Harvard Apparatus Regenerative Technology, Inc.
Form 10-K
March 27, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 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 Number 001-33957

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**45-5210462**
(State or other jurisdiction of Incorporation or organization)	(I.R.S. Employer Identification No.)

84 October Hill Road, Suite 11, Holliston, Massachusetts 01746

(Address of Principal Executive Offices, including zip code)

(774)233-7300

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.01 par value	**The NASDAQ Capital Market**
Preferred Stock Purchase Rights	

Securities registered pursuant to Section 12(g) of the Act:

None

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2014 was approximately $73,323,261. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding voting power of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

At March 20, 2015, there were 10,069,676 shares of the registrant's common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive Proxy Statement in connection with the 2015 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days after the end of the Registrant's fiscal year, are incorporated by reference into Part III of this Form 10-K. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

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ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2014

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This Annual Report on Form 10-K contains statements that are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"), each as amended. The forward-looking statements are principally, but not exclusively, contained in "Item 1: Business" and "Item 7: Management's Discussion and Analysis of Financial Condition and Results of Operations." These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about management's confidence or expectations and our plans, objectives, expectations and intentions that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "seek," "expects," "plans," "aim," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "think," "strategy," "potential," "objectives," "optimistic," "new," "goal," "strategy" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in detail under the heading "Item 1A. Risk Factors" beginning on page 21 of this Annual Report on Form 10-K. You should carefully review all of these factors, as well as other risks described in our public filings, and you should be aware that there may be other factors, including factors of which we are not currently aware, that could cause these differences. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information. Harvard Apparatus Regenerative Technology, Inc. is referred to herein as "we," "our," "us," and "the Company."

PART I

Item 1. ***Business.***

BUSINESS

We are a clinical stage biotechnology company making regenerated organs for transplant.

Our first product, the HART-Trachea, is intended to be used to restore the structure and/or function of a severely damaged trachea (windpipe). The HART-Trachea is comprised of the patient's own bone marrow cells seeded on our proprietary InBreath porous plastic scaffold in our proprietary InBreath organ bioreactor.

We believe our HART-Trachea could enable surgeons to cure nearly all life-threatening constrictions of the airway. Our HART-Trachea addresses both of the critical challenges to trachea transplant: the shortage of suitable donor tracheas and the risk and expense of lifelong anti-rejection drug therapy. Because the scaffolds are synthetic, they can be made in large quantities and therefore will eliminate the need to wait for suitable donor tracheas. Because the cells are from the patient, the patient's body does not reject the HART-Trachea and therefore the patients do not need to take anti-rejection drugs. Because these substantial costs and risks can be reduced or even eliminated with our technology, we believe our products can both help save lives and reduce overall healthcare costs.

To date, the HART-Trachea has been implanted in five adult human patients. Average survival among the three of these patients who have died to date has been 22 months. This is a significant improvement over the prognosis at the time of implant which was typically just a few months. Of the three patients who have died, none of them have died because of a failure of our scaffold. Two of the patients are still alive. Of those two patients, one is at approximately 9 months and the other is at approximately two and one half years from being first implanted.

Our products are currently in development and have not yet received regulatory approval for sale anywhere in the world.

The Office of Combination Products of the U.S. Food and Drug Administration, or FDA, has confirmed for us that the FDA intends to regulate the HART-Trachea as a combination product under the Biologics License Application, or BLA pathway under the primary jurisdiction of the Center for Biologics Evaluation and Research, or CBER. In the EU, the European Medicines Agency, or EMA, has designated the HART-Trachea as an Advanced Therapy Medicinal

Product, or ATMP. The ATMP regulatory pathway in Europe is approximately similar to the BLA pathway in the U.S. The initial indication for which we intend to seek FDA and EMA approvals will be to restore the structure and function of the trachea subsequent to tracheal damage or stenosis due to cancer, injury or infection.

We have received orphan drug designation from the FDA for the HART-Trachea in the U.S. market. Orphan drug designation provides market exclusivity in the U.S. for seven years from the date of the product's approval for marketing. This exclusivity is in addition to any exclusivity we may obtain due to our patents. Additionally, orphan designation provides a waiver of the BLA application fee of $672,000.

We have also filed an application for orphan designation in the EU for our HART-Trachea product. We expect to receive a response from the EMA with respect to our orphan designation application in the second quarter of 2015. In the EU orphan status would provide market exclusivity for ten years.

We are currently engaged in pre-clinical development of our HART-Trachea. Assuming we are able to complete the necessary pre-clinical work to the satisfaction of the U.S. and EU regulatory agencies we would expect to submit our request for IND approval for the HART-Trachea in the first half of 2016. Assuming we are then able to complete the clinical trials with approximately 30 patients and with a 3 month follow-up period we would expect to submit our BLA application for marketing in late 2017. If we are granted Fast Track, Accelerated Review and Breakthrough status in the U.S. we would expect our BLA to be reviewed quickly in which case it is possible we would receive FDA approval to market the HART-Trachea in the U.S. in the first half of 2018. Because the EU ATMP pathway allows for a "hospital exemption" it is possible that we could begin collecting clinical data in the EU before we do so in the U.S. This may allow us a somewhat faster path to approval in the EU than in the U.S. These estimates depend on many assumptions that are inherently uncertain and on scientific and clinical trials whose outcomes are unknowable at this time. The process of obtaining regulatory marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that our products will be approved in this timeframe, or at all.

In addition to the trachea, we believe that our bioreactor and scaffold technologies are applicable to the regeneration of other organs. In January 2015 we announced the signing of a joint development agreement with Mayo Clinic to bring the HART-Trachea to clinical trials, and to develop a tissue engineered solution for the esophagus using regenerative medicine principles.

Our History

We were incorporated under the laws of the State of Delaware on May 3, 2012 by Harvard Bioscience, Inc. ("Harvard Bioscience") to provide a means for separating its regenerative medicine business from its other businesses. Harvard Bioscience has been designing and manufacturing devices for life science researchers for over 100 years. Harvard Bioscience first explored the regenerative medicine market in 2007 and began focusing on providing devices to scientists involved in regenerative medicine research in 2008. Since early 2009, Harvard Bioscience's regenerative medicine business initiative operated as a division of Harvard Bioscience.

Harvard Bioscience decided to separate its regenerative medicine business into our company, a separate corporate entity (the "Separation"), and it spun off its interest in our business to its stockholders in 2013. Prior to the distribution of shares of our common stock to the Harvard Bioscience stockholders (the "Distribution") Harvard Bioscience contributed the assets of its regenerative medicine business, and approximately $15 million in cash, to our company to fund our operations following the Distribution. The Distribution was effected on November 1, 2013, and since that time we have been a separately traded public company. Also, since that time Harvard Bioscience has not been a stockholder of our common stock and has no longer controlled our operations. We had no material assets or activities as a separate corporate entity until the contribution to us by Harvard Bioscience of the regenerative medicine assets and business.

In connection with the Separation and immediately prior to the Distribution, we entered into a Separation and Distribution Agreement, Intellectual Property Matters Agreement, Product Distribution Agreement, Tax Sharing Agreement, Transition Services Agreement, and Sublicense Agreement with Harvard Bioscience to effect the Separation and Distribution and provide a framework for our relationship with Harvard Bioscience after the Separation. These agreements govern the current relationships among us and Harvard Bioscience and provided for the allocation among us and Harvard Bioscience of Harvard Bioscience's assets, liabilities and obligations (including employee benefits and tax-related assets and liabilities) attributable to periods prior to the Separation.

Market Opportunity

There are two major sources of life-threatening constrictions of the trachea: trachea stenosis (narrowing of the trachea caused by physical damage) and trachea cancer. We engaged third parties to analyze databases of clinical records of patients diagnosed with life-threatening trachea stenosis or trachea cancer, and based on that analysis we estimate that there are approximately 7,700 patients per year in the U.S. and EU combined. For more details please see the section "Industry Overview — Overview of the Trachea Transplant Opportunity" below.

While we cannot predict what the total potential market will be when and if we obtain regulatory approval to market our HART-Trachea, based solely on there being at least 7,700 patients per year at the time of such approval, we estimate the total potential revenue opportunity for the HART-Trachea could exceed $770 million per year if we were able to charge at least $100,000 per HART-Trachea. Although we have not yet established pricing for the HART-Trachea, we estimate that pricing between $100,000 and $200,000 may be justifiable based on the costs of treating these patients today, and the potentially life-saving nature of our product.

Additionally, we believe that our current technology may also in the future be used to address replacement or partial replacement of the esophagus and other hollow, tubular organs in the body. We believe that these markets collectively contain considerably more potential patients with life-threatening and expensive conditions than exist for the trachea alone.

Industry Overview

The first human organ transplant was a kidney transplant performed in 1954. The donor of the kidney was the identical twin of the recipient and therefore there was no immune rejection of the organ. The recipient lived for eight years following the transplant and the surgeon who performed the transplant, Dr. Joseph Murray, went on to win the Nobel Prize for this work. The recipient of the first heart transplant, performed in 1967 by Dr. Christiaan Barnard, lived only 18 days. The patient did not die because the new heart failed, but because of pneumonia that the patient acquired due to the patient's immune system being compromised by the anti-rejection drugs that the patient had to take. These two cases illustrate both the promise and the challenges of organ transplantation: donor organs can greatly extend life, but there is a critical shortage of donors and, unless the donor is the identical twin of the recipient, the recipient's body will always reject the donor organ. In order to combat this rejection, the patient must take lifelong anti-rejection drugs which compromise the immune system and greatly increase the risk of the patient dying from infections.

In the 1960s, anti-rejection drugs were very poor and hence very few organ transplants took place. In the 1970s, better anti-rejection drugs, particularly cyclosporine, were developed and by the late 1970s many heart transplant patients were living up to five years with their donor hearts. In 1983, the FDA approved cyclosporine for use in organ transplantation, and the first lung transplant patient survived more than six years.

Although the improved anti-rejection drugs increased the life expectancy for patients receiving organ transplants, they came with harmful side effects that shortened the recipient's natural life span. In addition to the side effects, the anti-rejection drugs are also very expensive and can cost $20,000 to $30,000 per year and must be taken for as long as the patient lives. Despite the side effects and costs, organ transplants have become common enough that the shortage of donors is now a key constraint to organ transplants. To increase the number of organ transplants the U.S. government made a considerable effort to increase organ donation. This included Congress passing seven separate pieces of legislation, Medicare paying for donor transplants, several Surgeons General making personal appeals for more organ donors and the U.S. Department of Health and Human Services making the Emmy award-winning documentary *No Greater Love* on the benefits of organ donation. Despite all these efforts, waiting lists for organ transplants continued to grow and by 2011 there were over 100,000 Americans waiting for a donor organ.

In the late 1980s, the field of regenerative medicine emerged as scientists began to apply principles of engineering and cell biology to develop techniques that could restore, maintain or improve body function. Regenerative medicine now includes products that use cells to repair damaged organs and to grow organs outside the body for transplant into the patient. Early successes in regenerative medicine included the skin grafting products Apligraf and Dermagraft, which were approved by the FDA in 1998 and 2001, respectively. Apligraf has since been used to treat over 200,000 patients. However, the regeneration of more complex three-dimensional structures like the trachea proved much harder than two-dimensional structures like the skin. Additional progress came with using regenerated tissue grafts to increase urinary bladder capacity and with regenerating blood vessels for grafting between veins and arteries.

In 2008, a milestone was reached when the two fields of organ transplant and regenerative medicine were combined with the world's first transplant of a regenerated airway. Even though the airway scaffold came from a donor, because the patient's own bone marrow cells were used to seed the scaffold after the cells from the donor had been removed, the patient did not require anti-rejection drugs. Other than the transplant of organs between genetically identical twins, such as the first kidney transplant described above, we believe this regenerated airway transplant was the world's first organ transplant that has not required anti-rejection drugs. In 2011, another milestone was reached with the world's first transplant of a regenerated airway using a synthetic scaffold. In 2013, additional milestones were reached with the first regenerated trachea transplant in the U.S. and the first regenerated trachea transplant using a synthetic scaffold in a child. To date, the patients receiving these transplants also have not needed to take anti-rejection drugs, and because the scaffolds were made in a laboratory, the patients did not have to wait for a suitable donor organ to become available. These breakthroughs open the possibility that the waiting lists for organ transplants can be reduced or even eliminated.

Overview of the Trachea Transplant Opportunity

There are two major sources of life-threatening constrictions of the trachea: trachea stenosis (narrowing of the trachea caused by physical damage) and trachea cancer. We commissioned an independent third-party (Exponent) to analyze a database (The National Inpatient Sample, or NIS) of U.S. hospital stays to identify the number of patients with life-threatening damage to the trachea. This database is provided by the Agency for Healthcare Research and Quality which is a Federal/State/Industry consortium. It contains patient diagnosis, treatment and discharge data on over 1000 hospitals in the U.S. stratified in such a way as be able to predict data for the entire U.S. Data is broken down by the diagnosis received by the patient at the hospital and uses the ICD9 (International Statistical Classification of Diseases) categories. The ICD9 codes for trachea trauma are:

- 519.02, mechanical complications of tracheostomy, including tracheal stenosis
- 519.09, other tracheostomy complications, and
- 519.19, tracheal stenosis

The data was analyzed for the average number of patients diagnosed annually from 2003 to 2011, which is the latest year for which the data is available. On average there were 39,375 patients diagnosed in these three categories each year in the U.S. Each patient with this diagnosis is also assigned a risk of death. The categories of risk of death are: minor likelihood of dying, moderate likelihood of dying, major likelihood of dying and extreme likelihood of dying. Taking only those patients in the above diagnostic codes with an extreme likelihood of dying there were, on average, 7,247 patients per year in the U.S. On average approximately 22% of these patients diagnosed with an extreme likelihood of death actually do die within that single hospital visit which averages approximately 22 days. We cannot tell from the NIS database how many of these patients die after discharge therefore the 22% actual death rate is a minimum death rate. The average cost of the hospital stay to treat these patients with an extreme likelihood of dying was $248,511. The total cost of treating these patients with an extreme likelihood of dying is approximately $1.8 billion per year in the U.S. We are working with our collaborators to further refine this data to identify the subset of these patients who are at an extreme likelihood of dying that would be candidates for the HART-Trachea. For the purposes of estimating the market size for treating tracheal stenosis patients we have assumed that 50% of these patients, or approximately 3,600 patients per year in the U.S. would be treatable with the HART-Trachea.

For trachea cancer we similarly commissioned Exponent to analyze a different database, the National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER) database. We used the SEER database for trachea cancer rather than the NIS database as some trachea cancer patients are not admitted as in-patients to the hospital and so do not appear in the NIS database whereas almost all patients with life-threatening trachea trauma are admitted to a hospital on an in-patient basis. This analysis showed there were approximately 250 patients per year diagnosed with trachea cancer in the U.S. We have excluded the much larger population of patients suffering from cancer of the main bronchi

as initially we are pursuing trachea transplant only and not transplant of the main bronchi. Cancer of the main bronchi is approximately 35 times more common than cancer of the trachea alone with an incidence in the U.S. of approximately 9,000 per year.

Current treatments for trachea cancer, such as radiation therapy, chemotherapy and surgery have poor outcomes, resulting in a five-year survival rate of only 27%.

Combining patients with trachea stenosis and trachea cancer we estimate the patient population potentially treatable with the HART-Trachea to be approximately 3,850 per year in the U.S. Assuming the EU market is approximately the same size as the U.S. market we estimate the combined U.S. and EU patient population potentially treatable with the HART-Trachea to be approximately 7,700 patients per year.

Previous attempts to implant a tracheal prosthetic have been unsuccessful in improving long-term survival as they have been unable to allow the body to create a functional lining of the trachea which is essential to the clearance of mucus or have caused other severe complications like narrowing of the trachea, migration of the implanted material into other organs or infections. Without the clearance of mucus, patients have poor prognosis and typically die from pneumonia or respiratory failure shortly after transplant.

Our Solution

We believe the HART-Trachea is a major advance over the current therapeutic options for treating trachea cancer and trachea trauma. We believe our products are the first to enable the application of regenerative medicine techniques to the production and transplant of complex, three-dimensional organs like the trachea. With continued development, we believe that our technologies will be applicable to the repair or transplant of other important human organs such as the esophagus, lungs, heart valves, and heart. Our bioreactor technology was used in both the world's first transplant of a regenerated airway in 2008 and in the world's first transplant of a synthetic regenerated airway in 2011. The complete HART-Trachea combining our scaffolds with our bioreactors and the patient's cells was used for the first time in April 2013.

We believe our products will overcome the major challenges in trachea and other organ transplantation. Unlike traditional organ transplants, our products will eliminate the need for a donor because the scaffold will be manufactured in a factory. In addition, for hollow organs, such as the trachea, our technology enables the production of an implant that precisely matches the patient's anatomy. Because we use the patient's own bone marrow cells to seed the scaffold, our technology also eliminates the risk and expense of lifelong anti-rejection drug therapy. In addition, patients with trachea cancer treated using our technology have not required either chemotherapy or radiation therapy after the transplant, thus eliminating the significant side effects and expense of such therapies. Because these substantial costs can be reduced or even eliminated with our technology, we believe our products can both help save lives and reduce overall healthcare costs.

Further, human embryonic stem cells have not been used in any of the procedures involving our trachea transplant products. This eliminates both the medical risks and ethical controversy associated with regenerative medicine approaches using human embryonic stem cells and other controversial sources of cells.

We believe the use of our products together with the patient's own bone marrow cells solves both the major challenges facing organ transplant: a synthetic scaffold avoids the need to wait for a donor and the use of the patient's own cells avoids the risk and costs of anti-rejection drug therapy. The first application of our products is in trachea repair or replacement but we believe the technology can be developed to apply to other important human organ transplants as well.

Our Strategy

Our objective is to be the leading supplier of regenerated organs for transplant. Our business strategy to accomplish this objective includes:

Target life-threatening medical conditions. We are focused on creating products to help surgeons treat life-threatening conditions like trachea cancer, trachea stenosis, and diseases requiring esophagus, heart or lung transplant. We are not targeting less severe conditions that have reasonable alternative treatment options like damage to the skin, bones, muscles, ears or nose. By targeting life-threatening conditions, we believe it is easier to get patient informed consent for treatment, hospital ethics committee or Institutional Review Board approval and government regulatory authority approval as the patients often have poor or no treatment alternatives. We believe it will also be easier for our customers to get reimbursement for treatments for life-threatening conditions that have poor and/or more expensive alternative treatments.

Develop products that have a relatively short time to market. Since the number of patients with trachea damage is relatively small, we expect the number of patients that we would likely need to enroll in a clinical trial would be relatively small. A small number of patients implies a relatively fast and inexpensive clinical trial. In addition, since lung function is likely to be a key endpoint in any trachea transplant trial and lung function can recover and be measured fairly quickly after transplant (for instance the first patient treated with a regenerated trachea was evaluated for FEV1 (forced expiratory volume in one second) at 3 months after the surgery) we expect we would be able to conduct a clinical trial in a relatively short period of time compared to clinical trials in indications with larger patient populations and longer required follow-up periods. We intend to work closely with regulatory agencies and clinical experts to design and size the clinical studies appropriately based on the specific conditions our products are intended to treat.

Use trachea transplant as a platform to address other organs. We believe our experience in developing proprietary scaffolds, bioreactors and cell seeding protocols for tissue engineered trachea implants gives us substantial expertise and intellectual property for developing products addressing diseases impacting other organs like the esophagus, lungs, heart valves, and heart. We intend to use such expertise and intellectual property to develop regenerated organs to help treat other serious medical conditions requiring organ repair or replacement.

Supply the finished organ implant to the surgeon. Our technology includes the bioreactor and scaffold which are used by us together with the cells from the patient to create the tissue engineered organ implant together with all the required quality control data. We believe there is considerable value in supplying the final organ to the surgeon so that the hospital and surgeon may focus solely on performing the transplant.

Collaborate with leading surgeons and institutions. We have and will continue to collaborate with leading surgeons and institutions. For example, we have collaborated with Professor Macchiarini of the Karolinska Institutet to improve our bioreactors and to create earlier versions of our scaffolds for use in trachea transplant, and we have collaborated with Dr. Harald Ott of Massachusetts General Hospital to develop our lung bioreactor system. We have collaborated with researchers at Mayo Clinic to develop our heart valve bioreactor and we recently expanded our collaboration with Mayo Clinic to include efforts to assist with the advancement of our HART-Trachea product to clinical trials and the development of a regenerated esophagus. We believe the use of our products by leading surgeons and institutions will increase the likelihood that other surgeons and institutions will use our products.

Our Products

HART-Trachea

The initial indication for which we intend to seek FDA and EMA approval for the HART-Trachea will be to restore the structure and function of the trachea subsequent to tracheal damage or stenosis due to cancer, injury or infection. The HART-Trachea consists of three key components: a scaffold, the patient’s cells and a bioreactor.

InBreath Scaffold Component

The InBreath Scaffold has a physical shape and strength similar to the natural trachea. This allows it to resist the forces of compression caused by the muscles, skin, bones and other organs of the neck that surround the trachea and also to resist collapse due to the partial vacuum caused by breathing air into the lungs through the trachea. In addition, the scaffold is porous which allows cells to penetrate the scaffold during the seeding process prior to implant and also allows blood vessels from the body to grow into the scaffold once it is in the body. The scaffold used for the first regenerated trachea transplant in 2008 was a donated human trachea with its cells removed before being seeded with bone marrow cells taken from the patient. All subsequent trachea transplants using our products have utilized synthetic scaffolds. Because the synthetic scaffolds are manufactured, they can be made to the exact dimensions of the patient and in large quantities. The synthetic scaffolds used in surgeries prior to 2013 were made by third parties including Nanofiber Solutions, Inc., or NFS, as well as Dr. Alex Seifalian and other scientists at University College London. The scaffold used in the first surgery using a synthetic scaffold was made in collaboration with University

College London and Dr. Macchiarini. The NFS scaffolds were made in collaboration with our company and Dr. Macchiarini. In order to improve upon and replace those scaffolds, we collaborated with Professor Macchiarini and others to develop our initial scaffold product and our manufactured synthetic trachea scaffold was first used in a surgery in April 2013. Our scaffolds can be made from a variety of plastic polymers but are typically made from polyethelyne terephthalate, or PET, which is the same polymer used in the well-known brand of implantable materials known by the trade name Dacron. PET has a long history of safe use in long-term human implants. We intend to continue providing our proprietary scaffolds to surgeons for use in future transplants. We believe that our scaffolds are superior in quality compared to those used in surgeries prior to 2013. Our scaffolds have several novel features including the sandwiching of stiff rings between layers of porous fabric to simulate the rigidity and flexibility of the natural trachea.

The Patient's Bone Marrow Cells

The cells we seed onto the scaffold are obtained from the patient's bone marrow. The bone marrow is obtained in a standard bone marrow biopsy approximately 2 days before the transplant surgery. The cells are purified using a standard sterile, automated centrifugation process to obtain the mononuclear cells. The mononuclear cells are all the cells left after the red blood cells have been removed by the centrifuge. These mononuclear cells are then seeded onto the scaffold in the bioreactor. The cell-seeded trachea construct is then kept in the bioreactor in a sterile incubator at body temperature for approximately 2 days before the transplant surgery.

InBreath Bioreactors

Our InBreath bioreactor is a device that we use to seed cells onto a scaffold as part of the manufacturing process of the HART-Trachea. The InBreath bioreactor enables us to:

- seed the patient's cells on the scaffold under sterile conditions;
- automatically rotate the scaffold to allow good cell distribution into the pores of the scaffold; and
- monitor the scaffold remotely during the course of the two to three days incubation period before the transplant.

We believe our InBreath hollow organ bioreactor is the world's first bioreactor that has been used to perform a human transplant of a regenerated organ.

Other Development Efforts

Esophagus

We believe that our current technology will also prove helpful in developing tissue engineered solutions for the regeneration of tubular organs other than the trachea. We recently manufactured our first human-sized synthetic scaffold prototypes for esophageal transplant. These scaffolds are intended to be used to replace a segment of the esophagus that has been removed due to infection, injury or disease. The first indication we are likely to pursue is esophageal cancer. Esophageal cancer is life-threatening and far more common than trachea cancer. We are beginning pre-clinical work now and expect further development, including animal studies, to occur on the esophagus in 2015. In January 2015 we announced our signing of a collaboration agreement with Mayo Clinic. That collaboration will focus on co-developing regenerative medicine solutions for the esophagus, as well as the trachea, and turning laboratory discoveries into proven treatments and making them available to patients.

Automated Solid Organ Bioreactor

A solid organ bioreactor shares many of the features of the InBreath bioreactor such as the ability to seed cells on an organ scaffold and keep them sterile and healthy during the growth phase prior to transplant. However, for solid organs like the heart and lungs, the bioreactor must also supply pulsatile blood flow and ventilation to mimic the natural action of the heart and lungs. In addition, the physiology of the heart and lung is considerably more complex than that of the trachea and so the measuring, monitoring and control equipment needed is considerably more advanced. During the first half of 2010, one of our physician collaborators, Dr. Harald Ott at Massachusetts General Hospital, succeeded in regenerating a lung that was subsequently transplanted into the body of a rat showing near normal lung function. In collaboration with Dr. Ott and Massachusetts General Hospital, we designed and developed a novel bioreactor that was used to grow the rat lung used in this procedure. The work was published in *Nature Medicine* in July 2010.

We have collaborated with Dr. Ott since 2008 and continue to develop organ bioreactor technologies for his use. The current generation bioreactor is considerably more advanced as it is capable of controlled decellularization and recellularization of an organ, including an organ as large as a human lung. We intend to continue developing bioreactors and scaffolds in collaboration with leading researchers with the goal of eventually using our products to perform a first-in-human transplant of a regenerated organ other than the trachea.

In addition to our human lung bioreactor we also make a similar system for the human heart. This system was developed in collaboration with Dr. Ott, Dr. Macchiarini, Dr. Doris Taylor (at the Texas Heart Institute) and others. We are also collaborating with leading clinical researchers to develop bioreactors for the esophagus and for the heart valve. The heart valve bioreactor is being developed at the Mayo Clinic. None of these solid organ technologies has yet to be extensively tested in animals.

Clinical Experience

Summary of Patient Experience

To date, the HART-Trachea has been implanted in five adult human patients. Average survival among the three of these patients who have died to date has been 22 months. This is a significant improvement over the prognosis at the time of implant which was typically just a few months. Of the three patients who have died, none of them have died because of a failure of our scaffold. Two of the patients are still alive. Of those two patients, one is at approximately 9 months and the other is at approximately two and one half years from being first implanted. In addition, the HART-Trachea has been implanted in one pediatric patient.

A description of individual patient trachea transplant information follows. In procedures prior to April 2013, the InBreath organ bioreactor was used, but not the HART-Trachea product which includes use of the InBreath organ bioreactor and HART's proprietary scaffold. In the procedures described below that occurred since April 2013 the HART-Trachea product was used. The patient's own bone marrow cells were used in each of the transplant procedures described below.

World's First Human Transplant of a Regenerated Airway

In 2008, our InBreath airway bioreactor technology was used to perform the world's first human transplant of a regenerated airway. The patient had suffered a collapse of her airway following a severe tuberculosis infection. To create the regenerated airway, a donor human trachea was obtained and stripped of its cells, and then the patient's own bone marrow cells were used to seed the donor trachea and prepare it for implantation. Following such regeneration, the regenerated airway was then implanted into the patient. In addition to improving her breathing, because the cells used in the transplant were her own cells taken from her own bone marrow, she has not had to take anti-rejection drugs after the surgery. This surgery was published in *The Lancet* in November 2008. In October 2013 the five-year follow up on this patient was published in *The Lancet* showing an excellent clinical outcome. In summary the authors stated, "...the tissue-engineered trachea itself remained open over its entire length, well vascularised, completely re-cellularised with respiratory epithelium, and had normal ciliary function and mucus clearance. Lung function and cough reflex were normal. No stem-cell-related teratoma formed and no anti-donor antibodies developed. Aside from intermittent bronchoscopic interventions, the patient had a normal social and working life." In terms of specific lung function, the patient's FEV1 (forced expiratory volume in one second, a clinically standard measure of lung function) improved by 85% from before the surgery to 3 months after the surgery. According to the American Thoracic Society the change in FEV1 should be greater than 20% to be clinically significant in evaluations in this time frame.

World's First Successful Transplantation of a Synthetic Tissue Engineered Trachea

In June 2011, our InBreath bioreactor was used for the world's first successful transplantation of a synthetic tissue engineered trachea. For the first time in history, a patient was given a new trachea made from a synthetic scaffold seeded with his own cells and grown in our bioreactor. The operation was performed at the Karolinska University Hospital in Stockholm, Sweden by Dr. Macchiarini and his team of surgeons. The patient had been suffering from late-stage trachea cancer, which before the surgery would have been inoperable. He was given only a few weeks to live and as such the transplant surgery using our product was a last-resort measure to save the patient's life. The patient required a tracheo-bronchial scaffold transplant, whereby the scaffold mimics the branched shape of the airway. To create the new synthetic trachea, Dr. Alex Seifalian and other scientists at University College London developed a plastic scaffold shaped like the patient's natural airway and Dr. Macchiarini seeded it with the patient's own bone marrow cells. This seeding process prepared the synthetic trachea for implantation and thereafter the regenerated synthetic trachea was implanted into the patient. Because the cells used to regenerate the trachea were the patient's own, there has been no rejection of the transplant, and, like the first patient described above, this patient is not taking anti-rejection drugs. This surgery was published in *The Lancet* on November 24, 2011.

World's Second Successful Transplantation of a Synthetic Tissue Engineered Trachea

In November 2011, our InBreath bioreactor was again used by Dr. Macchiarini to seed the cells on a synthetic scaffold to treat a patient who was suffering from late-stage trachea cancer and required a tracheo-bronchial transplant. The operation was performed at the Karolinska University Hospital by Dr. Macchiarini and his team of surgeons. The procedure was similar to the world's first successful transplantation of a synthetic tissue engineered trachea performed in June 2011, with the exception that the plastic scaffolding material was changed to a fiber construction rather than a porous solid construction. The fibrous scaffold seeded in our bioreactor for this November 2011 procedure was manufactured by NFS and was made in a different laboratory than the one made for the June 2011 patient. The patient recovered well from the transplant surgery and was discharged home from the hospital. Approximately four months after the surgery, the patient passed away from pneumonia secondary to a tracheal tumor. There is no indication that our bioreactor or the third-party scaffold played any role in his death. This patient, like the June 2011 patient, had undergone extensive radiation and chemotherapy treatment prior to the transplant, and his tumor was not responsive to these forms of treatment.

June 2012 Russian Transplants

In June 2012, our InBreath bioreactors were used for the world's first two successful laryngo-trachea transplants, using synthetic laryngo-trachea scaffolds seeded with cells taken from the patients' bone marrow. The surgeries took place at the Krasnodar Regional Hospital in Krasnodar, Russia and were performed by Professors Porhanov and Macchiarini and their team. These two surgeries differed from the June and November 2011 procedures described above in that the patients in those prior surgeries both had late stage trachea cancer and both required a tracheo-bronchial scaffold. These Russian patients each had trachea trauma caused by automobile accidents. Both of the Russian patients required laryngo-trachea transplants, whereby the scaffold mimics the shape of the windpipe from the larynx to the point where the trachea branches into the two bronchi which lead to the lungs. Both patients had difficulties breathing and talking and had suffered repeated infections prior to the surgeries. The scaffolds in these two cases were fibrous scaffolds manufactured by NFS and similar to the one used in the November 2011 surgery, but were made with a different fiber formulation.

August 2012 and 2013 Transplants — Outside the U.S.

In August 2012 a sixth patient received a trachea transplant created using our InBreath bioreactor. The surgery took place at the Karolinska Hospital and was performed by Dr. Macchiarini and his team of surgeons. The patient was in critical condition and the trachea transplant was performed in an emergency procedure in an attempt to save the patient's life. In July 2013, this patient had the original scaffold, which was not manufactured by us, removed and a new scaffold manufactured by us implanted to replace the explanted one. This was done due to the partial collapse of the previous scaffold. In the third calendar quarter of 2013 another two surgeries were performed using the

HART-Trachea in Krasnodar, Russia.

First Successful U.S. Transplant and First Use of Our Scaffold

On April 9, 2013, our HART-Trachea was used in the first successful transplant of a regenerated trachea in the United States. The recipient of the implant, a two-year-old girl, initially recovered well but approximately two months after the trachea transplant surgery the patient underwent a second surgery to correct a defect in her esophagus. On July 6, approximately one month after the second surgery and three months after the initial surgery the patient died from complications of the second surgery. Dr. Macchiarini, who led the team performing the trachea surgery, noted that the implanted trachea was not the cause of the patient’s death, pointing out that the girl's native tissue was very fragile.

The surgery was also the world’s first successful pediatric regenerated trachea transplant using a synthetic scaffold. The patient was born on August 22, 2010 in Seoul, South Korea with tracheal agenesis (lack of a trachea), and was only able to breathe through a tube inserted in her esophagus that connected to her lungs. Tracheal agenesis is 100 percent fatal, and children born with the condition typically die shortly after birth. The patient had lived in the intensive care unit for two and a half years at Seoul National Hospital before being transported to Illinois for the surgery. This was the first regenerated trachea transplant surgery using a scaffold manufactured by us. Other than the use of a scaffold manufactured by us the procedure was similar to the other surgeries described above. The procedure was performed by a team led by Dr. Macchiarini and Drs. Mark J. Holterman and Richard Pearl both of Children’s Hospital of Illinois. The surgery was approved by the FDA under an Investigational New Drug application made by Dr. Holterman.

In December 2013 and in June 2014 additional patients received the HART-Trachea in surgeries conducted in Krasnodar, Russia. One of those patients was a re-transplant, where a scaffold that was first transplanted into the patient in June 2012, as described above, was removed and replaced by a HART-Trachea. The other patient had a trachea transplant for the first time.

All these patients have been treated under compassionate-use protocols meaning their prognosis was very poor. Typically, their bodies are very weak as a result of disease, trauma and extensive treatments that often include radiation, chemotherapy and prior surgeries. We believe that patients that undergo such extensive treatments are inherently susceptible to serious medical complications following the transplants. These transplant surgeries are typically the last-resort measure to save the patient's life. We expect that some transplant patients are likely to suffer serious complications or death following the transplants due to issues that are not directly related to the use of our products.

Clinical Trials

In order to market the HART-Trachea widely, we will need to successfully complete clinical trials. The initial indication for which we intend to seek FDA and EMA approval will be to restore the structure and function of the trachea subsequent to tracheal damage or stenosis due to cancer, injury or infection.

Because trachea cancer and severe trachea stenosis combined affect only approximately 7,700 patients per year in the U.S. and EU we anticipate that our clinical trials will involve relatively few patients. Because lung function can be measured fairly shortly after transplant (for example at 3 months post-transplant) we expect a fairly short evaluation period for establishing the efficacy of the HART-Trachea.

We intend to pursue regulatory approval for the HART-Trachea in the U.S. and the EU. Hence, we expect clinical trials to take place in those markets. During the second half of 2014 we elected not to perform future transplant procedures at Krasnodar, Russia a site of previous compassionate-use cases as part of their ongoing airway transplant studies. This shift in focus allows us to concentrate our resources on completing preclinical work necessary to initiate clinical trials for our HART-Trachea product in the EU and U.S. as those are the markets within which we believe we have the fastest paths to treating the most patients and the best reimbursement rates.

Research and Development

Our primary research and development activities are in designing and testing synthetic organ scaffolds, testing the cellularization of the scaffolds and engineering and making our organ bioreactors. As of December 31, 2014, we employed 17 full-time engineers and scientists and we also hire other consultants and part-time employees from time to time.

In addition to our in-house engineering and scientific development team, we collaborate with leaders in the field of regenerative medicine who are performing the fundamental research and surgeries in this field to develop and test new products that will advance and improve the procedures being performed. As these procedures become more common, we will work with our collaborators to further enhance our products to make them more efficient and easier to use by surgeons. In the U.S., our principal collaboration is with Mayo Clinic. Collaboration typically involves us developing new technologies specifically to address issues these researchers and clinicians face. In certain instances, we have entered into agreements that govern the ownership of the technologies developed in connection with these collaborations. These agreements are discussed below in “Intellectual Property and Related Agreements.” Sometimes we are paid for our products directly, sometimes we are partners on grants and sometimes we give away or loan our technologies to the researchers or clinicians in return for feedback to improve the designs and/or license rights to intellectual property.

We have incurred approximately $9.7 million of research and development expenses in the last two fiscal years. As we have not yet sold any of our HART-Trachea products, no significant amount of these research and development costs have been passed on to our customers.

Manufacturing

For our scaffolds we use a process called electrospinning to create the fabric part of the scaffold. The rings that mimic the natural rings of the trachea are fabricated separately and the fabric and rings are combined. Electrospinning is a well-known fabrication process. It is useful for cell culture applications as it can create extremely thin fibers (much thinner than a human hair) that can make a fabric with pores approximately the same size as a cell. The electrospinning process parameters can be tuned to create a structure that is very similar to the natural structure of the collagen fibers in a decellularized human trachea. Our scaffolds are made from a polymer that does not dissolve in the human body, in other words our scaffolds are intended to be permanent. We believe permanent scaffolds are a better approach for trachea regeneration than using solely resorbable materials as it is hard to control the strength of the scaffold as the polymer resorbs.

While we do not manufacture the cells, they come from the patient's bone marrow, for regulatory purposes we are responsible for the quality control of the cells and the seeding of the cells onto the scaffold in the bioreactor. For this we have, in collaboration with our partners, developed standard operating procedures for the seeding of cells on the scaffold. For all the surgeries performed so far the seeding has been performed in the hospital by the medical team involved in the surgery in collaboration with our staff. For a U.S. clinical trial we anticipate that the seeding will be performed in an automated version of the InBreath bioreactor and under the supervision of our staff.

For our scaffolds, our primary materials are plastic resins and solvents used to liquefy the resins in our manufacturing process. These materials are readily available from a variety of suppliers and do not currently represent a large proportion of our total costs. For our bioreactors, we perform final assembly and test components we buy from third parties like machine shops, parts distributors, molding facilities and printed circuit board manufacturers. These operations are performed primarily at our Holliston, MA headquarters.

Sales and Marketing

We expect that most transplants with the HART-Trachea will be performed at a relatively small number of major hospitals in the U.S., EU and other developed countries. As a result we expect to need only a fairly small field sales force. We expect to price the product commensurate with the medical value created for the patient and the high costs avoided with the use of our product. We expect to be paid by the hospital that buys the product from us. We expect that the hospital would seek reimbursement from payors for the entire transplant procedure, including the use of our products.

Harvard Bioscience is the exclusive distributor for the research versions of our organ bioreactors. Harvard Bioscience can only sell those products to the research markets in accordance with the terms of our distribution agreement. We

retain all rights to manufacture and sell all our products for clinical use.

Intellectual Property and Related Agreements

We actively seek to protect our products and proprietary information by means of U.S. and foreign patents, trademarks and contractual arrangements. Our success will depend in part on our ability to obtain and enforce patents on our products, processes and technologies to preserve our trade secrets and other proprietary information and to avoid infringing on the patents or proprietary rights of others.

We have rights in the patent and the patent applications listed below. The patent or patents that may issue based on the patent applications are scheduled to expire as provided below:

Patent/Technology	Jurisdiction	Expiration
Patent application covering aspects of synthetic scaffolds and organ and tissue transplantation	U.S.	2032
Patent application relating to methods and compositions for producing elastic scaffolds for use in tissue engineering	U.S.	2033
Patent application relating to support configurations for tubular tissue scaffolds, and airway scaffold configurations	U.S.	2033
Patent application relating to support configurations for tubular tissue scaffolds, and airway scaffold configurations	E.P.	2033
Patent application relating to methods and compositions for promoting the structural integrity of scaffolds for tissue engineering	U.S.	2033
Patent application covering aspects of clinical scale bioreactors and tissue engineering	Australia, Canada, Europe, Japan, Russia, U.S.	2030
Issued Patent covering aspects of liquid distribution in a rotating bioreactor	Germany	2031
Issued Patent covering aspects of liquid distribution in a rotating bioreactor	Germany	2021
Patent application covering aspects of liquid distribution in a rotating bioreactor	Australia, Canada, Europe, Japan, Russia, Singapore, U.S.	2032
Patent application relating to bioreactors with supports to facilitate culturing organs	PCT – international stage	2034
Patent application relating to bioreactor adaptors for tubular tissue scaffolds	PCT – international stage	2034
Patent applications relating to engineered hybrid organs	PCT – international stage	2034
Patent applications relating to infrared-based methods for evaluating tissue health including methods for evaluating burns	U.S.	2033
Patent application covering aspects of syringe devices and methods for delivering cells to tissues	Canada, Europe, U.S.	2030
Patent application relating to meshes and patches for tissue repair	PCT – international stage	2034
Provisional application relating to systems and methods for delivering cells to fluid passages, such as respiratory passages	U.S.	N/A

We also rely on unpatented proprietary technologies in the development and commercialization of our products. We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as those of

our advisors, consultants and other contractors. To help protect our proprietary know-how that may not be patentable, and our inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require employees, consultants and advisors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions that arise from their activities for us. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party's proprietary technology.

Patent Rights Assignment — Dr. Macchiarini

We have entered into a patent rights assignment with Dr. Macchiarini pursuant to which he has assigned to us all of his rights to inventions associated with scaffold design and the clinical protocol used in the world's first transplant of a synthetic regenerated trachea.

Novel Surgery Agreements

In the past, we entered into novel surgery agreements with each of the State Budget Institution of Public Health Department Regional Clinical Hospital #1 in Krasnodar, Russia, or the Krasnodar Hospital, the employer of Dr. Porhanov, and OSF Healthcare System and Children's Hospital of Illinois, the employer of Dr. Holterman, pertaining to trachea transplant surgical procedures conducted at those facilities. Such agreements required us to provide our InBreath Bioreactors and/or InBreath Scaffolds for the procedures and the hospitals to provide all other equipment and services. Such agreements also provided that we will own all inventions arising from the use of our InBreath Bioreactor and/or InBreath Scaffolds in connection with such procedures, and each hospital granted us an option to license all inventions independently developed by the hospital in connection with such procedures.

Exclusive License Agreement and Sponsored Research Agreement — InBreath Bioreactor

We have an exclusive license agreement with Sara Mantero and Maria Adelaide Asnaghi to intellectual property rights relating to our InBreath Bioreactor. Under this agreement, we have worldwide rights to intellectual property (including patents, data, and know-how) relating to the hollow organ bioreactor, related techniques, and improvements thereof. We have exclusive worldwide rights to make, use and sell the hollow organ bioreactor, and the right to grant sublicenses and distribution rights. Under this agreement, we are obligated to pay the licensor royalties at various percentage rates in the low to mid-single digits pertaining to any applicable bioreactors we sell. This agreement terminates on the expiration date of the last to expire patent rights that may exist pertaining to inventions of Dr. Mantero or Ms. Asnaghi relating to the hollow organ bioreactor technology or improvements, or August 6, 2016 if on such date no such patent rights exist.

We have entered into a sponsored research agreement with Sara Mantero, Maria Adelaide Asnaghi, and the Department of Bioengineering of the Politecnico Di Milano, or PDM. Under the terms of this agreement, PDM is required to use its facilities and best efforts to conduct a research program relating to the development of bioreactors, clinical applications, and automated seeding processes. We are required to provide engineering support to PDM with respect to bioreactor designs. Intellectual property developed by PDM or its employees, including Dr. Mantero or Ms. Asnaghi, under this sponsored research agreement will be owned by Dr. Mantero or Ms. Asnaghi and covered by our

exclusive license agreement described above. In addition, we have an option to an exclusive license for intellectual property relating to new technology that may not be covered by the exclusive license agreement. We will own any inventions and discoveries that we solely develop in connection with the research program and any inventions and discoveries that are jointly developed in connection with the research program will be owned jointly by the parties. The sponsored research agreement will continue until terminated by a party thereto upon 90 days prior written notice.

Sublicense Agreement with Harvard Bioscience

We have entered into a sublicense agreement with Harvard Bioscience pursuant to which Harvard Bioscience has granted us a perpetual, worldwide, royalty-free, exclusive, except as to Harvard Bioscience and its subsidiaries, license to use the mark “Harvard Apparatus” in the name Harvard Apparatus Regenerative Technology. The mark “Harvard Apparatus” is used under a license agreement between Harvard Bioscience and Harvard University, and we have agreed to be bound by such license agreement in accordance with our sublicense agreement. We currently have no affiliation with Harvard University.

Government Regulation

The HART-Trachea and other products we make are subject to considerable regulation by governments. While we have been informed by the FDA that the HART-Trachea will be regulated under the Biologics License Application, or BLA, pathway in the U.S. and we have been informed by the EMA that the HART-Trachea will be regulated under the Advanced Therapy Medicinal Products, or ATMP, pathway in the EU, it is possible that some of our products may use alternative regulatory pathways.

Combination Product/Biologic

Government Regulation Combination Products/Biologics

We believe that some of our products, such as the HART-Trachea, may be defined as combination products consisting of two or more regulated components, a biologic and a medical device. In the U.S., a combination product usually is assigned by the FDA to one of the agency's centers, such as the CBER or the CDRH with the chosen center to take the lead in pre-marketing review and approval of the combination product. Other FDA centers also may review the product in regard to matters that are within their expertise. The FDA selects the lead center based on an assessment of the combination product's "primary mode of action." Some products also may require approval or clearance from more than one FDA center.

To determine which FDA center or centers will review a combination product submission, companies may submit a Request for Designation to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation. We believe that regenerative medicine products containing cells will be reviewed by CBER, possibly with CBER's consultation with CDRH.

Domestic Regulation of Our Products and Business

The testing, manufacturing, and potential labeling, advertising, promotion, distribution, import and marketing of our products are subject to extensive regulation by governmental authorities in the U.S. and in other countries. In the U.S., the FDA, under the Public Health Service Act, the Federal Food, Drug and Cosmetic Act, and its implementing

regulations, regulates biologics and medical device products.

The labeling, advertising, promotion, marketing and distribution of biopharmaceuticals, or biologics and medical devices also must be in compliance with the FDA and U.S. Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions and criminal prosecution. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice.

The FDA has broad post-market and regulatory enforcement powers. Manufacturers of biologics and medical devices are subject to unannounced inspections by the FDA to determine compliance with applicable regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by manufacturers or their suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities. Potential FDA enforcement actions include:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- operating restrictions;
- refusal to grant export approval for our products; or
- criminal prosecution.

In addition, other government authorities influence the success of our business, including the availability of adequate reimbursement from third party payors, including government programs such as Medicare and Medicaid. Medicare and Medicaid reimbursement policies can also influence corresponding policies of private insurers and managed care providers, which can further affect our business.

Biologics Regulation

Biological products must satisfy the requirements of the Public Health Services Act and the Food, Drug and Cosmetics Act and their implementing regulations. In order for a biologic product to be legally marketed in the U.S., the product must have a BLA approved by the FDA.

The BLA Approval Process

The steps for obtaining FDA approval of a BLA to market a biopharmaceutical, or biologic product in the U.S. include:

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's GLP regulations;

- submission to the FDA of an IND application, for human clinical testing, which must become effective before human clinical trials may begin and which must include Institutional Review Board, or IRB, approval at each clinical site before the trials may be initiated;

- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices, or GCP, to establish the safety and efficacy of the product for each indication;

- submission to the FDA of a BLA, which contains detailed information about the chemistry, manufacturing and controls for the product, extensive pre-clinical information, reports of the outcomes of the clinical trials, and proposed labeling and packaging for the product;

- the FDA's acceptance of the BLA for filing;

- satisfactory review of the contents of the BLA by the FDA, including the satisfactory resolution of any questions raised during the review or by the advisory committee, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with Current Good Manufacturing Practice ("cGMP") regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality and purity; and

- FDA approval of the BLA.

Preclinical studies include laboratory evaluations of product toxicity, as well as animal studies.

An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed.

Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to GCP. Adverse events must be reported and investigated timely. To conduct a clinical trial, a company is also required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. The sponsor, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to trial subjects outweigh the anticipated benefits. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each site at which the trial is conducted must approve the protocol and any amendments. If foreign clinical trials are intended to be considered by the FDA for approval of a product in the U.S. then those foreign clinical trials performed under an IND must meet the same requirements that apply to U.S. studies. The FDA will accept a foreign clinical trial not conducted under an IND only if the trial is well-designed, well-conducted, performed by qualified investigators in accordance with international principles for GCP, or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects. The FDA, however, has substantial discretion in deciding whether to accept data from foreign non-IND clinical trials.

Clinical trials involving biopharmaceutical products are typically conducted in three sequential phases. The phases may overlap or be combined. A fourth, or post-approval, phase may include additional clinical trials. These phases are described generally below. We note, however, that the exact number of study subjects required for each specific

intended use, and our intent to combine or “telescope” various study phases together, are both areas where we will actively seek FDA feedback to streamline the clinical evaluation process. Briefly, the phases of clinical development generally include the following:

- Phase I. Phase I clinical trials involve the initial introduction of the product into human subjects to determine the adverse effects associated with increasing doses. Such Phase I studies frequently are highly abbreviated or combined with Phase II studies (as outlined below), when the product involves the patient’s own cells.

- Phase II. Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the product for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Products that contain the patient’s own cells frequently are studied for initial safety and effectiveness determinations in combined or “telescoped” Phase I/II clinical studies.

- Phase III. If the product is found to be potentially effective and to have an acceptable safety profile in Phase II (or sometimes Phase I) trials, the clinical trial program will be expanded to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites. As noted, the exact number of subjects needed, the duration of clinical follow-up, and the endpoints by which safety and efficacy are demonstrated are based on the condition being treated.

- Post-Approval (Phase IV). Post-approval clinical trials are required of or agreed to by a sponsor as a condition of, or subsequent to marketing approval. Further, if the FDA becomes aware of new safety information about an approved product, it is authorized to require post approval trials of the biological product. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as Phase III/IV post approval clinical trials. Failure to promptly conduct Phase IV clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

Clinical testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA or the sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request that additional pre-clinical studies or clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, IRBs have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

Certain information about clinical trials, including a description of the trial, participation criteria, location of trial sites, and contact information, is required to be sent to the NIH for inclusion in a publicly-assessable database. Sponsors also are subject to certain state laws imposing requirements to make publicly available certain information on clinical trial results. In addition, the FDA Amendments Act of 2007 directs the FDA to issue regulations that will require sponsors to submit to the NIH the results of certain controlled clinical trials, other than Phase I studies.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the chemistry, manufacture and composition of the product, are submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. In most cases, the BLA must be accompanied by a substantial user fee. The FDA will initially review the BLA for completeness before it accepts the BLA for filing. There can be no assurance that the submission will be accepted for filing or that the FDA may not issue a refusal-to-file, or RTF. If a RTF is issued, there is opportunity for dialogue between the sponsor and the FDA in an effort to resolve all concerns. If the BLA submission is accepted for filing, the FDA will begin an in-depth review of the BLA to determine, among other things, whether a product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity.

Companies also may seek fast track designation for their products. Fast track products are those that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical

needs for such a condition. If awarded, the fast track designation applies to the product only for the indication for which the designation was received. Fast track products are eligible for two means of potentially expediting product development and FDA review of BLAs. First, a fast track product may be approved on the basis of either a clinical endpoint or a surrogate endpoint that is reasonably likely to predict clinical benefit. Approvals of this kind may be subject to requirements for appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the effect on the clinical endpoint, and to certain other conditions. Second, if the FDA determines after review of preliminary clinical data submitted by the sponsor that a fast track product may be effective, it may begin review of portions of a BLA before the sponsor submits the complete BLA, thereby accelerating the date on which review of a portion of the BLA can begin. There can be no assurance that any of our other products will receive designation as fast track products. And even if they are designated as fast track products, we cannot assure you that our products will be reviewed or approved more expeditiously for their fast track indications than would otherwise have been the case or will be approved promptly, or at all. Furthermore, the FDA can revoke fast track status at any time.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-approval clinical trials to verify and further define the product's clinical benefit and safety profile. There can be no assurance that any of our products will receive accelerated approval. Even if accelerated approval is granted, the FDA may withdraw such approval if the sponsor fails to conduct the required post-approval clinical trials, or if the post-approval clinical trials fail to confirm the early benefits seen during the accelerated approval process.

Fast track designation and accelerated approval should be distinguished from priority review although products awarded fast track status may also be eligible for priority review. Products regulated by the CBER may receive priority review if they provide significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. Products awarded priority review are given abbreviated review goals by the agency. Under the Prescription Drug User Fee Act of 2007, the agency has agreed to the performance goal of reviewing products awarded priority review within six months, whereas products under standard review receive a ten-month target. The review process, however, is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. Priority review is requested at the time the BLA is submitted, and the FDA makes a decision as part of the agency's review of the application for filing. If the HART-Trachea is regulated as a biologic through the BLA process, we intend to seek priority review. We cannot guarantee that the FDA will grant the designation and cannot predict if awarded, what impact, if any, it will have on the review time for approval of our product.

If granted, fast track designation, accelerated approval, and priority review may expedite the approval process, but they do not change the standards for approval.

Before approving a BLA, the FDA will generally inspect the facility or the facilities at which the finished product and its components are manufactured to ensure compliance with cGMP.

Separate approval is required for each proposed indication. If we want to expand the use of an approved product, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from

marketing our products. The FDA may limit the indications for use or place other conditions, such as post approval studies, on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

After regulatory approval of a product is obtained, companies are required to comply with a number of post-approval requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. For example, as a condition of approval of a BLA, the FDA may require post-approval testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved BLA are required to keep extensive records, to report certain adverse reactions and production deviations and problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Specifically, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death. In addition, the FDA could suspend the marketing of or withdraw a previously approved product from the market upon receipt of newly discovered information regarding the product's safety or effectiveness.

Orphan Drug Designations

In September 2014 the FDA granted orphan designation to our HART-Trachea product. The Orphan Drug Act provides incentives to manufacturers to develop and market drugs and biologics for rare diseases and conditions affecting fewer than 200,000 persons in the U.S. at the time of application for orphan drug designation, or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a new drug application, or NDA, or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. The first developer to receive FDA marketing approval for an orphan biologic is entitled to a seven year exclusive marketing period in the U.S. for that product as well as a waiver of the BLA user fee. The exclusivity prevents FDA approval of another application for the same product for the same indication for a period of seven years, except in limited circumstances where there is a change in formulation in the original product and the second product has been proven to be clinically superior to the first.

International

We plan to seek required regulatory approvals and comply with extensive regulations governing product safety, quality, manufacturing and reimbursement processes in order to market our products in other major foreign markets. The regulation of our products in the EU and in other foreign markets varies significantly from one jurisdiction to another. The classification of the particular products and related approval or CE marking procedures can involve additional product testing and additional administrative review periods. The time required to obtain these foreign approvals or to CE mark our products may be longer or shorter than that required in the U.S., and requirements for approval may differ from the FDA requirements. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

The marketing authorization of products containing viable human tissues or cells in the EU is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European parliament and of the Council, commonly known as the Community code on medicinal products. Regulation

1394/2007/EC lays down specific rules concerning the authorization, supervision and pharmacovigilance of medicinal products, cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the European Medicines Agency which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the European Medicines Agency. Regulation 1394/2007/EC also applies to combination products which consist of medical devices and advanced therapy medicinal products. In light of Regulation 1394/2007/EC, a medical device which forms part of a combined advanced therapy medicinal product must meet the Essential Requirements laid down in Annex I to Directive 93/42/EEC. The manufacturer of the combination product must include evidence of such compliance in its marketing authorization application. The application for a marketing authorization for a combined advanced therapy medicinal product must also, where available, include the results of the assessment of the medical device part by a notified body in accordance with Directive 93/42/EEC.

Legislation similar to the Orphan Drug Act has been enacted in other jurisdictions, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons. The marketing exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Employees

At December 31, 2014, we had 25 employees working in our business, of whom 24 are full-time and 1 is part-time. At that date, twenty two of our employees were based in the U.S., one in Germany and two in Sweden. None of our employees are unionized. In general, we consider our relations with our employees to be good.

Competition

We are not aware of any companies whose products are directly competitive with our bioreactor and scaffold system. However, in our key markets we may in the future compete with multiple pharmaceutical, biotechnology, medical device and scientific research instrument companies, including, among others, Aastrom Biosciences, Advanced Cell Technology, Aldagen, Athersys, BioTime, Baxter International, Inc., Bose Corporation, Celgene, Cytori Therapeutics, E. I. du Pont de Nemours and Company, Harvest Technologies, InVivo Therapeutics, Mesoblast, Miramatrix Medical, Nanofiber Solutions, NeoStem, Neuralstem, Organovo, Osiris Therapeutics, Pleuristem, Smiths Medical, Tissue Genesis, Inc., Tissue Growth Technologies (acquired by Instron), Transmedics, United Therapeutics and W.L. Gore and Associates. In addition, there are many academic and clinical centers that are developing regenerative technologies that may one day become competitors for us.

Many of our potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. We cannot forecast if or when these or other companies may develop competitive products.

We expect that other products will compete with products and potential products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include, in certain instances, obtaining marketing exclusivity under the Orphan Drug Act, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage.

Executive Officers of the Registrant

The following table shows information about our executive officers as of December 31, 2014.

Name	Age	Position(s)

David Green	50	President, Chief Executive Officer and Chairman of the Board of Directors
Thomas McNaughton	54	Chief Financial Officer

David Green — President, Chief Executive Officer, and Chairman

Mr. Green has served as our President, Chief Executive Officer, and Chairman of our Board of Directors since May 3, 2012. Mr. Green was also the President and a member of the Board of Directors of Harvard Bioscience from March 1996 and its CEO from May 2013, until the spinoff of our company from Harvard Bioscience on November 1, 2013. Mr. Green remains a director of Harvard Bioscience but no longer holds an executive position at Harvard Bioscience. Mr. Green's previous experiences include working as a strategy consultant with Monitor Company, a strategy consulting company, in Cambridge, Massachusetts and Johannesburg, South Africa from June 1991 until September 1995 and a brand manager for household products with Unilever PLC, a packaged consumer goods company, in London from September 1985 to February 1989. Mr. Green currently sits on the Advisory Board of the Harvard Business School Healthcare Initiative. Mr. Green graduated from Oxford University with a B.A. Honors degree in physics and holds a M.B.A. degree with distinction from Harvard Business School.

We believe Mr. Green's qualifications to sit on our Board of Directors include his executive leadership experience, his experience founding the regenerative medicine business at Harvard Bioscience, his significant operating and management expertise and the knowledge and understanding of our company that he has acquired over 16 years of service as the President, CEO and director of Harvard Bioscience.

Mr. Green's employment at Harvard Bioscience ended after the completion of the Distribution.

Thomas McNaughton — Chief Financial Officer

Mr. McNaughton has served as our Chief Financial Officer since May 3, 2012. Mr. McNaughton joined Harvard Bioscience as its Chief Financial Officer in November 2008, and served in that role until the spin-off of our company from Harvard Bioscience on November 1, 2013. During 2008 and prior to joining Harvard Bioscience, Mr. McNaughton was a consultant providing services primarily to an angel-investing group and a silicon manufacturing start-up. From 2005 to 2007, he served as Vice President of Finance and Chief Financial Officer for Tivoli Audio, LLC, a venture capital-backed global manufacturer of premium audio systems. From 1990 to 2005, Mr. McNaughton served in various managerial positions in the areas of financial reporting, treasury, investor relations, and acquisitions within Cabot Corporation, a global manufacturer of fine particulate products, and served from 2002 to 2005 as Finance Director, Chief Financial Officer of Cabot Supermetals, a $350 million Cabot division that provided high purity tantalum and niobium products to the electronics and semiconductor industries. Mr. McNaughton practiced from 1982 to 1990 as a Certified Public Accountant in the audit services group of Deloitte & Touche, LLP. He holds a B.S. in accounting and finance with distinction from Babson College.

Available Information and Website

Our website address is *www.harvardapparatusregen.com* . Our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and exhibits and amendments to those reports filed or furnished with the Securities and Exchange Commission pursuant to Section 13(a) of the Exchange Act are available for review on our website and the Securities and Exchange Commission's ("SEC") website at www.sec.gov. Any such materials that we file with, or furnish to, the SEC in the future will be available on our website as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information on our website is not incorporated by reference into this Annual Report on Form 10-K.

Item 1A. ***Risk Factors.***

The following factors should be reviewed carefully, in conjunction with the other information contained in this Annual Report on Form 10-K. As previously discussed, our actual results could differ materially from our forward-looking statements. Our business faces a variety of risks. We describe below what we believe are currently the material risks and uncertainties we face, but they are not the only risks and uncertainties we face. Additional risks and uncertainties of which we are unaware, or that we currently believe are not material, may also become important factors that adversely affect our business. In addition, past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods. If any of the following risks and uncertainties develops into actual events, these events could have a material adverse effect on our business, financial condition or results of operations. In such case, the trading price of our common stock could decline. The risk factors generally have been separated into three groups: (i) risks relating to our business, (ii) risks relating to the Separation and (iii) risks relating to our common stock. These risk factors should be read in conjunction with the other information in this Annual Report on Form 10-K.

Risks Relating to Our Business

Risks Associated with Regulatory Clearances and Approvals

If we fail to obtain, or experience significant delays in obtaining, regulatory clearances or approvals in the U.S. and the EU for our products, or are unable to maintain such clearances or approvals for our products, our ability to commercially distribute and market these products would suffer.

We currently do not have regulatory approval to market any of our products. Our products are subject to rigorous regulation by the FDA, and numerous other federal and state governmental authorities in the U.S., as well as foreign governmental authorities. In the U.S., the FDA permits commercial distribution of new medical products only after approval of a premarket approval application, or PMA, or biologics license application, or BLA, unless the product is specifically exempt from those requirements. A PMA or BLA must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use. There are similar approval processes in the EU and other foreign jurisdictions. Our failure to receive or obtain such clearances or approvals on a timely basis or at all would have an adverse effect on our results of operations.

The FDA has informed us that our HART-Trachea product will be viewed by the FDA as a combination product comprised of a biologic (cells) and medical device component. We cannot be sure how the FDA will regulate our products. The FDA may require us to obtain marketing clearance and approval from multiple FDA centers. The review of combination products is often more complex and more time consuming than the review of products under the jurisdiction of only one center within the FDA.

The FDA has informed us that the HART-Trachea will be regulated by the FDA as a combination product. For a combination product, the Office of Combination Products, or OCP, within FDA can determine which center or centers within the FDA will review the product and under what legal authority the product will be reviewed. Generally, the center within the FDA that has the primary role in regulating a combination product is determined based on the primary mode of action of the product. Generally, if the primary mode of action is as a device, then the Center for Devices and Radiological Health, or CDRH, takes the lead. Generally, if the primary mode of action is cellular, then the Center for Biologics Evaluation and Research takes the lead. On August 29, 2013, we received written confirmation from FDA's Office of Combination Products that FDA intends to regulate the HART-Trachea as a combination product under the primary jurisdiction of the Center for Biologics Evaluation and Research, or CBER. We further understand that CBER may choose to consult or collaborate with CDRH with respect to the characteristics of the synthetic scaffold component of the HART-Trachea based on CBER's determination of need for such assistance.

Although we have received this written response from the FDA, the process of obtaining FDA marketing approval is lengthy, expensive, and uncertain, and we cannot be sure that our products will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often more complex and can be more time consuming than the review of a product under the jurisdiction of only one center within the FDA.

We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only one FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be more lengthy and costly.

If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

In the EU, our HART-Trachea will likely be regulated as a combined advanced therapy medicinal product and our other products may also be viewed as advanced therapy medicinal products, which could delay approvals and clearances and increase costs of obtaining such approvals and clearances.

On May 28, 2014, we received notice from the European Medicines Agency that the HART-trachea would be regulated as a combined advanced therapy medicinal product. Based on such classification, it will be necessary to seek a marketing authorization for these products granted by the European Commission before being marketed in the EU.

Other products we may develop may similarly be regulated as advanced therapy medicinal products or combined advanced therapy medicinal products. The regulatory procedures leading to marketing approval of our products vary among jurisdictions and can involve substantial additional testing. Compliance with the FDA requirements does not ensure clearance or approval in other jurisdictions, and the ability to legally market our products in any one foreign country does not ensure clearance, or approval by regulatory authorities in other foreign jurisdictions. The foreign regulatory process leading to the marketing of the products may include all of the risks associated with obtaining FDA approval in addition to other risks. In addition, the time required to comply with foreign regulations and market products may differ from that required to obtain FDA approval, and we may not obtain foreign approval or clearance on a timely basis, if at all.

Risks Associated with Clinical Trials and Pre-Clinical Development

Clinical trials necessary to support a BLA license or other marketing authorization for our products will be expensive and will require the enrollment of sufficient patients to adequately demonstrate safety and effectiveness for the product's target populations. Suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any products and will adversely affect our business, operating results and prospects.

In the U.S., initiating and completing clinical trials necessary to support either BLA licenses or PMA applications, will be time consuming, expensive and the outcome uncertain. Moreover, the FDA may not agree that clinical trial results support an application for the indications sought in the application for the product. In other jurisdictions such as the EU, the conduct of extensive and expensive clinical trials may also be required in order to demonstrate the quality, safety and efficacy of our products, depending on each specific product, the claims being studied, and the target condition or disease. The outcome of these clinical trials, which can be expensive and are heavily regulated, will also be uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical trials will require the enrollment of a sufficient number of patients to support each trial's claims, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomfort and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products, or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomfort. Also, patients may not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA and foreign regulatory authorities may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA and foreign regulatory authorities may not consider our data adequate to demonstrate safety and efficacy. Although FDA regulations allow submission of data from clinical trials outside the U.S., there can be no assurance that such data will be accepted or that the FDA will not apply closer scrutiny to such data. Increased costs and delays necessary to generate appropriate data, or failures in clinical trials could adversely affect our business, operating results and prospects. In the U.S., clinical studies for our products will be reviewed through the Investigational New Drug, or IND, pathway for biologics or combination products. The first regenerated trachea transplant approved in the U.S. using the HART-Trachea was approved under the IND pathway through CBER for a compassionate use. In the second half of 2014, allegations that Dr. Macchiarini had failed to obtain informed consent and accurately report patient conditions, among other things, for surgeries performed at the Karolinska Institutet in Stockholm, Sweden, were made public. One of these three surgeries used a HART-Trachea. The Karolinska Institutet reported that it was investigating the allegations. In the event that any of these allegations are determined to be accurate, including a misrepresentation having occurred of the post-surgery condition of certain patients who received trachea transplants, whether using our HART-Trachea or a scaffold manufactured by a third-party, it may harm the perception of our product or company and make it difficult to recruit patients for a clinical trail.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We do not have the ability to independently conduct our preclinical and clinical trials for our products and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials, including data collection and analysis. We do not have direct control over such third parties' personnel or operations. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these 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 seek or obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all. Our business, operating results and prospects may also be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The results of our clinical trials or pre-clinical development efforts may not support our product claims or may result in the discovery of adverse side effects.

Even if our pre-clinical development efforts or clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that the FDA, foreign competent authorities or notified bodies will agree with our conclusions regarding them. Although we have obtained some positive results from the use of our scaffolds and bioreactors for trachea transplants performed to date, we may not see positive results when the bioreactors, or our scaffolds or other technologies undergo clinical testing in humans in the future. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our products are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Also, patients receiving transplants using our products as compassionate use or in clinical trails may experience significant adverse events following the transplants, including serious health complications or death, which may or may not be related to our products, and any such adverse events may cause the delay or termination of our clinical trials or pre-clinical development efforts. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our products and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product's profile. In addition, our current clinical experience and clinical trial for trachea transplant involves a small patient population. Because of the small sample size, the results may not be indicative of future results.

Risk Associated with Product Marketing

Even if our products are cleared or approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval in the U.S. or the EU, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory authorities or notified bodies. In particular, we and our suppliers are required to comply with the FDA's Quality System Regulations, or QSR, and Good Manufacturing Practices, or GMPs, for our medical products, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Manufacturing may also be subject to controls by the FDA for parts of the system or combination products that the FDA may find are controlled by the biologics regulations. Equivalent regulatory obligations apply in foreign jurisdictions. Regulatory authorities, such as the FDA, the competent authorities of the EU Member States, the European Medicines Agency and notified bodies, enforce the QSR, GMP and other applicable regulations in the U.S. and in foreign jurisdictions through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory authorities or notified bodies in the U.S. or in foreign jurisdictions, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- withdrawing BLA approvals or PMAs that have already been granted;
-

withdrawal of the marketing authorization granted by the European Commission or delay in obtaining such marketing authorization;

- withdrawal of the CE Certificates of Conformity granted by the notified body or delay in obtaining these certificates;
- refusal to grant export approval for our products; and
- criminal prosecution.

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Postmarket enforcement actions can generate adverse commercial consequences.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA or a foreign regulatory authority determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical products reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Extensive governmental regulations that affect our business are subject to change, and we could be subject to penalties and could be precluded from marketing our products and technologies if we fail to comply with new regulations and requirements.

As a manufacturer and marketer of biotechnology products, we are subject to extensive regulation that is subject to change. In March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA, which may have far-reaching consequences for most healthcare companies, including biotechnology companies. The PPACA could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, laboratory tests, drugs and devices. These structural changes, as well as those relating to proposals that may be made in the future to change the health care system, could entail modifications to the existing system of private payers and government programs, as well as implementation of measures to limit or eliminate payments for some medical procedures and treatments or subject the pricing of 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 regulatory authorities have granted marketing approval. Governments may adopt future legislative proposals and federal, state, foreign or private payers for healthcare goods and services may take action to limit their payments for goods and services.

Any of these regulatory changes and events could limit our ability to form collaborations and our ability to commercialize our products, and if we fail to comply with any such new or modified regulations and requirements it could adversely affect our business, operating results and prospects.

If we fail to complete the required IRS forms for exemptions, make timely semi-monthly payments of collected excise taxes, or submit quarterly reports as required by the Medical Device Excise Tax, we may be subject to penalties, such as Section 6656 penalties for any failure to make timely deposits.

Section 4191 of the Internal Revenue Code, enacted by Section 1405 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)), in conjunction with the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), imposed as of January 1, 2013, an excise tax on the sale of certain medical devices. The excise tax imposed by Section 4191 is 2.3% of the price for which a taxable medical device is sold within the U.S.

The excise tax will apply to future sales of any company medical device listed with the FDA under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. We will need to assess to what extent this excise tax may impact the sales price and distribution agreements under which any of our products are sold in the U.S. We also expect general and administrative expense to increase due to the medical device excise tax. We will need to submit IRS forms applicable to relevant exemptions, make semi-monthly payments of any collected excise taxes, and make timely (quarterly) reports to the IRS regarding the excise tax. To the extent we do not comply with the requirements of the Medical Device Excise Tax we may be subject to penalties.

Financial and Operating Risks

We will need additional funds in the near future and our operations will be adversely affected if we are unable to raise or obtain needed funding.

We believe that our existing cash resources will be sufficient to fund our planned operations through June 2016. Our cash requirements and cash resources will vary significantly depending upon the timing, financial and other resources that will be required to complete ongoing development and clinical testing of our products as well as regulatory efforts and collaborative arrangements necessary for our products that are currently under development. In addition to development and other costs, we expect to incur capital expenditures from time to time. These capital expenditures will be influenced by our regulatory compliance efforts, our success, if any, at developing collaborative arrangements with strategic partners, our needs for additional facilities and capital equipment and the growth, if any, of our business in general. We may seek to raise necessary funds through public or private equity offerings, debt financings, other financing mechanisms, strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. Restrictions pertaining to our separation from Harvard Bioscience and tax-free treatment thereof will severely limit the amount of shares we may issue in any offering through November 1, 2015. In addition, general market conditions may make it very difficult for us to seek financing from the capital markets.

Additional equity financing could result in significant dilution to our stockholders and possible restrictions on subsequent financings. Debt financing, if available, could result in agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or paying dividends. Other financing mechanisms may involve selling intellectual property rights, payment of royalties or participation in our revenue or cash flow. In addition, in order to raise additional funds through strategic collaborations or licensing arrangements, we may be required to relinquish rights to our technologies or products. If we cannot raise funds or engage strategic partners on acceptable terms when needed, we may not be able to continue our research and development activities, develop or enhance our products, take advantage of future opportunities, grow our business or respond to competitive pressures or unanticipated requirements.

We have generated insignificant revenue to date and have a history of losses since inception. We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability.

We have generated insignificant revenues to date and we have generated no revenues from sale of the HART-Trachea. From February 24, 2009, our business's inception, through December 31, 2014, we have incurred losses of approximately $32.3 million. We expect to continue to experience losses in the foreseeable future due to our limited anticipated revenues and significant anticipated expenses. We do not anticipate that we will achieve meaningful revenues for the foreseeable future. In addition, we expect that we will continue to incur significant operating expenses as we continue to focus on additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals of our products and technologies. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

Our products are in an early stage of development. If we are unable to develop or market any of our products, our financial condition will be negatively affected, and we may have to curtail or cease our operations.

We are in the early stage of product development. One must evaluate us in light of the uncertainties and complexities affecting an early stage biotechnology company. Our products require additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals or clearances before marketing. In addition, we may not succeed in developing new products as an alternative to our existing portfolio of products. If we fail to successfully develop and commercialize our products, including our HART-Trachea, our financial condition may be negatively affected, and we may have to curtail or cease our operations.

We have a limited operating history and it is difficult to predict our future growth and operating results.

We have a limited operating history and limited operations and assets. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties encountered by companies in the early stage of development. As a development stage company, our development timelines have been and may continue to be subject to delay that could negatively affect our cash flow and our ability to develop or bring products to market, if at all. Our estimates of patient population are based on published data and analysis of external databases by third parties and are subject to uncertainty and possible future revision as they often require inference or extrapolations from one country to another or one patient condition to another.

Our prospects must be considered in light of inherent risks, expenses and difficulties encountered by all early stage companies, particularly companies in new and evolving markets, such as regenerative medicine and organ transplant. These risks include, but are not limited to, unforeseen capital requirements, delays in obtaining regulatory approvals, failure to gain market acceptance and competition from foreseen and unforeseen sources.

If we fail to retain key personnel, we may not be able to compete effectively, which would have an adverse effect on our operations.

Our success is highly dependent on the continued services of key management, technical and scientific personnel and collaborators. Our management and other employees may voluntarily terminate their employment at any time upon short notice. The loss of the services of any member of our senior management team, including our Chief Executive Officer and President, David Green, our Chief Financial Officer, Thomas McNaughton, our Chief Medical Officer, Dr. Saverio La Francesca, and our other key scientific, technical and management personnel, may significantly delay or prevent the achievement of product development and other business objectives.

If our collaborators do not devote sufficient time and resources to successfully carry out their duties or meet expected deadlines, we may not be able to advance our products in a timely manner or at all.

We are currently collaborating with multiple academic researchers and clinicians at a variety of research and clinical institutions. Our success depends in part on the performance of our collaborators. Some collaborators may not be successful in their research and clinical trials or may not perform their obligations in a timely fashion or in a manner satisfactory to us. Typically, we cannot control the amount of resources or time our collaborators may devote to our programs or potential products that may be developed in collaboration with us. Our collaborators frequently depend on outside sources of funding to conduct or complete research and development, such as grants or other awards. In addition, our academic collaborators may depend on graduate students, medical students, or research assistants to conduct certain work, and such individuals may not be fully trained or experienced in certain areas, or they may elect to discontinue their participation in a particular research program, creating an inability to complete ongoing research in a timely and efficient manner. As a result of these uncertainties, we are unable to control the precise timing and execution of any experiments that may be conducted.

We do not have formal agreements in place with most of our collaborators, who retain the ability to pursue other research, product development or commercial opportunities that may be directly competitive with our programs. If these collaborators elect to prioritize or pursue other programs in lieu of ours, we may not be able to advance product development programs in an efficient or effective manner, if at all. If a collaborator is pursuing a competitive program and encounters unexpected financial or capability limitations, they may be motivated to reduce the priority placed on our programs or delay certain activities related to our programs. Any of these developments could harm or slow our product and technology development efforts.

Public perception of ethical and social issues surrounding the use of cell technology may limit or discourage the use of our technologies, which may reduce the demand for our products and technologies and reduce our revenues.

Our success will depend in part upon our collaborators' ability to develop therapeutic approaches incorporating, or discovered through, the use of cells. If regenerative medicine technology is perceived negatively by the public for social, ethical, medical or other reasons, governmental authorities in the U.S. and other countries may call for prohibition of, or limits on, cell-based technologies and other approaches to regeneration. Although the surgeons using our products have not to date used the more controversial stem cells derived from human embryos or fetuses in the human transplant surgeries using our products, claims that human-derived stem cell technologies are ineffective or unethical may influence public attitudes. The subject of cell and stem cell technologies in general has received negative publicity and aroused public debate in the U.S. and some other countries. Ethical and other concerns about such cells could materially harm the market acceptance of our products.

Our products will subject us to liability exposure.

We face an inherent risk of product liability claims, especially with respect to our products that will be used within the human body, including the scaffolds we manufacture. Product liability coverage is expensive and sometimes difficult to obtain. We may not be able to obtain or maintain insurance at a reasonable cost. We may be subject to claims for liabilities for unsuccessful outcomes of surgeries involving our products, which may include claims relating to patient death. We may also be subject to claims for liabilities relating to patients that suffer serious complications or death during or following transplants involving our products. Our current product liability coverage is $15 million per occurrence and in the aggregate. We will need to increase our insurance coverage if and when we begin commercializing any of our products. 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. If claims against us substantially exceed our coverage, then our business could be adversely impacted. Regardless of whether we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in, among others:

- significant awards against us;
- substantial litigation costs;
- injury to our reputation and the reputation of our products;
- withdrawal of clinical trial participants; and
- adverse regulatory action.

Any of these results would substantially harm our business.

If restrictions on reimbursements or other conditions imposed by payers limit our customers' actual or potential financial returns on our products, our customers may not purchase our products or may reduce their purchases.

Our customers' willingness to use our products will depend in part on the extent to which coverage for these products is available from government payers, private health insurers 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 treatments and products in the regenerative medicine field, and coverage and adequate payments may not be available for these treatments and products. In addition, third-party payers may require additional clinical trial data to establish or continue reimbursement coverage. These clinical trials, if required, could take years to complete and could be expensive. There can be no assurance that the payers will agree to continue reimbursement or provide additional coverage based upon these clinical trials. Failure to obtain adequate reimbursement would result in reduced sales of our products.

We depend upon a single-source supplier for the hardware used for our organ bioreactor control and acquisition system. The loss of this supplier, or future single-source suppliers we may rely on, or their failure to provide us with an adequate supply of their products or services on a timely basis, could adversely affect our business.

We currently have a single supplier for the hardware that we use for our organ bioreactor control and acquisition systems. We may also rely on other single-source suppliers for critical components of our products in the future. If we were unable to acquire hardware or other products or services from applicable single-source suppliers, we could experience a delay in developing and manufacturing our products.

We use and generate hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research, development and manufacturing involve the controlled use of hazardous chemicals, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. For example, certain volatile organic laboratory chemicals we use, such as fluorinated hydrocarbons, must be disposed of as hazardous waste. We are subject to laws and regulations enforced by the FDA, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our products, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, our operations could be interrupted. Further, we could be held liable for any damages that result and any such liability could exceed our resources.

Our products are novel and will require market acceptance.

Even if we receive regulatory approvals for the commercial use of our products, their commercial success will depend upon acceptance by physicians, patients, third party payers such as health insurance companies and other members of the medical community. Market acceptance of our products is also dependent upon our ability to provide acceptable evidence and the perception of the positive characteristics of our products relative to existing or future treatment methods, including their safety, efficacy and/or other positive advantages. If our products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. If our products do not become widely accepted, our business, financial condition and results of operations would be materially and adversely affected.

Our long-term growth depends on our ability to develop products for other organs.

Our growth strategy includes expanding the use of our products in treatments pertaining to organs other than the trachea, such as the esophagus, lungs, heart valves and heart. These other organs are more complex than the trachea. There is no assurance that we will be able to successfully apply our technologies to these other more complex organs, which will limit our expected growth.

Our success will depend partly on our ability to operate without infringing on, or misappropriating, the intellectual property or confidentiality rights of others.

We may be sued for infringing on the intellectual property or confidentiality rights of others, including the patent rights, trademarks and trade names and confidential information of third parties. For example, we have sublicensed certain rights pertaining to our use of the mark Harvard Apparatus from Harvard Bioscience, including the use in our corporate name. Harvard Bioscience has licensed the rights to such mark from Harvard University. If the license to Harvard Bioscience or our sublicense were terminated, it could have an adverse effect on us. We have also received correspondence from legal counsel to Nanofiber Solutions, Inc., or NFS, claiming that in developing our scaffold product and related intellectual property, we may have committed misappropriation, unauthorized use and disclosure of confidential information, and possible infringement of intellectual property rights of NFS. We have received correspondence from legal counsel to UCL Business PLC, or UCLB, challenging the validity of the assignment of certain patent applications that have been assigned to us by Dr. Macchiarini. We have also received correspondence from an academic researcher implying that one of our products may violate an issued patent. We do not believe that our current products violate this patent. To the extent that any of such claims are valid, if we had utilized, or were to utilize, such patent applications or patents without an agreement from the owner thereof, it could result in infringement of the intellectual property rights of the respective owner. Intellectual property and related litigation is costly and the outcome is uncertain. If we do not prevail in any such intellectual property or related litigation, in addition to any damages we might have to pay, we could be required to stop the infringing activity, or obtain a license to or design around the intellectual property or confidential information in question. If we are unable to obtain a required license on acceptable terms, or are unable to design around any third party patent, we may be unable to sell some of our products and services, which could result in reduced revenue.

We may be involved in lawsuits to protect or enforce our patents that would be expensive and time consuming.

In order to protect or enforce our patent rights, we may initiate patent litigation against third parties. We may also become subject to interference proceedings conducted in the patent and trademark offices of various countries to determine the priority of inventions. The defense and prosecution, if necessary, of intellectual property suits, interference proceedings and related legal and administrative proceedings would be costly, and may divert our technical and management personnel from their normal responsibilities. We may not prevail in any of these suits

should they occur. An adverse determination of any litigation or defense proceedings could put our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of being rejected and patents not being issued.

Furthermore, because of the substantial amount of discovery required 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. For example, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments in the litigation. Securities analysts or investors may perceive these announcements to be negative, which could cause the market price of our stock to decline.

If we are unable to effectively protect our intellectual property, third parties may use our technology, which would impair our ability to compete in our markets.

Our continued success will depend significantly on our ability to obtain and maintain meaningful patent protection for certain of our products throughout the world. Patent law relating to the scope of claims in the regenerative medicine and medical device fields in which we operate is still evolving. The degree of future protection for our proprietary rights is uncertain. We may rely on patents to protect a significant part of our intellectual property and to enhance our competitive position. However, our presently pending or future patent applications may not be accepted and patents might not be issued, and any patent previously issued to us may be challenged, invalidated, held unenforceable or circumvented. Furthermore, the claims in patents which have been issued or which may be issued to us in the future may not be sufficiently broad to prevent third parties from producing competing products similar to our products. We may also operate in countries where we do not have patent rights and in those countries we would not have patent protection. We also rely on trademarks and trade names in our business. The laws of various foreign countries in which we compete may not protect our intellectual property to the same extent as do the laws of the U.S. If we fail to obtain adequate patent protection for our proprietary technology, our ability to be commercially competitive could be materially impaired. It is also possible that our intellectual property may be stolen via cyber-attacks or similar methods.

In addition to patent protection, we also rely on protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade-secrets and proprietary information, we generally seek to enter into confidentiality agreements with our employees, consultants and strategic partners upon the commencement of a relationship. However, we may not be able to obtain these agreements in all circumstances in part due to local regulations. In the event of unauthorized use or disclosure of this information, these agreements, even if obtained, may not provide meaningful protection for our trade-secrets or other confidential information. In addition, adequate remedies may not exist in the event of unauthorized use or disclosure of this information. The loss or exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our operating results, financial condition and future growth prospects.

Our competitors and potential competitors may have greater resources than we have and may develop products and technologies that are more effective or commercially attractive than our products and technologies or may develop competing relationships with our key collaborators.

We expect to compete with multiple pharmaceutical, biotechnology, medical device and scientific research product companies. Companies working in competing areas include, among others, Aastrom Biosciences, Advanced Cell Technologies, Aldagen, Athersys, BioTime, Baxter International, Inc., Bose Corporation, Celgene, Cytori Therapeutics, E. I. du Pont de Nemours and Company, Harvest Technologies, InVivo Therapeutics, Mesoblast, Miramatrix Medical, Nanofiber Solutions, NeoStem, Neuralstem, Organovo, Osiris Therapeutics, Pleuristem, Smiths Medical, Tissue Genesis, Inc., Tissue Growth Technologies (acquired by Instron), Transmedics, United Therapeutics and W.L. Gore and Associates. In addition, there are many academic and clinical centers that are developing regenerative technologies that may one day become competitors for us. Many of our competitors and potential

competitors have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. We cannot, with any accuracy, forecast when or if these companies are likely to bring regenerative medicine medical products to market for indications that we are also pursuing. Many of these potential competitors may be further along in the process of product development and also operate large, company-funded research and development programs.

We expect that other products will compete with our current and future products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include obtaining marketing exclusivity under certain regulations, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage. Our competitors may develop or market products that are more effective or commercially attractive than our current or future products and may also develop competing relationships with our key collaborators. In addition, we may face competition from new entrants into the field. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. The effects of any such actions of our competitors may have a material adverse effect on our business, operating results and financial condition.

If we do not successfully manage our growth, our business goals may not be achieved.

To manage growth, we will be required to continue to improve existing, and implement additional, operational and financial systems, procedures and controls, and hire, train and manage additional employees. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth and we may not be able to hire, train, retain, motivate and manage required personnel. Competition for qualified personnel in the biotechnology and regenerative medicine area is intense, and we operate in several geographic locations where labor markets are particularly competitive, including Boston, Massachusetts, where demand for personnel with these skills is extremely high and is likely to remain high. As a result, competition for qualified personnel is intense and the process of hiring suitably qualified personnel is often lengthy and expensive, and may become more expensive in the future. If we are unable to hire and retain a sufficient number of qualified employees or otherwise manage our growth effectively, our ability to conduct and expand our business could be seriously reduced.

We are exposed to a variety of risks relating to our international sales and operations, including fluctuations in exchange rates, local economic conditions and delays in collection of accounts receivable.

We intend to generate significant revenues outside the U.S. in multiple foreign currencies including Euros, British pounds, and in U.S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. For those foreign customers who purchase our products in U.S. dollars, currency fluctuations between the U.S. dollar and the currencies in which those customers do business may have a negative impact on the demand for our products in foreign countries where the U.S. dollar has increased in value compared to the local currency.

Since we have operations based outside the U.S. and we generate revenues and incur operating expenses in multiple foreign currencies, we experience currency exchange risk with respect to those foreign currency-denominated revenues and expenses. We cannot predict the consolidated effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export, laws regarding transactions in foreign countries, the U.S. Foreign Corrupt Practices Act and local anti-bribery and other laws regarding interactions with healthcare professionals. Among other things, these laws restrict, and in some cases prohibit, U.S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices in foreign countries.

Local economic conditions, legal, regulatory or political considerations, disruptions from strikes, the effectiveness of our sales representatives and distributors, local competition and changes in local medical practice could also affect our sales to foreign markets. Relationships with customers and effective terms of sale frequently vary by country, often with longer-term receivables than are typical in the U.S.

Risks Related Our To Separation From Harvard Bioscience

We have limited operating history as an independent company, and we may be unable to make the changes necessary to operate as an independent public company.

Prior to our separation from Harvard Bioscience on November 1, 2013, or the Separation, our business was operated by Harvard Bioscience as part of its broader corporate organization rather than as a stand-alone company. Harvard Bioscience assisted us by providing financing and certain corporate functions. On November 1, 2013, all of the shares of our common stock were distributed to the Harvard Bioscience stockholders, and we separated from Harvard Bioscience to become a separately traded public company. Following the Separation, Harvard Bioscience has been under no obligation to provide assistance to us other than certain the interim transitional services, such as accounting, benefits administration, payroll and information technology services, which were provided by Harvard Bioscience for the twelve months following the Separation. Because our business has not been operated as an independent company for a significance period of time, we cannot assure you that we will be able to continue to successfully implement the changes necessary to operate independently or that we will not incur additional costs operating independently that would have a negative effect on our business, results of operations or financial condition.

We may be unable to achieve some or all of the benefits that we expect to achieve from our separation from Harvard Bioscience.

As a stand-alone, independent public company, we believe that our business will benefit from, among other things, allowing our management to design and implement corporate policies and strategies that are based primarily on the characteristics of our business, allowing us to focus our financial resources wholly on our own operations and implement and maintain a capital structure designed to meet our own specific needs. By separating from Harvard Bioscience there is a risk that our company may be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Harvard Bioscience. We may not be able to achieve some or all of the benefits that we expect to achieve as a stand-alone, independent regenerative medicine company or such benefits may be delayed or may not occur at all. For example, there can be no assurance that analysts and investors will place a greater value on our company as a stand-alone regenerative medicine company than on our business as a part of Harvard Bioscience.

If the Separation and related distribution of all of the shares of our common stock by Harvard Bioscience, together with certain related transactions, does not qualify as a transaction that is generally tax-free for U.S. federal income tax purposes, Harvard Bioscience could be subject to significant tax liability and, in certain circumstances, we could be required to indemnify Harvard Bioscience for material taxes pursuant to indemnification obligations under the tax sharing agreement.

Harvard Bioscience has informed us that on June 28, 2013 it received a Supplemental Ruling to the Private Letter Ruling dated March 22, 2013 from the IRS to the effect that, among other things, the Separation and related distribution of all of the shares of our common stock by Harvard Bioscience, or the Distribution, will qualify as a transaction that is tax-free for U.S. federal income tax purposes under Section 355 and 368(a)(1)(D) of the Internal Revenue Code continuing in effect. The private letter and supplemental rulings and the tax opinion that Harvard Bioscience received from Burns & Levinson LLP, special counsel to Harvard Bioscience, rely on certain representations, assumptions and undertakings, including those relating to the past and future conduct of our business, and neither the private letter and supplemental rulings nor the opinion would be valid if such representations, assumptions and undertakings were incorrect. Moreover, the private letter and supplemental rulings do not address all the issues that are relevant to determining whether the Distribution will qualify for tax-free treatment. Notwithstanding the private letter and supplemental rulings and opinion, the IRS could determine the Distribution should be treated as a taxable transaction for U.S. federal income tax purposes if, among other reasons, it determines any of the representations, assumptions or undertakings that were included in the request for the private letter and supplemental rulings are false or have been violated or if it disagrees with the conclusions in the opinion that are not covered by the IRS ruling.

If the Distribution fails to qualify for tax-free treatment, in general, Harvard Bioscience would be subject to tax as if it had sold our common stock in a taxable sale for its fair market value, and Harvard Bioscience stockholders who receive shares of our common stock in the Distribution would be subject to tax as if they had received a taxable Distribution equal to the fair market value of such shares.

Under the tax sharing agreement between Harvard Bioscience and us, we would generally be required to indemnify Harvard Bioscience against any tax resulting from the Distribution to the extent that such tax resulted from (i) an acquisition of all or a portion of our stock or assets, whether by merger or otherwise, (ii) other actions or failures to act by us, or (iii) any of our representations or undertakings being incorrect or violated. Our indemnification obligations to Harvard Bioscience and its subsidiaries, officers and directors are not limited by any maximum amount. If we are required to indemnify Harvard Bioscience or such other persons under the circumstances set forth in the tax sharing agreement, we may be subject to substantial liabilities.

We may not be able to engage in desirable strategic or capital-raising transactions. In addition, under some circumstances, we could be liable for adverse tax consequences resulting from engaging in significant strategic or capital-raising transactions.

To preserve the tax-free treatment to Harvard Bioscience of the Separation and Distribution, for the two-year period following the Distribution we may be limited, except in specified circumstances, from:

- entering into certain transactions pursuant to which all or a portion of our stock would be acquired, whether by merger or otherwise;
- issuing equity securities beyond certain thresholds, which such thresholds we are significantly closer to after taking into consideration the issuances in our February 2015 public offering and other issuances or potential issuances since the Separation;
- repurchasing our common stock;
- ceasing to actively conduct our regenerative medicine business; and
- taking or failing to take any other action that prevents the Separation and Distribution and related transactions from being tax-free.

These restrictions may limit our ability to pursue strategic transactions, raise additional capital or engage in new business or other transactions that may maximize the value of our business.

We may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as an independent company, and we may experience increased costs, potentially as a result of the Separation.

Following the completion of the Distribution, Harvard Bioscience was contractually obligated to provide to us only those services specified in the transition services agreement and the other agreements we entered into with Harvard Bioscience in connection with the Separation and Distribution. The transition services agreement provided for services to be provided for various time frames of limited length, ranging from six months from the date of the Distribution to 12 months thereafter. Since the expiration of the terms of the required services under the transition services agreement or other agreements, such services have been provided internally or by unaffiliated third parties, and we have in some instances incurred higher costs to obtain such services than we incurred under the terms of such agreements.

Our historical financial information is not necessarily representative of the results we would have achieved as a separate publicly traded company and may not be a reliable indicator of our future results.

The historical financial information we have included in this report may not reflect what our results of operations, financial position and cash flows would have been had we been an independent publicly traded company during all of the periods presented or what our results of operations, financial position and cash flows will be in the future. This is primarily because:

- our historical financial information for periods prior to the Separation reflect allocations for services historically provided to us by Harvard Bioscience, which allocations may not reflect the costs we will incur for similar services in the future as an independent company; and

- our historical financial information for periods prior to the Separation do not reflect changes that we have and continue to expect to incur in the future as a result of the Separation, including changes in the cost structure, personnel needs, financing and operations of the contributed business as a result of the Separation and from reduced economies of scale.

Since the Separation and Distribution, we are also responsible for the additional costs associated with being an independent public company, including costs related to corporate governance and listed and registered securities. Therefore, our financial statements may not be indicative of our future performance as an independent company. For additional information about our past financial performance and the basis of presentation of our financial statements, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the notes thereto included elsewhere in this report.

We may have received better terms from unaffiliated third parties than the terms we received in our agreements with Harvard Bioscience.

The agreements related to the Separation, including the separation and distribution agreement, tax sharing agreement, transition services agreement and the other agreements, were negotiated in the context of the Separation while we were still part of Harvard Bioscience and, accordingly, may not reflect terms that would have resulted from arm's-length negotiations among unaffiliated third parties. The terms of the agreements we negotiated in the context of the Separation related to, among other things, allocation of assets, liabilities, rights, indemnifications and other obligations among Harvard Bioscience and us. We may have received better terms from third parties because third parties may have competed with each other to win our business. Some of the members of our Board of Directors are also members of the Harvard Bioscience Board of Directors.

The ownership by our executive officers and some of our directors of shares of common stock, options, or other equity awards of Harvard Bioscience, as well as the continued roles of our executive officers and certain directors with Harvard Bioscience may create, or may create the appearance of, conflicts of interest.

The ownership by our executive officers and some of our directors of shares of common stock, options, or other equity awards of Harvard Bioscience may create, or may create the appearance of, conflicts of interest. Because of their current or former positions with Harvard Bioscience, certain of our executive officers, and some of our directors, own shares of Harvard Bioscience common stock, options to purchase shares of Harvard Bioscience common stock or other equity awards. The individual holdings of common stock, options to purchase common stock of Harvard Bioscience or our company or other equity awards, may be significant for some of these persons compared to such persons' total assets. Ownership by our directors and officers of common stock or options to purchase common stock of Harvard Bioscience, or any other equity awards, creates, or, may create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for Harvard Bioscience than the decisions have for us. In addition, certain of our directors are members of the Board of Directors

of Harvard Bioscience. The continued service at both companies creates, or, may create the appearance of, conflicts of interest when these directors are faced with decisions that could have different implications for Harvard Bioscience than the decisions have for us.

Third parties may seek to hold us responsible for liabilities of Harvard Bioscience that we did not assume in our agreements.

In connection with the Separation, Harvard Bioscience has generally agreed to retain all liabilities that did not historically arise from our business. Third parties may seek to hold us responsible for Harvard Bioscience's retained liabilities. Under our agreements with Harvard Bioscience, Harvard Bioscience has agreed to indemnify us for claims and losses relating to these retained liabilities. However, if those liabilities are significant and we are ultimately liable for them, we cannot assure you that we will be able to recover the full amount of our losses from Harvard Bioscience.

Any disputes that arise between us and Harvard Bioscience with respect to our past and ongoing relationships could harm our business operations.

Disputes may arise between Harvard Bioscience and us in a number of areas relating to our past and ongoing relationships, including:

- intellectual property, technology and business matters, including failure to make required technology transfers and failure to comply with non-compete provisions applicable to Harvard Bioscience and us;
- labor, tax, employee benefit, indemnification and other matters arising from the Separation;
- distribution and supply obligations;
- employee retention and recruiting;
- business combinations involving us;
- sales or distributions by Harvard Bioscience of all or any portion of its ownership interest in us; and
- business opportunities that may be attractive to both Harvard Bioscience and us.

We may not be able to resolve any potential conflicts, and even if we do, the resolution may be less favorable than if we were dealing with an unrelated party.

Risks Relating To Our Common Stock

A trading market that will provide you with adequate liquidity may not develop for our common stock.

The current public market for our common stock has limited trading and liquidity. We cannot predict the extent to which investor interest in our company will lead to the development of a more active trading market in our common

stock, or how liquid that market might be.

Our revenues, operating results and cash flows may fluctuate in future periods and we may fail to meet investor expectations, which may cause the price of our common stock to decline.

Variations in our quarterly and year-end operating results are difficult to predict and may fluctuate significantly from period to period. If our revenues or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. In addition to the other factors discussed under these "Risk Factors," specific factors that may cause fluctuations in our operating results include:

- demand and pricing for our products;

- government or private healthcare reimbursement policies;
- physician and patient acceptance of any of our current or future products;
- manufacturing stoppages or delays;
- introduction of competing products or technologies;
- our operating expenses which fluctuate due to growth of our business; and
- timing and size of any new product or technology acquisitions we may complete.

The market price of our shares may fluctuate widely.

The market price of our common stock may fluctuate widely, depending upon many factors, some of which may be beyond our control, including:

- the success or failure of surgeries and procedures involving the use our products;
- the success and costs of preclinical and clinical testing and obtaining regulatory approvals or clearances for our products;
- a shift in our investor base;
- our quarterly or annual results of operations, or those of other companies in our industry;
- actual or anticipated fluctuations in our operating results due to factors related to our business;
- changes in accounting standards, policies, guidance, interpretations or principles;
-

announcements by us or our competitors of significant acquisitions, dispositions or intellectual property developments or issuances;

- the failure to maintain our NASDAQ listing or failure of securities analysts to cover our common stock;
- changes in earnings estimates by securities analysts or our ability to meet those estimates;
- the operating and stock price performance of other comparable companies; our issuance of equity, debt or other financing instruments;
- overall market fluctuations; and
- general economic conditions.

Stock markets in general have experienced volatility that has often been unrelated to the operating performance of a particular company. These broad market fluctuations may adversely affect the trading price of our common stock.

Substantial sales of common stock may occur, which could cause our stock price to decline.

Some Harvard Bioscience stockholders, including possibly some of its large stockholders, have likely sold, and may continue to sell, our common stock received in the Distribution for reasons such as that our business profile or market capitalization as an independent company does not fit their investment objectives. Additionally, we expect that we will seek to raise additional capital from time to time in the future, which may involve the issuance of additional shares of common stock, or securities convertible into common stock. For example, in connection with our February 2015 public offering, we sold an aggregate of 2,070,000 shares of our common stock and 695,857 shares of Series B Convertible Preferred Stock, which are convertible into 3,479,285 shares of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock. Any future sales of significant amounts of our common stock, or the perception in the market that this will occur, may result in a decline in the price of our common stock.

Your percentage ownership will be diluted in the future.

Your percentage ownership will be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees, as well as shares of common stock, or securities convertible into common stock, we issue in connection with future capital raising or strategic transactions. Our 2013 Equity Incentive Plan provides for the grant of equity-based awards, including restricted stock, restricted stock units, stock options, stock appreciation rights and other equity-based awards to our directors, officers and other employees, advisors and consultants. In addition, your percentage ownership will be diluted by our issuance of common stock following the exercise of options, or vesting of restricted stock units, we issued pertaining to the adjustment and conversion of outstanding Harvard Bioscience equity awards as a result of the Separation. Further, a significant number of additional shares of our common stock may be issued upon the conversion of our Series B Convertible Preferred Stock. The issuance of any shares of our stock would dilute the proportionate ownership and voting power of existing security holders.

Our costs will increase significantly as a result of operating as a public company, and our management will be required to devote substantial time to complying with public company regulations.

Historically, our business was operated as a division of a public company. As a public company with separate SEC reporting, regulatory, and stock exchange listing requirements, we will incur additional legal, accounting, compliance, and other expenses that we have not incurred historically. We are obligated to file with the SEC annual and quarterly information and other reports that are specified in Section 13 and other sections of the Securities Exchange Act of

1934, as amended, and therefore need to have the ability to prepare financial statements that are compliant with all SEC reporting requirements on a timely basis. In addition, we are subject to other reporting and corporate governance requirements, including certain requirements of the NASDAQ Stock Market and certain provisions of the Sarbanes-Oxley Act and its associated regulations, which impose significant compliance obligations upon us. Sarbanes-Oxley and the Dodd-Frank Wall Street Reform and the Consumer Protection Act of 2010, as well as new rules subsequently implemented by the SEC and the NASDAQ Stock Market, have increased regulation of, and imposed enhanced disclosure and corporate governance requirements on, public companies. Our efforts to comply with evolving laws, regulations, and standards in this regard are likely to result in increased marketing, selling, and administrative expenses, as well as a diversion of management's time and attention from revenue-generating activities to compliance activities. These changes will require a significant commitment of additional resources. We may not be successful in implementing these requirements, and implementing them could materially adversely affect our business, results of operations, and financial condition. We also expect these recent regulations to increase our legal and financial compliance costs, make it more difficult to attract and retain qualified officers and members of our Board of Directors, particularly to serve on our audit committee, and make some activities more difficult, time-consuming, and costly. In addition, if we fail to implement the required controls with respect to our internal accounting and audit functions, our ability to report our results of operations on a timely and accurate basis could be impaired. If we do not implement such required controls in a timely manner or with adequate compliance, we might be subject to sanctions or investigation by regulatory authorities, such as the SEC or the NASDAQ Stock Market. Any such action could harm our reputation and the confidence of investors and clients in our company and could negatively affect our business and cause the price of our common stock to decline.

Provisions of Delaware law, of our amended and restated charter and amended and restated bylaws and our Shareholder Rights Plan may make a takeover more difficult, which could cause our stock price to decline.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and in the Delaware corporate law may make it difficult and expensive for a third party to pursue a tender offer, change in control or takeover attempt, which is opposed by management and the Board of Directors. Public stockholders who might desire to participate in such a transaction may not have an opportunity to do so. Our Board of Directors has adopted a Shareholder Rights Plan that could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, our company or a large block of our common stock. A third party that acquires 20% or more of our common stock could suffer substantial dilution of its ownership interest under the terms of the Shareholder Rights Plan through the issuance of common stock to all stockholders other than the acquiring person. We also have a staggered Board of Directors that makes it difficult for stockholders to change the composition of the Board of Directors in any one year. Any removal of directors will require a super-majority vote of the holders of at least 75% of the outstanding shares entitled to be cast on the election of directors which may discourage a third party from making a tender offer or otherwise attempting to obtain control of us. These anti-takeover provisions could substantially impede the ability of public stockholders to change our management and Board of Directors. Such provisions may also limit the price that investors might be willing to pay for shares of our common stock in the future.

Any issuance of preferred stock in the future may dilute the rights of our common stockholders.

Our Board of Directors has the authority to issue up to 2,000,000 shares of preferred stock and to determine the price, privileges and other terms of these shares. Our Board of Directors is empowered to exercise this authority without any further approval of stockholders. The rights of the holders of common stock may be adversely affected by the rights of future holders of preferred stock.

We have in the past issued, and we may at any time in the future issue, additional shares of authorized preferred stock. For example, in connection with our February 2015 public offering, we issued 695,857 shares of Series B Convertible Preferred Stock, each share of which is convertible into 5 shares of the Company’s common stock, subject to certain ownership restrictions.

We do not intend to pay cash dividends on our common stock.

Currently, we do not anticipate paying any cash dividends to holders of our common stock. As a result, capital appreciation, if any, of our common stock will be a stockholder’s sole source of gain.

The recently enacted JOBS Act will allow us to postpone the date by which we must comply with certain laws and regulations and to reduce the amount of information provided in reports filed with the SEC. We cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are and we will remain an "emerging growth company" until the earliest to occur of (i) the last day of the fiscal year during which our total annual revenues equal or exceed $1 billion (subject to adjustment for inflation), (ii) the last day of the fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement, (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt, or (iv) the date on which we are deemed a "large accelerated filer" under the Securities and Exchange Act of 1934, as amended, or the Exchange Act. For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on some or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. If we avail ourselves of certain exemptions from various reporting requirements, our reduced disclosure may make it more difficult for investors and securities analysts to evaluate us to a level acceptable by them and may result in less investor confidence.

Our management will have broad discretion over the use of proceeds from the sale of shares of our common stock and may not use such proceeds in ways that increase the value of our stock price.

In our February 2015 public offering, we sold 2,070,000 shares of common stock and 695,857 shares of Series B Convertible Preferred Stock for net proceeds of approximately $8.6 million. We will have broad discretion over the use of proceeds from the sale of those shares, and we could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

Item 1B. ***Unresolved Staff Comments.***

None.

Item 2. ***Properties.***

On November 1, 2013 we entered into a sublease of approximately 17,000 square feet of mixed use space of the facility located at 84 October Hill Road, Suite 11, Holliston, Massachusetts from Harvard Bioscience, which is our corporate headquarters. Our principal facilities incorporate manufacturing, laboratory, development, sales and marketing, and administration functions. We believe our current facilities are adequate for our needs for the foreseeable future.

Item 3. ***Legal Proceedings.***

From time to time, we may be involved in various claims and legal proceedings arising in the ordinary course of business. We are not currently a party to any such significant claims or proceedings.

Item 4. ***Mine Safety Disclosures.***

Not Applicable.

PART II

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

Price Range of Common Stock

Our common stock began regular-way trading on the NASDAQ Capital Market on November 4, 2013, and currently trades under the symbol "HART." The following table sets forth the range of the high and low sales prices per share of our common stock as reported on the NASDAQ Capital Market for the quarterly periods indicated.

Fiscal Year Ended December 31, 2014	High	Low
First Quarter	$11.89	$3.61
Second Quarter	10.74	6.29
Third Quarter	10.82	6.55
Fourth Quarter	$8.00	$2.20

Fiscal Year Ended December 31, 2013	High	Low
First Quarter	-	-
Second Quarter	-	-
Third Quarter	-	-
Fourth Quarter	$5.41	$3.37

On March 20, 2015, the closing sale price of our common stock on the NASDAQ Capital Market was $3.83 per share. There were 176 holders of record of our common stock as of March 20, 2015. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

Dividend Policy

We have never declared or paid cash dividends on our common stock in the past and do not intend to pay cash dividends on our common stock in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements and other factors our Board of Directors deems relevant.

Item 6. ***Selected Financial Data***

Not Applicable.

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

Forward-Looking Statements

The following section of this Annual Report on Form 10-K entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains statements that are not statements of historical fact and are forward-looking statements within the meaning of federal securities laws. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Factors that may cause our actual results to differ materially from those in the forward-looking statements include those factors described in "Item 1A. Risk Factors" beginning on page 21 of this Annual Report on Form 10-K. You should carefully review all of these factors, as well as the comprehensive discussion of forward-looking statements on page ii of this Annual Report on Form 10-K.

We are a clinical stage biotechnology company making regenerated organs for transplant.

Our first product, the HART-Trachea, is intended to be used to restore the structure and/or function of a severely damaged trachea (windpipe). The HART-Trachea is comprised of the patient's own bone marrow cells seeded on our proprietary InBreath porous plastic scaffold in our proprietary InBreath organ bioreactor.

We believe our HART-Trachea could enable surgeons to cure nearly all life-threatening constrictions of the airway. Our HART-Trachea addresses both of the critical challenges to trachea transplant: the shortage of suitable donor tracheas and the risk and expense of lifelong anti-rejection drug therapy. Because the scaffolds are synthetic, they can be made in large quantities and therefore will eliminate the need to wait for suitable donor tracheas. Because the cells are from the patient, the patient's body does not reject the HART-Trachea and therefore the patients do not need to take anti-rejection drugs. Because these substantial costs and risks can be reduced or even eliminated with our technology, we believe our products can both help save lives and reduce overall healthcare costs.

To date, the HART-Trachea has been implanted in five adult human patients. Average survival among the three of these patients who have died to date has been 22 months. This is a significant improvement over the prognosis at the time of implant which was typically just a few months. Of the three patients who have died, none of them have died because of a failure of our scaffold. Two of the patients are still alive. Of those two patients, one is at approximately 9 months and the other is at approximately two and one half years from being first implanted.

Our products are currently in development and have not yet received regulatory approval for sale anywhere in the world.

The Office of Combination Products of the U.S. Food and Drug Administration, or FDA, has confirmed for us that the FDA intends to regulate the HART-Trachea as a combination product under the Biologics License Application, or BLA pathway under the primary jurisdiction of the Center for Biologics Evaluation and Research, or CBER. In the EU, the European Medicines Agency, or EMA, has designated the HART-Trachea as an Advanced Therapy Medicinal Product, or ATMP. The ATMP regulatory pathway in Europe is approximately similar to the BLA pathway in the U.S. The initial indication for which we intend to seek FDA and EMA approvals will be to restore the structure and function of the trachea subsequent to tracheal damage or stenosis due to cancer, injury or infection.

We have received orphan drug designation from the FDA for the HART-Trachea in the U.S. market. Orphan drug designation provides market exclusivity in the U.S. for seven years from the date of the product’s approval for marketing. This exclusivity is in addition to any exclusivity we may obtain due to our patents. Additionally, orphan designation provides a waiver of the BLA application fee of $672,000.

We have also filed an application for orphan designation in the EU for our HART-Trachea product. We expect to receive a response from the EMA with respect to our orphan designation application in the second quarter of 2015. In the EU orphan status would provide market exclusivity for ten years.

We are currently engaged in pre-clinical development of our HART-Trachea. Assuming we are able to complete the necessary pre-clinical work to the satisfaction of the U.S. and EU regulatory agencies we would expect to submit our request for IND approval for the HART-Trachea in the first half of 2016. Assuming we are then able to complete the clinical trials with approximately 30 patients and with a 3 month follow-up period we would expect to submit our BLA application for marketing in late 2017. If we are granted Fast Track, Accelerated Review and Breakthrough status in the U.S. we would expect our BLA to be reviewed quickly in which case it is possible we would receive FDA approval to market the HART-Trachea in the U.S. in the first half of 2018. Because the EU ATMP pathway allows for a “hospital exemption” it is possible that we could begin collecting clinical data in the EU before we do so in the U.S. This may allow us a somewhat faster path to approval in the EU than in the U.S. These estimates depend on many assumptions that are inherently uncertain and on scientific and clinical trials whose outcomes are unknowable at this time. The process of obtaining regulatory marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that our products will be approved in this timeframe, or at all.

In addition to the trachea, we believe that our bioreactor and scaffold technologies are applicable to the regeneration of other organs. In January 2015 we announced the signing of a joint development agreement with Mayo Clinic to bring the HART-Trachea to clinical trials, and to develop a bioengineered solution for the esophagus using regenerative medicine principles.

Recent Developments

Development Agreement with Mayo Clinic

In December 2014, we signed a joint development agreement with Mayo Clinic with the intent of developing and improving regenerative medicine treatments for patients with severe diseases. We have collaborated with Mayo Clinic for the past two years as part of Mayo Clinic’s program to develop a synthetic human heart valve, and this new development agreement is designed to foster work on additional organs such as the trachea and the esophagus. Patented inventions made during the course of the collaboration may be licensed by us, and we will pay royalties to Mayo Clinic.

Pre-clinical Success with Esophageal Regeneration and Transplant

In 2014, we had success in pre-clinical studies involving esophageal regeneration and transplant. A research team at Karolinska Institutet in Sweden successfully transplanted a regenerated esophagus into a rat using a bioreactor developed by us. The rats survived and after two weeks the researchers found indications of the major components in the regenerated graft: epithelium, muscle cells, blood vessels and nerves. Research detailing the procedure was published in *Nature Communications* in April 2014.

In January 2015, we disclosed that we had manufactured our first human-sized synthetic scaffold prototypes for esophageal transplant. These scaffolds are intended to be used to replace a segment of the esophagus that has been removed due to infection, injury or disease. The first indication we are likely to pursue is esophageal cancer. Esophageal cancer is life-threatening and far more common than tracheal cancer. We expect to begin pre-clinical work with these scaffolds in 2015.

Pre-clinical Development of the HART-Trachea

We recently disclosed that we will need additional development and testing within our ongoing preclinical large-animal model testing of the HART-Trachea. We reported that we believe that the additional testing needed is readily achievable, however, we estimate that this testing will require an additional 2 to 6 months beyond our previous estimates. Our updated expectations regarding such anticipated milestones are as follows:

- The submission of the application for Clinical Trial Authorization, or CTA, with the Medicines and Healthcare Products Regulatory Agency, or MHRA, of the U.K. and the Investigational New Drug application, or IND, with the FDA, is expected to take place in the first half of 2016 rather than by the end of 2015;

- If we are granted Fast Track, Accelerated Review, Priority Review and Breakthrough status in the U.S., we anticipate completing our clinical trial by the end of 2017, rather than the middle of 2017. Completion of the clinical trial in the EU potentially could be sooner; and

- We expect to receive FDA approval to market the HART-Trachea in the U.S. during the first half of 2018, rather than by the end of 2017.

Results of Operations

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Revenues

Revenues increased $0.07 million, or 323%, to $0.09 million for the year ended December 31, 2014 compared with the year ended December 31, 2013. Revenues represent the sale of research bioreactor equipment through our distributor, Harvard Bioscience, to end users working on organ regeneration research.

Cost of revenues

Cost of revenues increased $0.04 million, or 336%, to $0.05 million for the year ended December 31, 2014 compared with the year ended December 31, 2013. Cost of revenues includes labor, materials and allocated overhead for our research bioreactor equipment.

Research and Development Expense

Research and development expense increased $0.6 million, or 12%, to $5.1 million for the year ended December 31, 2014 compared with $4.6 million for the year ended December 31, 2013. Of the $0.6 million increase, approximately $0.5 million related to an increase in non-cash stock-based compensation expense related to the initial stock option grants made to employees at the time of the spin-off, $0.2 million in cost from our initial animal studies, which was partially offset by $0.1 million from the elimination of certain costs in our foreign operations.

Sales and Marketing Expense

Sales and marketing expense increased approximately $70 thousand, or 27%, to $329 thousand for the year ended December 31, 2014 compared with $259 thousand for the year ended December 31, 2013. The increase was primarily due stock-based compensation costs.

General and Administrative Expense

General and administrative expense increased $1.6 million, or 41%, to $5.7 million for the year ended December 31, 2014 compared with $4.0 million for the year ended December 31, 2013. Of the $1.6 million increase, $0.7 million was due to greater non-cash stock-based compensation expense related to the initial stock option grants made to employees at the time of the spin-off. Approximately $0.6 million of the increase was due to greater payroll-related costs. Approximately $0.4 million of the year-to-year increase related to other costs from the Company operating as an independent, publicly traded entity for all of 2014.

Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses totaling $32.3 million since inception. From inception through the spin-off on November 1, 2013, our operations were funded by Harvard Bioscience. We are currently investing significant resources in the development and commercialization of our products for use by clinicians and researchers in the field of regenerative medicine. As a result, we expect to incur operating losses and negative operating cash flow for the foreseeable future.

We filed a Registration Statement on Form 10 with the SEC on July 31, 2013 to become a public reporting company under the Securities Exchange Act of 1934. Effective November 1, 2013, Harvard Bioscience spun off 100% of HART's common stock to Harvard Bioscience's stockholders in a pro-rata, tax-free dividend and contributed $15 million in cash to us. Our common stock was approved for listing on the NASDAQ Capital Market under the symbol "HART" in connection with our spin-off and related Form 10 filing.

Since the registration, listing and spin-off of HART's common stock, we and Harvard Bioscience operate, and our equity securities trade, as two separate public companies.

Operating activities. Net cash used in operating activities of $8.0 million for the year ended December 31, 2014 was primarily a result of our $11.1 million net loss, offset by a $2.9 million add-back of non-cash expenses of stock-based compensation and depreciation.

Net cash used in operating activities of $7.7 million for the year ended December 31, 2013 was primarily a result of our $8.8 million net loss, offset by a $1.5 million add-back of non-cash expenses of stock-based compensation and depreciation.

Investing activities. Net cash used in investing activities for the years ended December 31, 2014 and 2013 totaled $1.2 million and $0.3 million, respectively, and represented additions to property, plant and equipment.

Financing activities. Cash generated from financing activities of $0.4 million for the year ended December 31, 2014 was the result of the exercise of employee stock options. Cash generated from financing activities for the year ended December 31, 2013 totaled $22.0 million, and represented Harvard Bioscience's funding of our business activities.

Critical Accounting Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with Generally Accepted Accounting Principles in the United States ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We believe the following policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Carve-out of the Results of Operations, Financial Condition and Cash Flows of the Our Business

Prior to November 1, 2013, our business operated as part of Harvard Bioscience and not as a separate stand-alone entity. The consolidated financial statements for the period prior to the Separation have been prepared on a stand-alone basis and are derived from the financial statements and accounting records of Harvard Bioscience using the historical basis of assets and liabilities of our Company. The accompanying consolidated financial statements include allocations of direct costs and indirect costs attributable to our operations for the periods prior to November 1, 2013. Indirect costs relate to certain support functions that were provided on a centralized basis within Harvard Bioscience. The support functions provided to us by Harvard Bioscience included, but were not limited to: executive services, finance, treasury, corporate income tax, human resources, legal services and investor relations and information technology services. Allocation of expenses for these services in 2013 totaled $2.0 million through the Separation on October 31, 2013. These costs have been allocated to us for the purposes of preparing the consolidated financial statements based on our estimated usage of the resources. The allocation methods include time devoted to our Company activities, headcount, percentage of operating expenses or other relevant measures. We believe that such allocations have been made on a reasonable basis, but may not necessarily be indicative of the costs that would have been incurred if we had operated on a standalone basis.

Share-based Compensation

We account for our share-based compensation in accordance with the fair value recognition provisions of current authoritative guidance. Share-based awards, including stock options, are measured at fair value as of the grant date and recognized as expense over the requisite service period (generally the vesting period), which we have elected to amortize on a straight-line basis. Expense on share-based awards for which vesting is performance or milestone based is recognized on a straight-line basis from the date when we determine the achievement of the milestone is probable to the vesting/ milestone achievement date. Since share-based compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. We estimate forfeitures at the time of grant and revise our estimate, if necessary, in subsequent periods. We estimate the fair value of options granted using the Black-Scholes option valuation model. Significant judgment is required in determining the proper assumptions used in these models. The assumptions used include the risk free interest rate, expected term, expected volatility and expected dividend yield. We base our assumptions on historical data when available or when not available, on a peer group of companies. However, these assumptions consist of estimates of future market conditions, which are inherently uncertain and subject to our judgment, and therefore any changes in assumptions could significantly impact the future grant date fair value of share-based awards. Significant judgement is required in estimating the probability and timing of achievement of milestones associated with performance based option grants which impacts the timing of recognition of the related expense.

Total share-based compensation expense for the years ended December 31, 2014 and 2013 was $2.6 million and $1.4 million, respectively. The expense for periods prior to November 1, 2013 was allocated to us based on awards from Harvard Bioscience equity plans granted to Harvard Bioscience employees who had, directly or indirectly, provided

services to us. Share-based compensation expense for restricted stock units was measured based on the closing fair market value of Harvard Bioscience's ordinary shares on the date of grant. Share based compensation is further described in Note 13 to the Consolidated Financial Statements.

Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers," a new accounting standard that provides for a comprehensive model to use in the accounting for revenue arising from contracts with customers that will replace most existing revenue recognition guidance in U.S. GAAP. Under this standard, revenue will be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. This standard will be effective as of the beginning of our 2017 fiscal year. We are assessing the new standard and has not yet determined the impact to the consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The new guidance requires management to evaluate whether there are conditions that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The guidance is effective for fiscal years beginning after December 15, 2016. Management has evaluated the adoption of this guidance, which is related to disclosure only, and has determined that when adopted it would not have a material impact on our consolidated statements of operations and comprehensive loss, stockholders' equity, cash flows and related footnotes.

Off – Balance Sheet Arrangements

The Company does not have any off – balance sheet arrangements.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk.***

Not Applicable.

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

The information required by this item is contained in the consolidated financial statements filed as part of this Annual Report on Form 10-K listed under Item 15 of Part IV below.

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

None.

Item 9A. ***Controls and Procedures.***

This Report includes the certifications of our Chief Executive Officer and Chief Financial Officer required by Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). See Exhibits 31.1 and 31.2. This Item 9A includes information concerning the controls and control evaluations referred to in those certifications.

(a) Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

In connection with the preparation of this Annual Report on the Form 10-K, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2014. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and our

management necessarily was required to apply its judgment in evaluating and implementing our disclosure controls and procedures. Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer have concluded that they believe that our disclosure controls and procedures were effective, as of the end of the period covered by this report, in providing reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms.

(b) Management's Annual Report on Internal Control Over Financial Reporting

Our management, under the supervision of the Chief Executive Officer and the Chief Financial Officer, is responsible for establishing and maintaining an adequate system of internal control over financial

reporting. Internal control over financial reporting (as defined in Rules 13a-15(f) and 15d(f) under the Exchange Act) 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 in the United States of America ("U.S. GAAP").

A company's internal control over financial reporting includes those policies and procedures that: (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. GAAP; (c) provide reasonable assurance that receipts and expenditures are being made only in accordance with appropriate authorization of management and the board of directors; and (d) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated 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 connection with the preparation of this report, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2014 based on the criteria established in *Internal Control — Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). As a result of that evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2014.

As an "emerging growth company" under the Jumpstart Our Business Startups Act, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result, KPMG LLP, our independent registered public accounting firm, has not audited or issued an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2014.

(c) Changes in Internal Controls Over Financial Reporting

Our management, with the participation of the Chief Executive Officer and the Chief Financial Officer, has evaluated whether any change in our internal control over financial reporting occurred during the fourth quarter ended December 31, 2014. Based on that evaluation, management concluded that there were no changes in our internal controls over financial reporting during the quarter ended December 31, 2014 that materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

Item 9B. ***Other Information.***

None.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance.***

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act, in connection with our 2014 Annual Meeting of Stockholders. Information concerning executive officers of our Company is included in Part I of this Annual Report on Form 10-K as Item 1. Business-Executive Officers of the Registrant and incorporated herein by reference.

Item 11. ***Executive Compensation.***

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2014 Annual Meeting of Stockholders.

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

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2014 Annual Meeting of Stockholders.

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

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2014 Annual Meeting of Stockholders.

Item 14. ***Principal Accounting Fees and Services.***

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2014 Annual Meeting of Stockholders.

Item 15. ***Exhibits, Financial Statement Schedules.***

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

(1) Financial Statements. The consolidated financial statements of Harvard Apparatus Regenerative Technology, Inc. and its subsidiaries filed under this Item 15:

(2) Financial Statement Schedules: None. Financial statement schedules have been omitted since the required information is included in our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K.

(3) Exhibits. The exhibits listed in the accompanying Exhibit Index are filed as a part of this Annual Report on Form 10-K.

(b) Exhibits: The exhibits listed in the accompanying Exhibit Index are filed as a part of this Annual Report on Form 10-K.

(c) Separate Financial Statements and Schedules: None. Financial statement schedules have been omitted since the required information is included in our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC. AND SUBSIDIARIES

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Harvard Apparatus Regenerative Technology, Inc.:

We have audited the accompanying consolidated balance sheets of Harvard Apparatus Regenerative Technology, Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2014. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 Harvard Apparatus Regenerative Technology, Inc. and subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Boston, Massachusetts

March 26, 2015

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except par value and share data)

	December 31, 2014	December 31, 2013
ASSETS		
Current assets:		
Cash	$ 5,272	$ 14,008
Related party receivables	27	22
Other non-trade receivables	5	-
Inventories, net	207	38
Prepaid expenses	317	421
Total current assets	5,828	14,489
Property, plant and equipment, net	1,376	575
Total non-current assets	1,376	575
Total assets	$ 7,204	$ 15,064
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 370	$ 244
Related party payable	16	90
Accrued and other current liabilities	324	161
Total current liabilities	710	495
Total non-current liabilities	-	-
Total liabilities	710	495
Commitments and contingencies (note 11)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, 2,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, par value $0.01 per share, 30,000,000 shares authorized; 7,856,607 and 7,742,080 shares issued and outstanding, respectively	79	77
Additional paid-in capital	19,449	16,466
Accumulated deficit	(13,035)	(1,974)
Accumulated other comprehensive loss	1	-
Total stockholders' equity	6,494	14,569
Total liabilities and stockholders' equity	$ 7,204	$ 15,064

See accompanying notes to consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share data)

	Years ended December 31,	
	2014	2013
Revenues	$ 93	$ 22
Cost of revenues	48	11
Gross profit	45	11
Operating expenses:		
Research and development	5,119	4,562
Sales and marketing	329	259
General and administrative	5,654	4,007
Total operating expenses	11,102	8,828
Operating loss	(11,057)	(8,817)
Other income (expense), net	(4)	-
Loss before income taxes	(11,061)	(8,817)
Income taxes	-	-
Net loss	$ (11,061)	$ (8,817)
Basic and diluted net loss per share	$ (1.41)	$ (1.14)
Weighted average common shares, basic and diluted	7,821	7,740
Comprehensive loss:		
Net loss	$ (11,061)	$ (8,817)
Foreign currency translation adjustments	1	-
Total comprehensive loss	$ (11,060)	$ (8,817)

See accompanying notes to consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Number of Shares Issued	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Harvard Bioscience Net Investment	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2012	-	$ -	$ -	$ -	$ 27	$ -	$ 27
Contribution of net assets to Harvard Apparatus Regenerative Technology by Harvard Bioscience and issuance of common stock	7,740	77	15,681	-	-	-	15,758
Net loss				(1,974)	(6,843)	-	(8,817)
Share based compensation	-	-	782	-	588	-	1,370
Net funding provided by Harvard Bioscience	-	-	-	-	6,228	-	6,228
Stock option exercises	1	-	3	-	-	-	3
Vesting of restricted stock units	2	-	-	-	-	-	-
Balance at December 31, 2013	7,743	77	16,466	(1,974)	-	-	14,569
Net loss	-	-	-	(11,061)	-	-	(11,061)
Share based compensation	-	-	2,565	-	-	-	2,565
Stock option exercises	106	2	418	-	-	-	420
Vesting of restricted stock units	7	-	-	-	-	-	-
Other comprehensive loss	-	-	-	-	-	1	1
Balance at December 31, 2014	7,856	$ 79	$ 19,449	$ (13,035)	$ -	$ 1	$ 6,494

See accompanying notes to consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,	
	2014	2013
Cash flows used in operating activities:		
Net loss:	$ (11,061)	$ (8,817)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,565	1,370
Depreciation	363	158
Changes in operating assets and liabilities:		
Increase in related party receivables	(5)	(22)
Increase in non-trade receivables	(5)	-
Increase in inventories	(169)	(38)
Decrease (increase) in prepaid expenses	104	(421)
Increase in accounts payable	126	65
(Decrease) increase in related party payable	(74)	90
Increase (decrease) in accrued and other current liabilities	163	(71)
Net cash used in operating activities	(7,993)	(7,686)
Cash flows used in investing activities:		
Additions to property, plant and equipment	(1,164)	(295)
Net cash used in investing activities	(1,164)	(295)
Cash flows from financing activities:		
Proceeds from funding provided by Harvard Bioscience, Inc.	-	21,986
Proceeds from issuance of common stock	420	3
Net cash provided by financing activities	420	21,989
Effect of exchange rate changes on cash	1	-
Net (decrease) increase in cash	(8,736)	14,008
Cash at the beginning of the period	14,008	-
Cash at the end of the period	$ 5,272	$ 14,008

See accompanying notes to consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Overview

Prior to November 1, 2013, Harvard Apparatus Regenerative Technology, Inc. ("HART" or "the Company") was a business segment of Harvard Bioscience, Inc. ("Harvard Bioscience"). The Company is engaged in the development and commercialization of regenerated organs for human transplant. Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and acquiring operating assets.

HART was incorporated in Delaware on May 3, 2012 by Harvard Bioscience, as a wholly-owned subsidiary, to provide a means for separating Harvard Bioscience's regenerative medicine business from its other businesses. On October 31, 2013, Harvard Bioscience contributed its regenerative medicine business assets, plus $15 million of cash, into HART (the "Separation"). On November 1, 2013, the previously announced spin-off of the Company from Harvard Bioscience was completed. On that date, the Company became an independent company that operates the regenerative medicine business previously owned by Harvard Bioscience. The spin-off was completed through the distribution to Harvard Bioscience stockholders of all the shares of common stock of HART (the "Distribution"). In the Distribution, Harvard Bioscience distributed to its stockholders one share of HART common stock for every four shares of Harvard Bioscience common stock they owned as of the close of business on October 21, 2013, the record date for the Distribution. Fractional shares of HART common stock were not included in the Distribution. Instead, Registrar & Transfer Company aggregated fractional shares into whole shares, sold the whole shares in the open market and distributed the aggregate net cash proceeds pro rata to each holder who otherwise would have been entitled to receive a fractional share in the Distribution.

Immediately following the Distribution, the Company had 30.0 million common shares authorized and 7.7 million common shares issued and outstanding. Additionally, the Company's Board of Directors has the authority to issue up to 2.0 million shares of preferred stock and to determine the price, privileges and other terms of these shares, and may exercise this authority without any further approval of stockholders.

Basis of Presentation

The Company historically operated as part of Harvard Bioscience, and not as a stand-alone company. For periods prior to the Separation on October 31, 2013, the consolidated financial statements presented herein, and discussed below, have been prepared on a stand-alone basis and are derived from the financial statements and accounting records of Harvard Bioscience using the historical basis of assets and liabilities of HART. The Company's financial statements from that period include expenses of Harvard Bioscience allocated to HART for certain functions provided by Harvard Bioscience, including, but not limited to, general corporate expenses related to executive services, finance, treasury, corporate income tax, human resources, legal services and investor relations. These expenses were allocated to HART on the basis of headcount, time devoted to HART activities, percentage of operating expenses or other relevant measures. The Company believes the assumptions and allocations underlying the financial statements are reasonable and appropriate under the circumstances. Both HART and Harvard Bioscience consider the basis on which the expenses have been allocated to be a reasonable reflection of the utilization of services provided to or the benefits received by the Company during the periods presented. However, the amounts recorded for these transactions and allocations are not necessarily representative of the amounts that would have been reflected in the financial statements had HART operated independently of Harvard Bioscience. Accordingly, the financial statements for these periods are not necessarily indicative of HART's future results of operations, financial position and cash flows.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization – (continued)

Prior to the Separation on October 31, 2013, Harvard Bioscience used a centralized approach to manage substantially all of its liquid resources and to finance its operations and, as a result, no separate cash accounts for HART were historically maintained, and debt and liquid resources maintained at the Harvard Bioscience group level are not included in the accompanying consolidated financial statements prior to the Separation. Harvard Bioscience has funded all of HART's operating and capital resource requirements prior to the Distribution. The Harvard Bioscience net investment in the consolidated financial statements constitutes Harvard Bioscience's investment in HART and represents the excess of total assets over total liabilities, including the netting of intercompany funding balances between HART and Harvard Bioscience. Changes in Harvard Bioscience net investment represent Harvard Bioscience's net investment in HART, after giving effect to its net loss, contributions from Harvard Bioscience in the form of share-based compensation to HART's employees and net funding provided by Harvard Bioscience.

After October 31, 2013 the accompanying consolidated financial statements reflect the consolidated financial position and results of operations of the Company as an independent publicly traded company.

The Company has one business segment and does not have significant costs or assets outside the United States.

The historical deferred tax assets, including the operating losses and credit carryforwards generated by HART prior to the Separation, remained with Harvard Bioscience subsequent to the Separation.

The financial statements reflect the Company's financial position, results of operations and cash flows in conformity with generally accepted accounting principles in the United States ("GAAP").

2. Summary of Significant Accounting Policies

(a) Principles of Consolidation

The consolidated financial statements include the accounts of HART and its three wholly-owned subsidiaries, Harvard Apparatus Regenerative Technology GmbH (Germany), Harvard Apparatus Regenerative Technology AB (Sweden) and and Harvard Apparatus Regenerative Technology Limited (UK). All intercompany balances and transactions have been eliminated in consolidation.

(b) Use of Estimates

The process of preparing financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Such estimates include, but are not limited to, stock-based compensation, accruals, depreciation and income taxes. Actual results could differ from those estimates and changes in estimates may occur.

(c) Inventories

The Company values its inventories at the lower of the actual cost to purchase (first-in, first-out method) and/or manufacture the inventories or the current estimated market value of the inventories. The Company regularly reviews inventory quantities on hand and records a provision to write down excess and obsolete inventories to its estimated net realizable value if less than cost, based primarily on its estimated forecast of product demand.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies – (continued)

(d) Property, Plant and Equipment

Property, plant and equipment are carried at cost and depreciated using the straight-line method over the estimated useful lives of the assets as follows:

Leasehold improvements	Shorter of expected useful life or lease term
Furniture, machinery and equipment, computer equipment and software	3- 7 years

Maintenance and repairs are charged to expense as incurred, while any additions or improvements are capitalized.

(e) Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An asset, or group of assets, are considered to be impaired when the undiscounted estimated net cash flows expected to be generated by the asset, or group of assets, are less than its carrying amount. The impairment recognized is the amount by which the carrying amount exceeds the fair market value of the impaired asset, or group of assets.

(f) Revenue Recognition

The Company follows the provisions of FASB ASC 605, " *Revenue Recognition* ". The Company recognizes product revenue when persuasive evidence of a sales arrangement exists, the price to the buyer is fixed or determinable, delivery has occurred, and collectability of the sales price is reasonably assured. To date, the Company has recognized revenues only for sales of its research bioreactor systems. Sales of some of its products include additional services such as installation and training. Revenues on these products are recognized when the additional services have been performed. Service agreements on its equipment are typically sold separately from the sale of the equipment.

The Company accounts for shipping and handling fees and costs in accordance with the provisions of FASB ASC 605-45-45, " *Revenue Recognition — Principal Agent Considerations* ", which requires all amounts charged to customers for shipping and handling to be classified as revenues. Costs related to shipping and handling are classified as cost of revenues. Provisions for warranties and product returns are estimated and accrued at the time sales are recorded. The Company has no obligations to customers after the date products are shipped or installed, if applicable, other than pursuant to warranty obligations. The Company provides for the estimated amount of future returns upon shipment of products or installation, if applicable, based on historical experience.

(g) Research and Development

Research and development costs are expensed as incurred.

(h) Stock-based Compensation

The Company accounts for stock-based payment awards in accordance with the provisions of FASB ASC 718, " *Compensation — Stock Compensation* ", which requires it to recognize compensation expense for all stock-based payment awards made to employees and directors including employee stock options, restricted stock units, and employee stock purchases related to the Employee Stock Purchase Plan ("employee stock purchases").

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies – (continued)

FASB ASC 718 requires companies to estimate the fair value of stock-based payment awards, except restricted stock units, on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in its consolidated statements of income.

Under FASB ASC 718, the Company elected the Black-Scholes option-pricing model for valuation of stock-based payment awards. The determination of fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by its stock price as well as assumptions regarding a number of and subjective variables. These variables include, but are not limited to its expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors. The Company records stock compensation expense on a straight-line basis over the requisite service period for all awards granted since the adoption of FASB ASC 718. When performance based grants are issued the company recognizes no expense until achievement of the performance requirement is deemed probable.

The fair values of restricted stock units are based on the number of shares granted and market price of the stock on the date of grant and are recorded as compensation expense ratably over the applicable service period, which is generally four years. Unvested restricted stock units and vested and unvested stock options are forfeited in the event of termination of employment with HART or Harvard Bioscience.

The compensation expense recognized for all equity-based awards is net of estimated forfeitures and is recognized using the straight-line method over the applicable service period, where the minimum amount of expense recorded is at least equal to the percent of an award vested.

(i) Income Taxes

Prior to the Separation, HART operations were included in Harvard Bioscience’s consolidated U.S. federal and certain state income tax returns. The provision for income taxes prior to the Separation was determined as if HART had filed separate tax returns for the periods presented. Accordingly, the effective tax rate of HART in future years could vary

from its historical effective tax rates based on the legal structure of HART and related tax elections. The historical deferred tax assets, including the operating losses and credit carryforwards generated by HART prior to the Separation, remained with Harvard Bioscience subsequent to the Separation.

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to be applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

A valuation allowance is recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, the Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are expected to be realizable.

Tax positions taken or expected to be taken in the course of preparing our tax returns are required to be evaluated to determine whether the tax positions are “more-likely-than-not” of being sustained by the applicable tax authority. Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in the current year.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies – (continued)

(j) Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the periods presented. The computation of diluted net loss per share is similar to the computation of basic earnings per share, except that the denominator is increased for the assumed exercise of dilutive options and other potentially dilutive securities using the treasury stock method unless the effect is antidilutive. Basic and diluted net loss per share are the same for all periods presented as the exercise of options and other unvested Restricted Stock Units (RSU) would be antidilutive. Prior to the Separation and Distribution, the Company operated as part of Harvard Bioscience and not as a separate entity. As a result, the Company's Financial Statements did not reflect any ordinary shares outstanding prior to November 1, 2013. The calculation of basic and diluted net loss per share assumes that the 7,740,026 shares issued to Harvard Bioscience shareholders in connection with the separation from Harvard Bioscience have been outstanding for all periods presented prior to November 1, 2013.

(k) Foreign Currency Translation

The functional currency of the Company's foreign subsidiaries is their local currency. All assets and liabilities of its foreign subsidiaries are translated at exchange rates in effect at period-end. Income and expenses are translated at rates which approximate those in effect on the transaction dates. The resulting translation adjustment is recorded as a separate component of stockholders' equity in accumulated other comprehensive loss in the consolidated balance sheets. Gains and losses resulting from foreign currency transactions are included in net loss.

(l) Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive loss. The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 220, "Comprehensive Income". FASB ASC 220 requires companies to report all changes in equity during a period, resulting from net income (loss) and transactions from non-owner sources, in a financial statement in the period in which they are recognized. We have chosen to disclose comprehensive loss, which encompasses net loss, foreign currency translation adjustments, net of tax, in the consolidated statements of operations and comprehensive loss.

(m) Recently Issued Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, “Revenue from Contracts with Customers,” a new accounting standard that provides for a comprehensive model to use in the accounting for revenue arising from contracts with customers that will replace most existing revenue recognition guidance in U.S. GAAP. Under this standard, revenue will be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. This standard will be effective as of the beginning of the Company’s 2017 fiscal year. The Company is assessing the new standard and has not yet determined the impact to the consolidated financial statements.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies – (continued)

In August 2014, the FASB issued ASU 2014-15, “Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” The new guidance requires management to evaluate whether there are conditions that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. The guidance is effective for fiscal years beginning after December 15, 2016. Management has evaluated the adoption of this guidance, which is related to disclosure only, and has determined that when adopted it would not have a material impact on the Company’s consolidated statements of operations and comprehensive loss, stockholders’ equity, cash flows and related footnotes.

3. Concentrations

Effective November 1, 2013 the Company entered into a 10 year product distribution agreement with Harvard Bioscience under which each company will be the exclusive distributor for the other party for products such other party develops for sale in the markets served by the other. In addition, Harvard Bioscience agreed that except for certain then-existing activities of its German subsidiary, to the extent that any Harvard Bioscience businesses desire to resell or distribute any bioreactor that is then manufactured by HART, HART will be the exclusive manufacturer of such bioreactors and Harvard Bioscience will purchase such bioreactors from the Company.

Sales to Harvard Bioscience accounted for 100% of the revenues and related party receivables for all periods presented.

4. Liquidity

The Company has incurred net losses of $32.3 million since inception through December 31, 2014. Since inception, the Company has received funding for operating losses from Harvard Bioscience through the Separation, a $15.0 million cash contribution at the Separation, $0.4 million in proceeds from the exercise of employee stock options, and $8.6 million in net proceeds from the February 15, 2015 underwritten sale of common and preferred shares (see

footnote 14 Subsequent Events for additional details). The Company is currently investing significant resources in development and commercialization of products for use by clinicians and researchers in the field of regenerative medicine. The Company expects to continue to incur operating losses and negative cash flows from operations. Management believes that the Company's cash at March 26, 2015, the date of this filing, will be sufficient to meet the Company's obligations for at least the next twelve months from that date based on management's current business plans.

5. Inventories

Inventories consist of the following:

	December 31,	
	2014	2013
	(in thousands)	
Finished goods	$ -	$ 7
Raw materials	207	31
Total	$ 207	$ 38

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

6. Related Party Transactions

Agreements with Harvard Bioscience

In connection with the Separation, the Company entered into a series of agreements with Harvard Bioscience. These agreements include: (i) a Separation and Distribution Agreement to effect the separation and spin-off distribution and provide other agreements to govern the Company's relationship with Harvard Bioscience after the spin-off; (ii) an Intellectual Property Matters Agreement, which governs various intellectual property related arrangements between the Company and Harvard Bioscience, including the separation of intellectual property rights between the Company and Harvard Bioscience, as well as certain related cross-licenses between the two companies; (iii) a Product Distribution Agreement, which provided that each company be the exclusive distributor for the other party for products such other party develops for sale in the markets served by the other; (iv) a Tax Sharing Agreement, which governs the Company's and Harvard Bioscience's respective rights, responsibilities and obligations with respect to tax liabilities and benefits, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings and other matters regarding taxes for periods before, during and after the spin-off; and (v) a Transition Services Agreement, which provided for certain services to be performed on a transitional basis by Harvard Bioscience to facilitate HART's transition into a separate public reporting company. As part of the Transition Services Agreement, and for one year following the spin-off date, Harvard Bioscience provided certain support services to HART, including, among others, accounting, payroll, human resources and information technology services, with the charges for the transition services generally intended to allow Harvard Bioscience to fully recover the costs directly associated with providing the services, plus all out-of-pocket costs and expenses. Some of these agreements require HART to pay fees to Harvard Bioscience for services provided subsequent to the Separation, and will remain in place through at least October 31, 2014. The Company's operating expenses for the twelve months subsequent to the Separation include fees from Harvard Bioscience for services provided pursuant to the Transition Services Agreement, and operating supplies. Fees for the year ended December 31, 2014 and the period from November 1, 2013 to December 31, 2013 were $0.2 million and $0.1 million, respectively. In addition, the Company's rent and related costs subsequent to the Separation was incurred and paid to Harvard Bioscience pursuant to a sublease between the two companies. Sublease related expenses for the years ended December 31, 2014 and 2013 was $169 thousand and $26 thousand, respectively. Refer to Note 8 for further details on the sublease.

David Green, who is currently the Chairman and CEO of the Company was also formerly Harvard Bioscience's President and interim CEO and, is currently a director of Harvard Bioscience.

Cost Allocations

For all periods prior to the Separation HART's operations were fully integrated with Harvard Bioscience, including executive services, finance, treasury, corporate income tax, human resources, legal services and investor relations. The accompanying financial statements reflect the application of certain estimates and allocations of operating expenses and the Company believes the methods used to allocate these operating expenses are reasonable. The allocation methods include time devoted to HART activities, headcount, percentage of operating expenses or other relevant measures. Allocation of expenses for these services in 2013 totaled $2.0 million through the Separation on October 31, 2013. The Company's financial statements for the periods prior to the Separation may not be indicative of the future performance and do not necessarily reflect what the results of operations, financial position and cash flows would have been had the Company operated as an independent, publicly-traded company during the full periods presented.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

7. Property, Plant and Equipment, Net

Property, plant and equipment, net consist of the following:

	December 31,	
	2014	2013
	(in thousands)	
Leasehold improvements	$449	$281
Furniture, machinery and equipment	1,138	388
Computer equipment and software	400	154
	1,987	823
Less: accumulated depreciation	(611)	(248)
Property, plant and equipment, net	$1,376	$575

8. Leases

In October 2013, the Company entered into a sublease with Harvard Bioscience effective November 1, 2013 for its headquarters, offices, manufacturing, and research and development facilities located in Holliston, Massachusetts. The operating lease is noncancelable for an initial eighteen month period. The sublease automatically extends for additional successive twelve month periods, if neither party provides notice of termination 180 days in advance, through May 31, 2017. Total rent expense was $94,962 and $44,776 for the years ended December 31, 2014 and 2013, respectively.

Future minimum lease payments for operating leases with initial or remaining terms in excess of one year at December 31, 2014 were:

	Operating Leases (in thousands)
2015	$ 97
2016	41
Thereafter	-
Future minimum lease payments	$ 138

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Income Taxes

Prior to the Separation, HART's operating results were historically included in Harvard Bioscience's income tax returns. For periods up to the date of the Separation, the provision for income taxes has been determined as if HART had filed separate tax returns for the periods presented. Accordingly, the effective tax rate of HART in the future years could vary from its historical effective tax rates depending on the future legal structure of HART and related tax elections. The historical deferred tax assets, including the operating loss and credit carryforwards generated by HART up to the date of Separation, remained with Harvard Bioscience. Net operating loss and tax carryforwards generated by HART after the Separation will remain with HART.

Income taxes for the years ended December 31, 2014 and 2013 differed from the amount computed by applying the U.S. federal income tax rate of 34% to pre-tax loss as a result of the following:

	Years ended December 31,	
	2014	2013
	(in thousands)	
Computed "expected" income tax benefit	$ (3,761)	$ (2,998)
Increase (decrease) in income taxes resulting from:		
2013 pre-Separation losses remaining with Harvard Bioscience	-	2,327
Foreign tax rate and regulation differential	40	13
State income tax benefit, net of federal income tax benefit	(663)	(118)
Non-deductible stock-based compensation expense	94	18
Tax credits	(178)	(50)
Change in valuation allowance allocated to income tax expense	4,468	808
Total income taxes	$ -	$ -

The Company has incurred pre-tax losses for the years ended December 31, 2014 and 2013:

	Years ended December 31,	
	2014	2013
	(in thousands)	
Domestic	$ (10,780)	$ (8,602)
Foreign	(281)	(215)

Total	$ (11,061)	$ (8,817)

Income taxes are based on the pre-tax losses of $1.8 million domestic and $0.09 million foreign for the period from Separation to December 31, 2013.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Income Taxes – (continued)

The components of HART's deferred tax asset are as follows:

	Years ended December 31,	
	2014	2013
	(in thousands)	
Deferred tax assets:		
Operating loss and credit carryforwards	$ 2,543	$ 514
Capitalized research and development	1,612	-
Stock-based compensation	1,086	294
Accrued expenses	27	-
Property, plant and equipment	9	-
Total deferred tax assets	5,277	808
Less: valuation allowance	(5,277)	(808)
Deferred tax assets, net	$ -	$ -

The amounts recorded as deferred tax assets as of December 31, 2014 and 2013 represent the amount of tax benefits of existing deductible temporary differences or carryforwards that are more likely than not to be realized through the generation of sufficient future taxable income within the carryforward period. Significant management judgment is required in determining any valuation allowance recorded against deferred tax assets and liabilities. Due to the operating results, the Company's cumulative loss position and uncertainty surrounding its forecasts, the Company concluded that a full valuation allowance was needed to offset its deferred tax assets at each period end. As previously mentioned, all deferred tax assets prior to the Separation remained with Harvard Bioscience, Inc. The Company has determined that any uncertain tax positions would have no material impact on the consolidated financial statements of the Company.

Tax free distribution

Harvard Bioscience received a Supplemental Ruling to the Private Letter Ruling dated March 22, 2013 from the IRS to the effect that, among other things, the Separation and related distribution of all of the shares of the Company's common stock by Harvard Bioscience will qualify as a transaction that is tax-free for U.S. federal income tax purposes under Section 355 and 368(a)(1)(D) of the Internal Revenue Code continuing in effect. The private letter and

supplemental rulings and the tax opinion that Harvard Bioscience received from legal counsel to Harvard Bioscience rely on certain representations, assumptions and undertakings, including those relating to the past and future conduct of the HART business, and neither the private letter and supplemental rulings nor the opinion would be valid if such representations, assumptions and undertakings were incorrect. Moreover, the private letter and supplemental rulings do not address all the issues that are relevant to determining whether the Distribution will qualify for tax-free treatment. Notwithstanding the private letter and supplemental rulings and opinion, the IRS could determine the Distribution should be treated as a taxable transaction for U.S. federal income tax purposes if, among other reasons, it determines any of the representations, assumptions or undertakings that were included in the request for the private letter and supplemental rulings are false or have been violated or if it disagrees with the conclusions in the opinion that are not covered by the IRS ruling.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

9. Income Taxes – (continued)

To preserve the tax-free treatment to Harvard Bioscience of the Separation and Distribution, for the two-year period following the Distribution the Company may be limited, except in specified circumstances, from entering into certain transactions pursuant to which all or a portion of the Company's stock would be acquired, whether by merger or otherwise; issuing equity securities beyond certain thresholds; repurchasing the Company's common stock; ceasing to actively conduct the Company's regenerative medicine business; and taking or failing to take any other action that prevents the Separation and Distribution and related transactions from being tax-free.

If the Distribution fails to qualify for tax-free treatment, in general, Harvard Bioscience would be subject to tax as if it had sold the Company's common stock in a taxable sale for its fair market value, and Harvard Bioscience stockholders who receive shares of HART common stock in the Distribution would be subject to tax as if they had received a taxable Distribution equal to the fair market value of such shares.

Under the tax sharing agreement between Harvard Bioscience and the Company, the Company would generally be required to indemnify Harvard Bioscience against any tax resulting from the Distribution to the extent that such tax resulted from (i) an acquisition of all or a portion of our stock or assets, whether by merger or otherwise, (ii) other actions or failures to act by the Company, or (iii) any of the Company's representations or undertakings being incorrect or violated. The Company's indemnification obligations to Harvard Bioscience and its subsidiaries, officers and directors are not limited by any maximum amount. If the Company is required to indemnify Harvard Bioscience or such other persons under the circumstances set forth in the tax sharing agreement, the Company may be subject to substantial liabilities.

10. Employee Benefit Plans

The Company and Harvard Bioscience sponsor retirement plans for their U.S. employees, which includes employee savings plans established under Section 401(k) of the U.S. Internal Revenue Code (the "401(k) Plans"). The 401(k) Plans cover substantially all full-time employees who meet certain eligibility requirements. Contributions to the

retirement plans are at the discretion of management. For the years ended December 31, 2014 and 2013, the Company's matching contributions to the plans were approximately $90 thousand and $84 thousand, respectively.

11. Commitments and Contingent Liabilities

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. The Company is not currently a party to any such significant claims or proceedings.

12. Capital Stock

Preferred Stock

The Company's Board of Directors has the authority to issue up to 2.0 million shares of preferred stock and to determine the price privileges and other terms of the shares. The Board of Directors may exercise this authority without any further approval of stockholders. As of December 31, 2014, the Company had no preferred stock issued or outstanding. On February, 18, 2015 the Company issued 695,857 shares of its Series B Convertible Preferred Stock in a registered public offering, see footnote 14 Subsequent Events for additional details.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

12. Capital Stock – (continued)

Common Stock

At the Company's incorporation in May of 2012, the Company issued 100 shares of common stock which was wholly-owned by Harvard Bioscience. In March of 2013, the Company performed an 80,000-for-1 stock split to achieve a desired 8 million shares outstanding. Immediately prior to the Distribution on October 31, 2013 HART affected a reverse stock split so that shares outstanding became 7.7 million to facilitate the 1-for-4 ratio for the Distribution. The distribution of the 7.7 million HART common shares to the shareholders of Harvard Bioscience is reflected as an issuance of common stock in the consolidated statements of stockholders' equity.

The Company has adopted a Shareholder Rights Plan and declared a dividend distribution of one preferred stock purchase right for each outstanding share of the Company's common stock. Initially, these rights will not be exercisable and will trade with the shares of the Company's common stock. Under the Shareholder Rights Plan, the rights generally will become exercisable if a person becomes an "acquiring person" by acquiring 20% or more of the common stock of the Company or if a person commences a tender offer that could result in that person owning 20% or more of the common stock of the Company. If a person becomes an acquiring person, each holder of a right (other than the acquiring person) would be entitled to purchase, at the then-current exercise price, such number of shares of preferred stock which are equivalent to shares of the Company's common stock having a value of twice the exercise price of the right. If the Company is acquired in a merger or other business combination transaction after any such event, each holder of a right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the right.

On February, 18, 2015, in the registered public offering of the Series B Convertible Preferred Stock described above, the Company also issued 2,070,000 shares of its Common Stock. See footnote 14 Subsequent Events for additional details.

Employee Stock Purchase Plan

In 2013, the Company approved an employee stock purchase plan. Under this plan, participating employees can authorize the Company to withhold a portion of their base pay during consecutive six-month payment periods for the purchase of shares of the Company's common stock. At the conclusion of the period, participating employees can purchase shares of the Company's common stock at 85% of the lower of the fair market value of the Company's common stock at the beginning or end of the period. Shares are issued under the plan for the six-month periods ending June 30 and December 31. The initial six month participation period for the plan began on January 1, 2014. Under this plan, 150,000 shares of common stock are authorized for issuance of which 17,042 shares related to 2014 withholdings were issued on January 2, 2015.

13. Share-Based Compensation

Harvard Bioscience maintains the Third Amended and Restated 2000 Stock Option and Incentive Plan as amended, (the "Harvard Bioscience Plan") for the benefit of certain of its officers, directors and employees.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

The disclosure prior to the Separation represents the Company's portion of the plan maintained by Harvard Bioscience in which the Company's employees and directors participated. All options and awards granted under the Harvard Bioscience Plan consist of Harvard Bioscience common shares. Accordingly, the amounts presented are not necessarily indicative of future performance and do not necessarily reflect the results that the Company would have experienced as an independent, publicly-traded company for the periods presented.

HART maintains the 2013 Plan for the benefit of certain of its officers, directors and employees. All options and awards granted under the 2013 Plan consist of HART common shares. Additionally, equity awards related to shares of the Company's common stock were issued from the 2013 Plan at the time of the Distribution to the holders of Harvard Bioscience equity awards as part of an adjustment (the "Adjustment") to those equity awards to prevent a loss of value due to the Distribution.

Prior to the Separation, HART stock-based compensation expense represented an allocation from Harvard Bioscience's stock-based compensation expense for employees whose time had been allocated to HART. After the Separation, HART continues to record the expense on stock-based awards of Harvard Bioscience stock options and restricted stock units, issued by Harvard Bioscience, to former Harvard Bioscience employees now employed by HART.

Harvard Bioscience award holders were also issued stock-based compensation awards in HART stock options and restricted stock units. HART recognizes compensation expense on those awards to former Harvard Bioscience employees who now are employed by HART, and does not recognize expense on the Adjustment awards given to individuals not now employed by HART. Additionally, HART records expense on grants made under the 2013 Plan to HART officers, directors and employees granted subsequent to the Adjustment.

In connection with the spin-off, certain required adjustments were made to the Harvard Bioscience outstanding equity compensation awards under their employee benefit plans. Each outstanding option to purchase Harvard Bioscience common stock was converted on the date of the Distribution into both an adjusted Harvard Bioscience option to

purchase Harvard Bioscience common stock and an option to purchase HART common stock. Black-Scholes valuation modeling was used to determine the value that each Harvard Bioscience option had lost at the time of the Distribution. To ensure the holder maintained such lost value, 80% of such lost value was provided back to the holder by making appropriate adjustments to the share amount and exercise price of the existing Harvard Bioscience option and 20% of such lost value was provided back to the holder through the issuance of an option to purchase HART common stock. Similar to the adjustment of the existing Harvard Bioscience options, with respect to unvested Harvard Bioscience restricted stock units outstanding at the time of the Distribution, such Harvard Bioscience restricted stock units were converted on the date of the Distribution into both an adjusted Harvard Bioscience restricted stock unit and a HART restricted stock unit. The market prices of Harvard Bioscience and HART common stock were used to determine the value that each Harvard Bioscience restricted stock unit lost at the time of the Distribution and then to ensure the holder maintained such lost value, 80% of such lost value was provided back to the holder by making an appropriate increase of the share amount of the existing Harvard Bioscience restricted stock unit and 20% of such lost value was provided back to the holder through the issuance of a HART restricted stock unit. The share amounts and exercise prices of the adjusted Harvard Bioscience options and HART options, as well as the share amounts of the adjusted Harvard Bioscience restricted stock unit and HART restricted stock unit, were each adjusted and set in a manner to ensure the intrinsic value held by the holder pertaining to the existing Harvard Bioscience award just prior to the Distribution would be maintained immediately following the Distribution and were determined such that tax was not triggered under Section 409A of the Internal Revenue Code. As part of these required adjustments, the Company issued approximately 0.3 million HART options and approximately 0.02 million HART restricted stock units, all of which are reflected below. The Company records compensation expense only on those HART awards issued to HART employees. The Company also records compensation expense on those Harvard Bioscience awards issued to HART employees.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

Harvard Bioscience Plan

Harvard Bioscience maintains the Harvard Bioscience Plan for the benefit of certain of its officers, directors and employees. Prior to the Separation stock-based compensation expense for HART represented an allocation from Harvard Bioscience's stock-based compensation expense for employees and directors whose time was partly or wholly allocated to HART. The disclosure for periods prior to the Separation represents the Company's portion of the plan maintained by Harvard Bioscience in which the Company's employees and directors participated. All options and awards granted under the Harvard Bioscience Plan consist of Harvard Bioscience common shares. Accordingly, the amounts presented are not necessarily indicative of future performance and do not necessarily reflect the results that the Company would have experienced as an independent, publicly-traded company for the periods presented.

During the year ended December 31, 2013 all awards were granted to the Company's employees and directors at exercise prices equal to or greater than fair market value of the Harvard Bioscience's common stock on the date of grant.

Harvard Bioscience Plan Award Information

The following is a summary of stock option and restricted stock unit activity:

	Stock Options		Restricted Stock Units	
	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2012	622,340	$ 4.07	184,264	$ 3.90
Granted	217,902	5.08	63,929	5.08

Exercised	(487,031)	3.33	—	—
Vested (RSUs)	—	—	(55,247)	—
Cancelled/forfeited	(29,972)	4.34	(10,892)	3.83
Adjustment (1)	2,177,100		144,131	
Balance at December 31, 2013	2,500,339	3.20	326,185	5.46
Granted	—	—	—	—
Exercised	(66,056)	3.34	—	—
Vested (RSUs)	—	—	(154,628)	—
Cancelled/forfeited	(311,635)	5.58	—	—
Balance at December 31, 2014	2,122,648	$ 2.84	171,557	$ 5.67

(1) Prior to the Separation, this rollforward included only those Harvard Bioscience options and restricted stock units which were issued while giving service to the regenerative technology operations of Harvard Bioscience. If employees were splitting time between regenerative technology and other parts of Harvard Bioscience, only an allocated portion of that year's activity would be reflected. As of the time of the Separation, the rollfoward was "Adjusted" to exclude all Harvard Bioscience employees not employed by HART at the time of the Separation, and to include 100% of the Harvard Bioscience awards held by HART employees (regardless of level of service in prior years).

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

The following table summarizes information concerning the Harvard Bioscience Plan currently outstanding and exercisable options as of December 31, 2014:

	Options Outstanding				Options Exercisable			
Range of Exercise Price	Number Outstanding at December 31. 2014	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares Exercisable at December 31. 2014	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.43 - 2.59	1,365,645	5.07	$ 2.26	$4,651,366	1,188,461	4.71	$ 2.22	$4,100,190
3.64	246,575	8.41	3.64	500,547	56,663	8.41	3.64	115,026
3.71 - 3.99	276,653	2.33	3.98	468,475	276,653	2.33	3.98	468,475
4.04	233,775	6.42	4.04	381,053	175,332	6.42	4.04	285,791
$1.43- 4.04	2,122,648	5.25	$ 2.84	$6,001,441	1,697,109	4.62	$ 2.74	$4,969,482

The aggregate intrinsic value in the preceding table represents the total pre-tax intrinsic value, based on Harvard Bioscience's closing stock price of $5.67 as of December 31, 2014, which would have been received by the option holders had all option holders exercised their options as of that date. The aggregate intrinsic value of options exercised for the years ended December 31, 2014 and 2013 was approximately $0.1 million and $1.1 million, respectively. The total number of in-the-money options that were exercisable as of December 31, 2014 was 1,697,109.

For the year ended December 31, 2014, the total compensation costs related to unvested awards not yet recognized is $0.6 million and the weighted average period over which it is expected to be recognized is 1.49 years.

Harvard Bioscience Plan Valuation and Expense Information under Stock-Based-Payment Accounting

Stock-based compensation expense related to Harvard Bioscience employee stock options and restricted stock units for the years ended December 31, 2014 and 2013 was allocated as follows:

	Years Ended December 31,	
	2014	2013
	(in thousands)	
Research and development	$ 66	$ 136
Sales and marketing	14	16
General and administrative	683	622
Total stock-based compensation	$ 763	$ 774

The Company did not capitalize any stock-based compensation.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

The weighted-average estimated value of Harvard Bioscience employee stock options granted during 2013 was $2.64, using the Black-Scholes model with the following weighted-average assumptions:

	Year Ended December 31, 2013	
Volatility	57.18	%
Risk-free interest rate	1.42	%
Expected holding period	5.67 years	
Dividend yield	-	%

The Company used Harvard Bioscience's historical volatility to calculate the expected volatility. Historical volatility was determined by calculating the mean reversion of the daily adjusted closing stock price. The risk-free interest rate assumption is based upon observed Treasury bill interest rates (risk-free) appropriate for the term of the Harvard Bioscience employee stock options. The expected life of employee stock options represents the period of time options are expected to be outstanding and were based on historical experience of Harvard Bioscience.

Stock-based compensation expense recognized in the Company's consolidated statements of operations related to Harvard Bioscience options for the years ended December 31, 2014 and 2013 is based on awards ultimately expected to vest and has been reduced for annualized estimated forfeitures. Stock-based-payment accounting requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience of Harvard Bioscience.

Harvard Apparatus Regenerative Technology, Inc. 2013 Equity Incentive Plan

The 2013 Equity Incentive Plan (the “2013 Plan”) was adopted by the Board of Directors on October 11, 2013. The aggregate number of shares authorized for issuance under the Plan is 3,320,000 shares of common stock.

The Company currently has 3,320,000 shares of its common stock reserved for the issuance of awards under the 2013 Plan. As of December 31, 2014, there were options outstanding to purchase 2,006,980 shares, and 7,980 restricted stock units outstanding.

Through December 31, 2014, incentive stock options to purchase 130,122 shares and non-qualified stock options to purchase 2,224,604 shares had been granted to employees and directors under the plan.

During the year ended December 31, 2013, 2,117,226 options were granted under the 2013 Plan to HART and Harvard Bioscience employees and directors at exercise prices equal to or greater than fair market value of the Company’s common stock on the date of grant, of which 298,784 were issued as part of the Adjustment made to the Harvard Bioscience outstanding equity compensation awards.

During 2013, 23,715 restricted stock units were granted to certain HART and Harvard Bioscience employees and directors under the 2013 Plan, all of which were issued as part of the Adjustment made to the Harvard Bioscience outstanding equity compensation awards.

During 2014 no options or restricted stock units were granted to Harvard Bioscience employees or directors, and the company does not anticipate issuing any to Harvard Bioscience employees in the future.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

2013 Plan Award Information

The following is a summary of stock option and restricted stock unit activity:

	Stock Options		Restricted Stock Units	
	Stock Options Outstanding	Weighted Average Exercise Price	Restricted Stock Units Outstanding	Grant Date Fair Value
Balance at December 31, 2012	-	$ -	-	$ -
Granted	2,117,226	4.36	23,715	6.00
Exercised	(693)	5.38	-	-
Vested (RSUs)	-	-	(2,021)	-
Cancelled/forfeited	(40,826)	4.96	(2,202)	-
Balance at December 31, 2013	2,075,707	4.34	19,492	6.00
Granted	237,500	7.93	-	-
Exercised	(115,950)	4.90	(9,796)	-
Vested (RSUs)	-	-	-	-
Cancelled/forfeited	(190,277)	4.42	(1,716)	-
Balance at December 31, 2014	2,006,980	$ 4.73	7,980	$ 6.00

The Company’s policy is to issue stock available from its registered but unissued stock pool through its transfer agent to satisfy stock option exercises and vesting of the restricted stock units.

The following table summarizes information concerning 2013 Plan currently outstanding and exercisable options as of December 31, 2014:

	Options Outstanding				Options Exercisable			
Range of Exercise Price	Number Outstanding at December 31. 2014	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares Exercisable at December 31. 2014	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value
$2.05 - 3.60	54,108	4.05	$ 3.13	$ 2,705	54,108	4.05	$ 3.13	$ 2,705
3.61 - 5.16	1,668,023	8.80	4.28	-	508,375	8.59	4.28	-
5.17-6.72	77,349	6.27	5.52	-	50,114	5.35	5.61	-
6.73 - 8.28	57,500	9.76	7.32	-	-	-	-	-
8.29 - 9.84	150,000	9.34	8.87	-	-	-	-	-
$2.05- 9.84	2,006,980	8.64	$ 4.73	$ 2,705	612,597	7.92	$ 4.28	$ 2,705

The aggregate intrinsic value in the preceding table represents the total pre-tax intrinsic value, based on the Company’s closing stock price of $3.18 as of December 31, 2014, which would have been received by the option holders had all option holders exercised their options as of that date. The aggregate intrinsic value of options exercised for the year ended December 31, 2014 and 2013 was approximately $507,466 and $810, respectively. The total number of in-the-money options that were exercisable as of December 31, 2014 was 12,905.

For the year ended December 31, 2014, the total compensation costs related to unvested awards not yet recognized is $4.4 million and the weighted average period over which it is expected to be recognized is 2.17 years.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

13. Share-Based Compensation – (continued)

2013 Plan Valuation and Expense Information under Stock-Based-Payment Accounting

Stock-based compensation expense related to the 2013 Plan including employee stock options, restricted stock units, and the employee stock purchase plan for the years ended December 31, 2014 and 2013 was allocated as follows:

	Years Ended December 31,	
	2014	2013
	(in thousands)	
Research and development	$ 554	$ 39
Sales and marketing	94	32
General and administrative	1,154	525
Total stock-based compensation	$ 1,802	$ 596

The Company did not capitalize any stock-based compensation.

The weighted-average estimated value of employee stock options granted during 2014 and 2013 was $5.25 and $3.33, respectively, using the Black Scholes model with the following weighted-average assumptions:

	Year Ended December 31,			
	2014		2013	
Volatility	74.00	%	73.59	%
Risk-free interest rate	1.61	%	2.01	%
Expected holding period	6.25 years		5.81 years	
Dividend yield	-	%	-	%

Post spin-off, the Company used the published volatility of comparable companies, as management did not believe that our trading history was of a sufficient duration to provide an accurate estimate of expected volatility. The risk-free interest rate assumption is based upon observed Treasury bill interest rates (risk-free) appropriate for the term of the Company's employee stock options. After the Separation, the simplified method of estimating expected life was used. The vesting period is approximately four years and the contractual life is ten years.

Stock-based compensation expense recognized in the Company's consolidated statements of operations for the years ended December 31, 2014 and 2013 is based on awards ultimately expected to vest and has been reduced for annualized estimated forfeitures. Stock-based-payment accounting requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience and weighting of various employee classes.

14. Subsequent Events

On February 18, 2015 the Company closed an underwritten public offering of 2,070,000 registered shares of its common stock, at a price to the public of $1.75 per share, and 695,857 registered shares of its Series B Convertible Preferred Stock ("Series B") at a price to the public of $8.75 per share. At the option of the investor, each share of Series B is convertible into five shares of common stock of HART, and will vote with the common stock on all matters on an as-converted basis, each subject to certain beneficial ownership caps. The Series B has no preference to the common shares in respect of dividends, voting, liquidation or otherwise. The number of shares of common stock sold in the offering included the underwriters' full exercise of their over-allotment option of 270,000 shares of common stock.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

14. Subsequent Events – (continued)

The Company intends to use the net proceeds of approximately $8.6 million from the offering primarily for research and development, including funding pre-clinical and clinical studies relating to the HART-Trachea, business development, sales and marketing, capital expenditures, working capital and other general corporate purposes.

15. Quarterly Financial Information (Unaudited)

Statement of Operations Data:

2014	**First Quarter**	**Second Quarter**	**Third Quarter**	**Fourth Quarter**	**Fiscal Year**
	(in thousands, except per share data)				
Revenues	$23	$23	$2	$45	$93
Cost of product revenues	12	12	1	23	48
Gross profit	11	11	1	22	45
Total Operating expenses	3,017	2,544	2,677	2,864	11,102
Operating loss	(3,006)	(2,533)	(2,676)	(2,842)	(11,057)
Other (expense) income, net	-	-	(4)	-	(4)
Loss before income taxes	(3,006)	(2,533)	(2,680)	(2,842)	(11,061)
Income taxes	-	-	-	-	-
Net loss	$(3,006)	$(2,533)	$(2,680)	$(2,842)	$(11,061)
Basic and diluted net loss per share	$(0.39)	$(0.32)	$(0.34)	$(0.36)	$(1.41)

Statement of Operations Data:

2013	**First Quarter**	**Second Quarter**	**Third Quarter**	**Fourth Quarter**	**Fiscal Year**
	(in thousands, except per share data)				

Revenues	$-	$-	$-	$22	$22
Cost of product revenues	-	-	-	11	11
Gross profit	-	-	-	11	11
Total Operating expenses	2,020	2,089	2,060	2,659	8,828
Operating loss	(2,020)	(2,089)	(2,060)	(2,648)	(8,817)
Other (expense) income, net	-	-	-	-	-
Loss before income taxes	(2,020)	(2,089)	(2,060)	(2,648)	(8,817)
Income taxes	-	-	-	-	-
Net loss	$(2,020)	$(2,089)	$(2,060)	$(2,648)	$(8,817)
Basic and diluted net loss per share	$(0.26)	$(0.27)	$(0.27)	$(0.34)	$(1.14)

SIGNATURES

Pursuant to the requirements of Section 13 and 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.

Date: March 26, 2015 By:
/s/ David Green

David Green
Chief Executive Officer and President

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

Signature	**Title**	**Date**
/s/ David Green **David Green**	Chief Executive Officer, President and Director (Principal Executive Officer)	March 26, 2015
/s/ Thomas McNaughton **Thomas McNaughton**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 26, 2015
/s/ John Canepa **John Canepa**	Director	March 26, 2015
/s/ John Kennedy **John Kennedy**	Director	March 26, 2015
/s/ James McGorry **James McGorry**	Director	March 26, 2015

EXHIBIT INDEX

The following exhibits are filed as part of this Annual Report on Form 10-K. Where such filing is made by incorporation by reference to a previously filed document, such document is identified.

Exhibit Number	Description of Exhibit
2.1§ (3)	Separation and Distribution Agreement between Harvard Apparatus Regenerative. Technology, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.
3.1 (1)	Amended and Restated Certificate of Incorporation of Registrant.
3.2 (1)	Amended and Restated By-laws of the Registrant.
3.3 (2)	Certificate of Designations, Preferences and Rights of Series A Preferred Stock of Harvard Apparatus Regenerative Technology, Inc. classifying and designating the Series A Junior Participating Cumulative Preferred Stock.
3.4(6)	Certificate of Designation of Series B Convertible Preferred Stock of Harvard Apparatus Regenerative Technology, Inc. classifying and designating the Series B Convertible Preferred Stock.
4.2*	Specimen Series B Convertible Preferred Stock Certificate
4.3 (2)	Shareholder Rights Agreement, dated as of October 31, 2013, between Harvard Apparatus Regenerative Technology, Inc. and Registrar and Transfer Company, as Rights Agent.
4.4(6)	Amendment to Shareholder Rights Agreement, dated as of February 12, 2015 between Harvard Apparatus Regenerative Technology, Inc. and Computershare Trust Company, N.A., as successor to Registrar and Transfer Company.
10.1 (3)	Intellectual Property Matters Agreement between Harvard Apparatus Regenerative Technology, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.
10.2 (3)	Product Distribution Agreement between Harvard Apparatus Regenerative Technology, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.
10.3 (3)	Tax Sharing Agreement between Harvard Apparatus Regenerative Technology, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.
10.4 (3)	Transition Services Agreement between Harvard Apparatus Regenerative Technology, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.
10.5 (3)	Sublease by and between Harvard Apparatus Regenerative Technology, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.
10.6# (3)	Employment Agreement between Harvard Apparatus Regenerative Technology, Inc. and David Green dated as of October 31, 2013.
10.7# (3)	Employment Agreement between Harvard Apparatus Regenerative Technology, Inc. and Thomas McNaughton dated as of October 31, 2013.
10.8 (1)	Form of Indemnification Agreement for Officers and Directors.
10.8 (1)	2013 Equity Incentive Plan.
10.9 (1)	Employee Stock Purchase Plan.
10.10 (1)	Form of Incentive Stock Option Agreement.
10.11 (1)	Form of Non-Qualified Stock Option Agreement for executive officers.
10.12 (1)	Form of Non-Qualified Stock Option Agreement for directors.
10.13 (1)	Form of Deferred Stock Award Agreement.

10.14# (1)	Director Compensation Arrangements.
10.15†(4)	Sublicense Agreement dated as of December 7, 2012 between Harvard Apparatus Regenerative Technology, Inc. and Harvard Bioscience, Inc., and related Trademark License Agreement, dated December 19, 2002, by and between Harvard Bioscience, Inc. and President and Fellows of Harvard College.
10.16 (1)	Patent Rights Assignment dated December 21, 2012 between Harvard Apparatus Regenerative Technology, Inc. and Dr. Paolo Macchiarini.
10.17 (1)	Sponsored Research Agreement dated August 5, 2009 by and among Harvard Apparatus Regenerative Technology, Inc. (as assignee of Harvard Bioscience, Inc.), Sara Mantero, Maria Adelaide Asnaghi, and Department of Bioengineering of the Politecnico Di Milano

Exhibit Number	Description of Exhibit
10.18†[5]	Exclusive License Agreement dated August 6, 2009 by and between Harvard Apparatus Regenerative Technology, Inc. (as assignee of Harvard Bioscience, Inc.) and Sara Mantero and Maria Adelaide Asnaghi.
10.19 [1]	Novel Surgery Agreement dated as of May 21, 2012 between Harvard Apparatus Regenerative Technology, Inc. and State Budget Institution of Public Health Department Regional Clinical Hospital #1 and Vladimir Alekseevich Porhanov.
10.20 [1]	Novel Surgery Agreement dated as of May 24, 2012 between Harvard Apparatus Regenerative Technology, Inc. and OSF Healthcare System, owner and operator of Saint Francis Medical Center and Children's Hospital of Illinois, and Mark Holterman, M.D.
10.21 [1]	Amendment to Novel Surgery Agreement dated as of April 5, 2013 between Harvard Apparatus Regenerative Technology, Inc. and OSF Healthcare System, owner and operator of Saint Francis Medical Center and Children's Hospital of Illinois, and Mark Holterman, M.D.
10.22 [1]	Amendment to Novel Surgery Agreement dated as of June 26, 2013 between Harvard Apparatus Regenerative Technology, Inc. and State Budget Institution of Public Health Department Regional Clinical Hospital #1 and Igor S. Polyakov.
10.23[6]	Underwriting Agreement dated as of February 12, 2015, between Harvard Apparatus Regenerative Technology, Inc. and National Securities Corporation as representative of the underwriters named therein.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP.
31.1*	Certification of Chief Financial Officer of Harvard Bioscience, Inc., pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Executive Officer of Harvard Bioscience, Inc., pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Financial Officer of Harvard Bioscience, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Executive Officer of Harvard Bioscience, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Previously filed as an exhibit to the Company's Registration Statement on Form 10-12B (filed July 31, 2013) and incorporated by reference thereto.

(2) Previously filed as an exhibit to the Company's Registration Statement on Form 8-A (filed October 31, 2013) and incorporated by reference thereto.

(3)

Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on November 6, 2013) and incorporated by reference thereto.

(4) Previously filed as an exhibit to the Company's Amendment No. 2 to Form S-1 Registration Statement (filed on February 15, 2013) and incorporated by reference thereto.

(5) Previously filed as Exhibit 10.19 to the Registrant's Amendment No. 2 to Form S-1 Registration Statement (filed on February 15, 2013) and incorporated by reference thereto.

(6) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on February 12, 2015) and incorporated by reference thereto.

* Filed herewith.

** This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

Management contract or compensatory plan or arrangement.

§ The schedules and exhibits to the Separation and Distribution Agreement have been omitted. A copy of any omitted schedule or exhibit will be furnished to the SEC supplementally upon request.
The Company will furnish to stockholders a copy of any exhibit without charge upon written request.

† Confidential portions of this exhibit have been redacted and filed separately with the SEC pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.