Harvard Apparatus Regenerative Technology, Inc.
Form 424B3
December 29, 2015

Filed pursuant to Rule 424(b)(3)
Registration No. 333-208559

2,688,933 Shares

Common Stock

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This prospectus relates to the sale of up to 2,688,933 shares of our common stock by Aspire Capital Fund, LLC. Aspire Capital is also referred to in this prospectus as the selling stockholder. The prices at which the selling stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive proceeds of up to $15.0 million from the sale of our common stock to the selling stockholder, pursuant to a common stock purchase agreement entered into with the selling stockholder on December 15, 2015.

The selling stockholder is an "underwriter" within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling stockholder will be paid by the selling stockholder.

Our common stock is listed on the NASDAQ Capital Market under the ticker symbol "HART." On December 28, 2015, the last reported sale price per share of our common stock was $2.07 per share.

You should read this prospectus and any prospectus supplement, together with additional information described under the headings "Incorporation of Certain Documents by Reference" and "Where You Can Find More Information," carefully before you invest in any of our securities.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 5 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is December 29, 2015.

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Neither we nor the selling stockholder has authorized anyone to provide any information or to make any representations other than as contained in this prospectus or in any free writing prospectuses we have prepared. We and the selling stockholder take no responsibility for, and provide no assurance as to the reliability of, any information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

For investors outside of the United States: Neither we nor the selling stockholder have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about, and to observe any restrictions relating to, this offering and the distribution of this prospectus outside of the United States.

All trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We obtained the industry and market data included or incorporated by reference in this prospectus from our own internal estimates and research as well as from publicly available industry and general publications and research, surveys, studies and trials conducted by third parties. We believe and act as if the third-party data contained herein, and the underlying economic assumptions relied upon therein, are generally reliable. Some data is also based on our good faith estimates, which are derived from management's knowledge of the industry and independent sources. This

data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Similarly, we believe our internal research is reliable, even though such research has not been verified by any independent sources. In addition, while we believe the market opportunity information included or incorporated by reference in this prospectus is generally reliable and is based on reasonable assumptions, such data involves risks and uncertainties and are subject to change based on various factors, including those discussed under "Risk Factors." These and other factors could cause our results to differ materially from those expressed in the estimates made by third parties and by us.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus (including any accompanying prospectus supplement and documents incorporated by reference herein and therein) contains statements with respect to us which constitute ‘‘forward-looking statements’’ within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and are intended to be covered by the ‘‘safe harbor’’ created by those sections. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to the regulatory approval of our Gen2 product candidates for the esophagus and airways or any other product candidates, by the FDA, EMA, MHRA or otherwise, which such approvals may not be obtained on a timely basis or at all; anticipated future earnings or other financial measures; success with respect to any clinical trials and other regulatory approval efforts and the number of patients who can be treated with our products or product candidates; commercialization efforts and marketing approvals of our products as well as the success thereof, including our Gen2 product candidates for the esophagus and airways; the continued availability of a market for our securities; our ability to raise sufficient capital to finance our planned operations, and our estimates concerning capital requirements and need for additional financing; the amount and timing of costs associated with our development of bioreactors, scaffolds and other devices and products; our failure to comply with regulations and any changes in regulations; our ability to access debt and equity markets; unpredictable difficulties or delays in the development of new technology; our collaborators not devoting sufficient time and resources to successfully carry out their duties or meet expected deadlines; our ability to attract and retain qualified personnel and key employees and retain senior management; the availability and price of acceptable raw materials and components from third-party suppliers; difficulties in obtaining or retaining the management and other human resource competencies that we need to achieve our business objectives; increased competition in the field of regenerative medicine and the financial resources of our competitors; our ability to obtain and maintain intellectual property protection for our device and product candidates; and our inability to implement our growth strategy.

In some cases, you can identify forward-looking statements by terms such as “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “could,” “would,” “target,” “seek,” “aim,” “believe,” “predicts,” “think,” “objectives,” “optim “strategy” “potential,” “is likely,” “will,” “expect,” “plan” “project,” “permit” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events, are based on assumptions and are 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 greater detail under the heading “Risk Factors” in our SEC filings, and under the caption “Risk Factors” in this prospectus.

You should read this prospectus and any accompanying prospectus supplement and the documents that we incorporate by reference herein and therein and have filed as exhibits to the registration statement, of which this prospectus is part, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this prospectus and any accompanying prospectus supplement is accurate as of the date on the cover of this prospectus or such prospectus supplement only. Our business, financial condition, results of operations and prospects may change.

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. We qualify all of the information presented in this prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements.

PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and selected information contained in the prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider the more detailed information in the prospectus, including "Risk Factors" and the financial statements and related notes. Unless we specify otherwise, all references in this prospectus to "HART," "we," "our," "us" and "our company" refer to Harvard Apparatus Regenerative Technology, Inc.

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

Company Overview

We are a biotechnology company developing bioengineered organ implants for life-threatening conditions. Our technology initially is focused on restoring organ function to a patient's esophagus or airways (the bronchus and trachea). We have built a dedicated internal team of materials scientists, engineers and biologists who are working with our collaborators, including teams at Mayo Clinic and Connecticut Children's Medical Center, to develop our products.

We are currently developing our second-generation (Gen2) bioengineered implants for the esophagus, trachea, and bronchus, aiming to address damage to those organs caused by cancer, and in the case of the trachea damage caused by stenosis and trauma, as well. Our products are meant to guide the repair or regeneration of tissue and restore the organ's function.

We are now conducting confirmatory large-animal studies with Mayo Clinic's team of regenerative medicine experts. We expect that those studies will provide the key data to determine if our Gen2 scaffolds are ready for use in patients. We believe positive results from these studies would support the use of a Gen2 product in compassionate use surgeries.

In addition to our product development collaboration with Mayo Clinic, we have an ongoing collaboration with Connecticut Children's Medical Center to develop an innovative process for repairing or replacing the esophagus to treat life-threatening pediatric conditions such as esophageal atresia.

Assuming we receive positive data from the preclinical studies with Mayo Clinic, we expect to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for our first product coming from our bioengineered organ implant product platform during 2016.

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

Corporate Information

We were incorporated under the laws of the State of Delaware on May 3, 2012. Our principal executive offices are located at 84 October Hill Road, Suite 11, Holliston, Massachusetts. Our telephone number is (774) 233-7300. We maintain a web site at *www.harvardapparatusregen.com*. The reference to our web site is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our web site is not a part of this prospectus.

The name “Harvard Apparatus” is used under a license agreement between Harvard Bioscience and Harvard University. Harvard Bioscience has granted us a sublicense under this license agreement with respect to the name “Harvard Apparatus” for use in the name Harvard Apparatus Regenerative Technology.

The Offering

Common stock being offered by the selling stockholder	2,688,933 shares
Common stock outstanding	14,101,395 (1)
Use of proceeds	The selling stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling stockholder. However, we may receive up to $15.0 million in proceeds from the sale of our common stock to the selling stockholder under the common stock purchase agreement described below. Any proceeds from the selling stockholder that we receive under the purchase agreement are expected be used for working capital and general corporate purposes.
Nasdaq Capital Market Symbol	HART
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the "Risk Factors" section of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.

(1) The total shares of common stock outstanding immediately following this offering is based on 14,101,395 shares outstanding as of December 15, 2015, which includes 150,000 Commitment Shares and 500,000 Initial Purchase Shares issued to Aspire Capital pursuant to the Purchase Agreement. It excludes:

3,334,783 shares issuable upon exercise of outstanding stock options;

1,105 shares issuable pursuant to outstanding deferred stock awards of restricted stock units; and

264,631 shares available for future grants under our the 2013 Equity Incentive Plan and our Employee Stock Purchase Plan.

On December 15, 2015, we entered into a common stock purchase agreement (referred to in this prospectus as the "Purchase Agreement"), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as "Aspire Capital" or the "selling stockholder"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of our shares of common stock over the approximately 30-month term of the Purchase Agreement. In

consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 150,000 shares of our common stock as a commitment fee (referred to in this prospectus as the "Commitment Shares"). Upon execution of the Purchase Agreement, the Company agreed to sell to Aspire Capital 500,000 shares of common stock at $2.00 per share for proceeds of $1,000,000 (referred to in this prospectus as the "Initial Purchase Shares"). Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital (referred to in this prospectus as the "Registration Rights Agreement"), in which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of December 15, 2015, there were 13,451,395 shares of our common stock outstanding (12,560,986 shares held by non-affiliates) excluding the 2,688,933 shares offered that have been issued or may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of such 2,688,933 shares of our common stock offered hereby were issued and outstanding as of the date hereof, such shares would represent 19.99% of the total common stock outstanding or 21.41% of the non-affiliate shares of common stock outstanding as of the date hereof. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 2,688,933 shares of our common stock under the Securities Act, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital and 2,038,933 shares of common stock which we may issue to Aspire Capital. All 2,688,933 shares of common stock are being offered pursuant to this prospectus.

On December 29, 2015, the conditions necessary for purchases under the Purchase Agreement to commence were satisfied. On any trading day on which the closing sale price of our common stock exceeds $0.50, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 150,000 shares of our common stock per trading day, up to $15.0 million of our common stock in the aggregate at a per share price (the "Purchase Price") calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice for 150,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than $0.50 per share of Common Stock , we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the Nasdaq Capital Market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of shares we may determine (the "VWAP Purchase Share Volume Maximum") and a minimum trading price (the "VWAP Minimum Price Threshold") (as more specifically described below). The purchase price per Purchase Share pursuant to such VWAP Purchase Notice (the "VWAP Purchase Price") is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.50 per share (the "Floor Price"). This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Aspire Capital may not assign its rights or obligations under the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

RISK FACTORS

If you purchase our securities, you will assume a high degree of risk. In deciding whether to invest, you should carefully consider the following risk factors, as well as the other information contained elsewhere in this prospectus. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our securities to decline, which could cause you to lose all or part of your investment. We may experience additional risks and uncertainties not currently known to us, or, as a result of developments occurring in the future, conditions that we currently deem to be immaterial may also materially and adversely affect our business, financial condition, cash flows and results of operations. In any such case, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Relating To Our Business

Risks Associated with Clinical Trials and Pre-Clinical Development

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 also discovered that our first generation trachea product design encountered certain body response issues that we have sought to resolve with our ongoing development of our second generation scaffold and implant design. We cannot be certain that our second generation scaffold and implant design or any future modifications or improvements with respect thereto will support our claims, and any such developments may result in the discovery of further adverse side effects. We also may not see positive results when our products 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. Our pre-clinical development efforts and any 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 surgeries using our products as compassionate use or in clinical trials may experience significant adverse events following the surgeries, 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 pre-clinical development efforts or 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

clinical experience to date for trachea implant surgeries has involved a small patient population. Because of the small sample size, the results may not be indicative of future results.

Clinical trials necessary to support a biological product 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 biological license applications, or BLAs, or premarket approval applications, or PMAs, 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 bioengineered trachea transplant approved in the U.S. using our first generation trachea product was approved under the IND pathway through CBER for a compassionate use. Such initial U.S. surgery was led by Professor Paolo Macchiarini, M.D., a surgeon pioneering tracheal replacement techniques. 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. The Karolinska Institutet investigated the allegations and concluded that while in some instances Dr. Macchiarini did act without due care, his actions did not qualify as scientific misconduct. These allegations and the results of the investigation have and may continue to harm the perception of our products or company and make it difficult to recruit patients for any clinical trials.

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, any third-party clinical trial investigators pertaining to our products may be delayed in conducting our clinical trials for reasons outside of their control.

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, including those for the esophagus and airways, 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, including those for the esophagus and airways (trachea and bronchus). 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 PMA 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 first generation trachea product would be viewed by the FDA as a combination product comprised of a biologic (cells) and medical device component. Nevertheless, 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.

While the FDA has informed us that our first generation trachea product would be regulated by the FDA as a combination product, we cannot be sure that our second generation or any other products would also 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 our first generation trachea product 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 our product based on CBER's determination of need for such assistance.

Although we have received this written response from the FDA with respect to our first generation trachea product, the process of obtaining FDA marketing approval is lengthy, expensive, and uncertain, and we cannot be sure that our products, including products pertaining to the airways, esophagus or otherwise, 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 trachea product will likely be regulated as a combined advanced therapy medicinal product and our other products, including for the esophagus or bronchus, 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 our first generation trachea product 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, including any products pertaining to the esophagus, airways or otherwise, 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.

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.

Post-market 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 September 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 require additional funding during the next twelve months, in addition to the proceeds of sales of common stock to Aspire Capital, if any, as described in this prospectus, to continue our operations and support our capital needs. 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. In addition, general market conditions may

make it very difficult for us to seek financing from the capital markets.

Any 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.

The extent to which we utilize the Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the agreement is limited. See “The Aspire Capital Transaction” section of this prospectus for additional information. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our common stock is less than $0.50 per share. Even if we are able to access the full $15.0 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

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 sales of any clinical products. From February 24, 2009, our business's inception, through September 30, 2015, we have incurred losses of approximately $41.7 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 esophageal or airway products, 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, bioengineered organs and organ implants. 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, James McGorry, our Chief Financial Officer, Thomas McNaughton, our Chief Medical Officer, Dr. Saverio La Francesca, our Vice President of Research & Development, Dr. Thomas Bollenbach 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.

Although we have formal co-development collaboration agreements with Mayo Clinic and Connecticut Children's Medical Center, we do not have formal agreements in place with many of our collaborators, and most of our collaborators retain the ability to pursue other research, product development or commercial opportunities that may be directly competitive with our programs. If any of our 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 either regenerative medicine or bioengineered organ 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 and bioengineering. 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 fields of regenerative medicine and biotechnology, 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 esophagus and airways, such as the lungs, GI tract, among others. These other organs are more complex than the esophagus and airways. 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, biotechnology 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, Aldagen (acquired by Nuo Therapeutics, formerly Cytomedix), Athersys, BioTime, Baxter International, Inc., Bose Corporation, Caladrius (formerly NeoStem), Celgene, Cytori Therapeutics, E. I. du Pont de Nemours and Company, Harvest Technologies, InVivo Therapeutics, Mesoblast, Miramatrix Medical, Nanofiber Solutions, Neuralstem, Ocata Therapeutics, Inc. (formerly Advanced Cell Technologies), Organovo, Osiris Therapeutics, Pleuristem Therapeutics, Smiths Medical, Tissue Genesis, Inc., Tissue Growth Technologies (acquired by Instron), Transmedics, United Therapeutics, Vericel

(formerly Aastrom Biosciences), and W.L. Gore and Associates. In addition, there are many academic and clinical centers that are developing regenerative or bioengineered organ 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 or bioengineered organ 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 vendors and customers outside the U.S. and we may generate revenues and incur operating expenses in multiple foreign currencies, we will experience currency exchange risk with respect to any 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 activities 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

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 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 one of 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 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, one 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

Substantial sales of common stock have and may continue to occur, which have and could continue to 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 that they 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. Since the February 2015 public offering, the holders of the shares of Series B Convertible Preferred Stock have converted all such shares and have sold substantially all of the common stock they received upon such conversion. We believe that the effect of these conversions and sales contributed to a decline in the price of our common stock. Further, we cannot predict the effect, if any, that any additional market sales of common stock (whether from the Distribution, by Aspire Capital with respect the shares acquired pursuant to the Purchase Agreement, or otherwise) 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.

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.

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. 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 and each preferred share was subsequently converted into 5 shares of our common stock.

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 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.

Risks Relating To This Offering

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

We have registered for sale the Commitment Shares and Initial Purchase Shares that we have issued and 2,038,933 shares of common stock that we may otherwise sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 30 months from the date of this prospectus. The number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending on a variety of factors, including market liquidity of our common stock, the sale of shares under the Purchase Agreement may cause the trading price of our common stock to decline.

Aspire Capital may ultimately purchase all or only some of the $15.0 million of common stock that, together with the Commitment Shares, is the subject of this prospectus. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital in this offering, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire. However, we have the right under the Purchase Agreement to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Aspire Capital. We will not receive any proceeds upon the sale of shares by Aspire Capital. However, we may receive proceeds up to $15.0 million under the Purchase Agreement with Aspire Capital.

The proceeds received from the sale of the shares under the Purchase Agreement will be used for general corporate purposes and working capital requirements. However, we cannot guarantee that we will receive any proceeds in connection with the Purchase Agreement because we may be unable or choose not to issue and sell any securities pursuant to the Purchase Agreement. This anticipated use of net proceeds from the sale of our common stock to Aspire Capital under the Purchase Agreement represents our intentions based upon our current plans and business conditions.

The Aspire Capital Transaction

General

On December 15, 2015, we entered into the Purchase Agreement which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of our shares of common stock over the term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company agreed to sell to Aspire Capital 500,000 Initial Purchase Shares for proceeds of $1,000,000. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 150,000 Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of December 15, 2015, there were 13,451,395 shares of our common stock outstanding (12,560,986 shares held by non-affiliates) excluding the 2,688,933 shares offered that may be issuable to Aspire Capital pursuant to the Purchase Agreement. If all of such 2,688,933 shares of our common stock offered hereby were issued and outstanding as of the date hereof, such shares would represent 19.99% of the total common stock outstanding or 21.41% of the non-affiliate shares of common stock outstanding as of the date hereof. The number of shares of our common stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 2,688,933 shares of our common stock under the Securities Act, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital and 2,038,933 shares of common stock which we may issue to Aspire Capital. All 2,688,933 shares of common stock are being offered pursuant to this prospectus. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 2,688,933 shares of common stock included in this prospectus to Aspire Capital. As of the date hereof, we do not have any plans or intent to issue to Aspire Capital any shares of common stock in addition to the 2,688,933 shares of common stock offered hereby.

On December 29, 2015 the conditions necessary for purchases under the Purchase Agreement to commence were satisfied. On any trading day on which the closing sale price of our common stock is not less than $0.50 per share, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 150,000 shares of our common stock per business day, up to $15.0 million of our common stock in the aggregate over the term of the Purchase Agreement, at a Purchase Price calculated by reference to the prevailing market price of our common stock over the preceding 10-business day period (as more specifically described below); however, no sale pursuant to a Purchase Notice may exceed $500,000 per trading day.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 150,000 Purchase Shares and the closing price of our common stock is not less than $0.50 per share, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the Nasdaq Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than the Floor Price. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Aspire Capital may not assign its rights or obligations under the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

Purchase Of Shares Under The Common Stock Purchase Agreement

Under the common stock Purchase Agreement, on any trading day selected by us on which the closing sale price of our common stock exceeds $0.50 per share, we may direct Aspire Capital to purchase up to 150,000 shares of our common stock per trading day. The Purchase Price of such shares is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for purchase of 150,000 shares and on which the closing price of our common stock exceeds $0.50 per share, we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the our common stock traded on the Nasdaq Capital Market on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 80% of the closing price of the Company's common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by the Company in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

- the Closing Sale Price on the VWAP Purchase Date; or
- 97% of the volume-weighted average price for our common stock traded on the Nasdaq Capital Market:
  - on the VWAP Purchase Date, if the aggregate shares to be purchased on that date have not exceeded the VWAP Purchase Share Volume Maximum or
  - during that portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the Nasdaq Capital Market exceed the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of the Company's common stock falls below the VWAP Minimum Price Threshold.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the trading day(s) used to compute the Purchase Price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

Minimum Share Price

Under the Purchase Agreement, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement on any trading day that the closing sale price of our common stock is less than $0.50 per share.

Events of Default

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following, among other, events of default:

- the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of our shares of common stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC such lapse or unavailability may continue for a period of no more than 40 consecutive business days;

- the suspension from trading or failure of our common stock to be listed on our principal market for a period of three consecutive business days;

- the delisting of our common stock from our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the NYSE MKT, the Nasdaq Capital Market, the Nasdaq Global Select Market, the Nasdaq Global Market, the OTB Bulletin Board or the OTCQB marketplace or OTCQX marketplace of the OTC Markets Group;

- our transfer agent's failure to issue to Aspire Capital shares of our common stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;

- any breach by us of the representations or warranties or covenants contained in the Purchase Agreement or any related agreements which could have a material adverse effect on us, subject to a cure period of five business days;

- if we become insolvent or are generally unable to pay our debts as they become due; or

- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Our Termination Rights

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

No Short-Selling or Hedging by Aspire Capital

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 2,688,933 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 30 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and/or to be highly volatile. Aspire Capital may ultimately purchase all, some or none of the 2,038,933 shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in substantial dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to $15.0 million of our shares of common stock. However, we estimate that we will sell no more than 2,538,933 shares to Aspire Capital under the Purchase Agreement (exclusive of the 150,000 Commitment Shares), all of which are included in this offering. Subject to any required approval by our board of directors, we have the right but not the obligation to issue more than the 2,688,933 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 2,688,933 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying purchase prices:

Assumed Average Purchase Price	**Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering**	**Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price (1)**	**Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital (2)**
$1.00	$2,538,933	2,538,933	16.7%
$1.50	$3,808,400	2,538,933	16.7%
$2.00	$5,077,866	2,538,933	16.7%
$2.50	$6,347,333	2,538,933	16.7%
$3.00	$7,616,799	2,538,933	16.7%
$5.00	$12,694,665	2,538,933	16.7%
$6.00	$15,000,000	2,500,000	16.5%
$7.00	$15,000,000	2,142,857	14.6%
$8.00	$15,000,000	1,875,000	13.1%

(1) Excludes 150,000 Commitment Shares issued under the Purchase Agreement between the Company and Aspire Capital.

(2) The denominator is based on 13,601,395 shares outstanding as of December 15, 2015, which includes the 150,000 Commitment Shares previously issued to Aspire Capital and the number of shares set forth in the adjacent column which we would have sold to Aspire Capital. The numerator is based on the number of shares which we may issue to Aspire Capital under the Purchase Agreement (that are the subject of this offering) at the corresponding assumed purchase price set forth in the adjacent column.

Selling Stockholder

The selling stockholder may from time to time offer and sell any or all of the shares of our common stock set forth below pursuant to this prospectus. When we refer to the "selling stockholder" in this prospectus, we mean the entity listed in the table below, and its respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling stockholder's interests in shares of our common stock other than through a public sale.

The following table sets forth, as of the date of this prospectus, the name of the selling stockholder for whom we have registered shares for sale to the public, the number of shares of common stock beneficially owned by the selling stockholder prior to this offering, the total number of shares of common stock that the selling stockholder may offer pursuant to this prospectus and the number of shares of common stock that the selling stockholder will beneficially own after this offering. Except as noted below, the selling stockholder does not have, or within the past three years has not had, any material relationship with us or any of our predecessors or affiliates and the selling stockholder is not or was not affiliated with registered broker-dealers.

Based on the information provided to us by the selling stockholder, assuming that the selling stockholder sells all of the shares of our common stock beneficially owned by it that have been registered by us and does not acquire any additional shares during the offering, the selling stockholder will not own any shares other than those appearing in the column entitled "Beneficial Ownership After This Offering." We cannot advise you as to whether the selling stockholder will in fact sell any or all of such shares of common stock. In addition, the selling stockholder may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of our common stock in transactions exempt from the registration requirements of the Securities Act of 1933 after the date on which it provided the information set forth in the table below.

			Beneficial Ownership After this Offering (1)	
Name	**Shares of Common Stock Owned Prior to this Offering**	**Shares of Common Stock Being Offered**	**Number of Shares**	**%**
Aspire Capital Fund, LLC (2)	650,000 (3)	2,688,933	—	—

* Represents less than 1% of outstanding shares.

(1) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the selling stockholder is under no obligation known to us to sell any shares of common stock at this time.

(2) Aspire Capital Partners LLC ("Aspire Partners") is the Managing Member of Aspire Capital Fund LLC ("Aspire Fund"). SGM Holdings Corp ("SGM") is the Managing Member of Aspire Partners. Mr. Steven G. Martin ("Mr. Martin") is the president and sole shareholder of SGM, as well as a principal of Aspire Partners. Mr. Erik J. Brown ("Mr. Brown") is the president and sole shareholder of Red Cedar Capital Corp ("Red Cedar"), which is a principal of Aspire Partners. Mr. Christos Komissopoulos ("Mr. Komissopoulos") is president and sole shareholder of Chrisko Investors Inc ("Chrisko"), which is a principal of Aspire Partners. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos may be deemed to be a beneficial owner of common stock held by Aspire Fund. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos disclaims beneficial ownership of the common stock held by Aspire Fund.

(3) As of the date hereof, 650,000 shares of our common stock have been acquired by Aspire Capital under the Purchase Agreement, consisting of shares we issued to Aspire Capital as a commitment fee and the Initial Purchase Shares sold to Aspire Capital. We may elect in our sole discretion to sell to Aspire Capital up to an additional 2,038,933 shares under the Purchase Agreement but Aspire Capital does not presently beneficially own those shares as determined in accordance with the rules of the SEC.

Plan of Distribution

The common stock offered by this prospectus is being offered by Aspire Capital, the selling stockholder. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling stockholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

Aspire Capital is an “underwriter” within the meaning of the Securities Act.

Neither we nor Aspire Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Aspire Capital, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have agreed to indemnify Aspire Capital and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Aspire Capital has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Aspire Capital specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Aspire Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Burns & Levinson LLP, Boston, Massachusetts.

EXPERTS

The consolidated financial statements of Harvard Apparatus Regenerative Technology, Inc. as of December 31, 2014 and 2013 and for each of the years in the two-year period ended December 31, 2014, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 with the SEC under the Securities Act with respect to the common stock offered by this prospectus. This prospectus is a part of that registration statement and, as allowed by SEC rules, does not include all of the information you can find in the registration statement or the exhibits to the registration statement. For additional information relating to our company and the distribution, reference is made to the registration statement and the exhibits to the registration statement. Statements contained in this prospectus as to the contents of any contract or document referred to are not necessarily complete and in each instance, if the contract or document is filed as an exhibit to the registration statement, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each such statement is qualified in all respects by reference to the applicable document.

We are subject to the informational and reporting requirements of the Securities Exchange Act of 1934, as amended, and file annual, quarterly and special reports, proxy statements and other information with the SEC. We furnish our stockholders with annual reports containing financial statements audited by an independent registered public accounting firm. The prospectus is, and any of these filings with the SEC are, available to the public over the Internet on the SEC's web site at *http://www.sec.gov*. You may read and copy any filed document at the SEC's public reference rooms in Washington, D.C. at 100 F Street, N.E., Washington, D.C. 20549 and at the SEC's regional offices in New York at 233 Broadway, New York, New York 10279 and in Chicago at Citicorp Center, 500 W. Madison Street, Suite 1400, Chicago, Illinois 60661. Please call the SEC at 1-800-SEC-0330 for further information about the public reference rooms.

We maintain an Internet site at *http://www.harvardapparatusregen.com*. Our web site and the information contained on that site, or connected to that site, are not incorporated into this prospectus or the Registration Statement on Form S-1.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information and reports we file with it, which means that we can disclose important information to you by referring you to these documents. The information incorporated by reference is an important part of this prospectus. We are incorporating by reference the documents listed below, which we have already filed with the SEC:

- Our Annual Report on Form 10-K for the year ended December 31, 2014;

- Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2015, June 30, 2015 and September 30, 2015;

- Our Current Reports on Form 8-K filed with the SEC on January 30, 2015, February 12, 2015, April 27, 2015, May 26, 2015, July 6, 2015, July 17, 2015, November 10, 2015 and December 15, 2015 (in each case, except for information contained therein which is furnished rather than filed); and

- The description of our common stock contained in our registration statement on Form 10-12B filed with the SEC on July 31, 2013 and amended on September 20, 2013 and October 11, 2013.

Upon request, we will provide, without charge, to each person, including any beneficial owner, to whom a copy of this prospectus is delivered a copy of the documents incorporated by reference into this prospectus. You may request a copy of these filings, and any exhibits we have specifically incorporated by reference as an exhibit in this prospectus, at no cost by writing or telephoning us at the following address:

Harvard Apparatus Regenerative Technology, Inc., 84 October Hill Road, Suite 11, Holliston, Massachusetts 01746-1371 Telephone: (774) 233-7300.

You also may access these filings on our Internet site at *http://www.harvardapparatusregen.com*. Our web site and the information contained on that site, or connected to that site, are not incorporated into this prospectus or the Registration Statement on Form S-1.

This prospectus is part of a registration statement we filed with the SEC. We have incorporated exhibits into this registration statement. You should read the exhibits carefully for provisions that may be important to you.

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus or in the documents incorporated by reference is accurate as of any date other than the date on the front of this prospectus or those documents.

2,688,933 Shares

Common Stock

PROSPECTUS

December 29, 2015