance	(2,244)	(967)	(850)

\$                      \$                      \$

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, 2014. 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. The valuation allowance increased by approximately \$1,277,000 and increased by approximately \$117,000 for the year ended March 31, 2014 and the three months ended March 31, 2013, respectively.

The Company had federal and state net operating loss carryforwards of approximately \$34,838,000 and \$34,833,000 at March 31, 2014, respectively. The federal and state net operating loss carryforwards will begin expiring in 2028, unless previously utilized. The net operating loss carryforwards included approximately \$3,389,000 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 \$450,000 and \$548,000 at March 31, 2014, 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, 2014.

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, 2014.

The Company does not have any unrecognized tax benefits that will significantly decrease or increase within 12 months of March 31, 2014.

The Company is subject to tax in the United States and in the state of California. As of March 31, 2014, 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.

F-34

**Table of Contents**

**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 primarily located in San Diego. Accounts at these institutions are secured by the Federal Deposit Insurance Corporation. At times, 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.

F-35

## **Table of Contents**

### **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 \_\_\_\_\_ 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, 2014. In making this assessment, we used the framework included in *Internal Control – Integrated Framework* (1992) 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* (1992), our management concluded that our internal control over financial reporting was effective as of March 31, 2014.

### **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, 2014.

### **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 fiscal quarter to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**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.

**Table of Contents**

**Item 9B. Other Information.**

None.

**Table of Contents**

**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 2014 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](http://www.organovo.com).

**Item 11. Executive Compensation**

Information relating to executive compensation will be included in the proxy statement for the 2014 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 2014 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 2014 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 2014 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.



**Table of Contents**

**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 year ended March 31, 2014, the three months ended March 31, 2013 and 2012 and the years ended December 31, 2012 and 2011, 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.

Table of Contents**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 10, 2014

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	Chief Executive Officer and President (Principal Executive Officer)	June 10, 2014
Keith Murphy		
/s/ Barry Michaels	Chief Financial Officer and Corporate Secretary (Principal Financial Officer)	June 10, 2014
Barry Michaels		
/s/ Robert Baltera, Jr.	Director	June 10, 2014
Robert Baltera, Jr.		
/s/ James Glover	Director	June 10, 2014
James Glover		

/s/ Tamar Howson	Director	June 10, 2014
Tamar Howson		
/s/ Richard Heyman	Director	June 10, 2014
Richard Heyman		

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
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 Securities and Exchange Commission (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

Edgar Filing: ORGANOVO HOLDINGS, INC. - Form 10-K

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)

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
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)
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

Edgar Filing: ORGANOVO HOLDINGS, INC. - Form 10-K

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)

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
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)
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)

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>
21.1	Subsidiaries of Organovo Holdings, Inc. (incorporated by reference from Exhibit 10.25 to the Company's Current Report on Form 8-K, as filed with the SEC on February 13, 2012)
23.1	Consent of Independent Registered Public Accounting Firm*
24.1	Power of Attorney (included on signature page hereto)*
31.1	Certification of Chief Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.*
31.2	Certification of Chief Financial Officer 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	Interactive Data File*

\* Filed herewith

+ Designates management contracts and compensation plans.