Harvard Apparatus Regenerative Technology, Inc.
Form 424B5
February 11, 2015

The information in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. This prospectus supplement and the accompanying prospectus are not offers to sell these securities, and we are not soliciting offers to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION
DATED FEBRUARY 11, 2015

FILED PURSUANT TO RULE 424(b)(5)
REGISTRATION NO. 333-200926

PROSPECTUS SUPPLEMENT

(to Prospectus dated December 29, 2014)

[ ] Shares of Common Stock

[ ] Shares of Series B Convertible Preferred Stock

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

We are offering [ ] shares of our common stock at a price of $[ ] per share, [ ] shares of our Series B Convertible Preferred Stock at a price of $[ ] per share. The offering also includes up to [ ] shares of our common stock issuable upon conversion of our Series B Convertible Preferred Stock. The offering of Series B Convertible Preferred Stock contemplated by this prospectus supplement is the first issuance of shares of this series by us.

You may purchase common stock, Series B Convertible Preferred Stock or both in this offering. While we cannot assure you that this offering will be completed, this offering is not contingent upon any particular threshold of shares of common stock or Series B Convertible Preferred Stock being the sold in the offering.

Our common stock is listed on The NASDAQ Capital Market under the symbol HART. The last reported sale price of our common stock on February 9, 2015 was $2.34 per share. We are not listing our Series B Convertible Preferred Stock on an exchange or any trading system and we do not expect that a market for our Series B Convertible Preferred Stock will develop.

Each share of our Series B Convertible Preferred Stock is convertible into five shares of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Convertible Preferred Stock into shares of our common stock if, as a result of such conversion, the holder would own more than 4.98% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock, or such holder, together with its affiliates, would own more than 9.98% of the number of shares of common stock outstanding

immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock.

In the event of our liquidation, dissolution or winding up, holders of our Series B Convertible Preferred Stock are entitled to receive *pari passu* with the holders of common stock, out of the assets available for distribution to the stockholders an amount equal to such amount per share as would have been payable had all shares of Series B Convertible Preferred Stock been converted into common stock immediately before such liquidation. Shares of Series B Convertible Preferred Stock are generally entitled to vote with the holders of outstanding shares of common stock, voting together as a single class, with respect to any and all matters presented to the stockholders of the Corporation for their action or consideration. For a more detailed description of our Series B Convertible Preferred Stock, see the section entitled Description of Securities We Are Offering beginning on page S-31.

David Green, our Chief Executive Officer and one of our directors, has agreed to purchase 50,000 shares of our common stock in this offering at the price offered to the public.

As of January 7, 2015, the aggregate market value of our outstanding common stock held by non-affiliates was $29,255,120 based on 7,877,377 shares of outstanding common stock, of which 7,444,051 shares are held by non-affiliates, and a per share price of $3.93 based on the closing sale price of our common stock as quoted on The NASDAQ Capital Market on January 7, 2015.

Investing in our securities involves a high degree of risk. Please read Risk Factors beginning on page S-8 of this prospectus supplement and in the information incorporated by reference into this prospectus supplement.

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

	Per Share	Total
Public offering price of common stock	$	$
Public offering price of Series B Convertible Preferred Stock	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds before expenses, to us	$	$

(1) See Underwriting for additional details on the underwriting compensation.

The underwriter expects to deliver the shares of common stock and Series B Convertible Preferred Stock on or about [ ].

We have granted the underwriter an option for a period of 30 days to purchase up to [ ] additional shares of common stock at the public offering price, less the underwriting discounts and commissions, to cover over-allotment, if any. If the underwriter exercises the option in full, the total underwriting discounts and commissions payable by us will be $ and the total proceeds to us, before expenses, will be $.

National Securities Corporation
Sole Book Runner

Summer Street Research Partners Co-Manager

Prospectus Supplement dated [ ], 2015

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You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus or any free writing prospectus that we have authorized for use in connection with this offering. Neither we nor the underwriters have authorized anyone to provide you with information different from that contained in this prospectus supplement, the accompanying prospectus or any accompanying free writing prospectus. We are offering to sell, and seeking offers to buy, common stock, Series B Convertible Preferred Stock, and the common stock issuable upon conversion of such Series B Convertible Preferred Stock, only in jurisdictions where offers and sales are permitted. If anyone provides you with different or inconsistent information, you should not rely on it. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus supplement, the accompanying prospectus and any accompanying free writing prospectus is accurate only as of the date of this prospectus supplement, the accompanying prospectus and any such accompanying free writing prospectus, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus, any such accompanying free writing prospectus or of any sale of our common stock, Series B Convertible Preferred Stock or the common stock issuable upon conversion of such Series B Convertible Preferred Stock. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus

that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled Where You Can Find More Information and Incorporation of Information by Reference.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the common stock, the Series B Convertible Preferred Stock, or the common stock issuable upon conversion of such securities, or possession or distribution of this prospectus supplement, the accompanying prospectus or any free writing prospectus in that jurisdiction. Persons who come into possession of this prospectus supplement, the accompanying prospectus or any free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus supplement, the accompanying prospectus and any accompanying free writing prospectus applicable to that jurisdiction.

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ABOUT THIS PROSPECTUS SUPPLEMENT

On December 12, 2014, we filed with the Securities and Exchange Commission, or the SEC, a registration statement on Form S-3 (File No. 333-200926) utilizing a shelf registration process relating to the securities described in this prospectus supplement, which registration statement was declared effective on December 29, 2014. Under this shelf registration process, we may, from time to time, sell common stock, preferred stock, warrants and/or units, of which this offering is a part.

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering of our shares of common stock and Series B Convertible Preferred Stock and also adds to and updates information contained in the accompanying prospectus and the information incorporated by reference into the prospectus and this prospectus supplement. The second part, the accompanying prospectus, gives more general information, some of which does not apply to this offering. Generally, when we refer to this prospectus, we are referring to both parts of this document combined.

If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information contained in this prospectus supplement. However, if any statement in one of these documents is inconsistent with a statement in another document having a later date, the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in the prospectus supplement or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Unless we have indicated otherwise, or the context otherwise requires, references in this prospectus supplement and the accompanying prospectus to HART, the Company, we, us and our or similar terms are to Harvard Appara Regenerative Technology, Inc. and its subsidiaries.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the Risk Factors section contained in this prospectus supplement, our financial statements and the related notes thereto and the other documents incorporated by reference in this prospectus supplement and the accompanying prospectus.

About Harvard Apparatus Regenerative Technology, Inc.

Harvard Apparatus Regenerative Technology, Inc. (NASDAQ: HART) is a clinical stage biotechnology company making regenerated organs for transplant. Our first product, the HART-Trachea, is intended to be used to restore the structure and/or function of a severely damaged trachea (windpipe). To date, six human patients have so for been treated with the HART-Trachea under compassionate use rules. Of the five adults treated with the HART-Trachea two are still alive and the average survival, among the three that died, has been 22 months. This compares favorably with the survival time expected by the patients doctors of typically only a few months without the transplant of the HART-Trachea. According to the patients doctors, the three patients who did not survive died of unrelated causes which did not involve the failure of the HART-Trachea. The patients doctors informed us that the causes of death in the three patients that died were: trauma following a car accident, acute live failure due to alcohol consumption and pneumonia. The HART-Trachea is made of the patient s own bone marrow cells seeded on our proprietary InBreath porous plastic scaffold in our proprietary InBreath organ bioreactor. The HART-Trachea has received orphan drug designation from the U.S. Food and Drug Administration, or FDA, for trachea transplant. Orphan drug designation will provide us with 7 years of market exclusivity from the date of FDA approval of the HART-Trachea.

We are currently engaged in pre-clinical development of our HART-Trachea. The HART-Trachea and our other transplant products are currently in development and have not yet received regulatory approval for sale anywhere in the world.

We believe our HART-Trachea could enable surgeons to treat nearly all life-threatening constrictions of the windpipe. Our HART-Trachea addresses both of the critical challenges to trachea transplant: the shortage of suitable donor tracheas and the risk and expense of lifelong anti-rejection drug therapy. Because the scaffolds are synthetic, they can be made in large quantities and therefore will eliminate the need to wait for suitable donor tracheas. Because the cells are from the patient, the patient s body is unlikely to reject the HART-Trachea and therefore the patients do not need to take anti-rejection drugs. In addition, to date, patients with trachea cancer treated using the HART-Trachea have not required either chemotherapy or radiation therapy after the transplant, thus potentially eliminating the significant side effects and expense of such therapies. Because these substantial costs and risks can be reduced or even eliminated with our technology, we believe our products can both help save lives and reduce overall healthcare costs.

Recent Developments

Development Agreement with Mayo Clinic

In December 2014, we signed a joint development agreement with Mayo Clinic with the intent of developing and improving regenerative medicine treatments for patients with severe diseases. We have collaborated with Mayo Clinic for the past two years as part of Mayo Clinic s program to develop a synthetic human heart valve, and this new

development agreement is designed to foster work on additional organs such as the trachea and the esophagus. Patented inventions made during the course of the collaboration may be licensed by us, and we will pay royalties to Mayo Clinic.

Pre-clinical Success with Esophageal Regeneration and Transplant

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

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

Pre-clinical Development of the HART-Trachea

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

- The submission of the application for Clinical Trial Authorization, or CTA, with the Medicines and Healthcare Products Regulatory Agency, or MHRA, of the U.K. and the Investigational New Drug, application, or IND, with the FDA, is expected to take place in the first half of 2016 rather than by the end of 2015;
- If we are granted Fast Track, Accelerated Review, Priority Review and Breakthrough status in the U.S., we anticipate completing our clinical trial by the end of 2017, rather than the middle of 2017. Completion of the clinical trial in the EU potentially could be sooner; and
- We expect to receive FDA approval to market the HART-Trachea in the U.S. during the first half of 2018, rather than by the end of 2017.

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 *http://www.hartregen.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 incorporated by reference into this prospectus, and you should not consider it part of this prospectus supplement or the accompanying prospectus.

The name Harvard Apparatus is used under a license agreement between Harvard Bioscience, Inc., or 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. We have filed a trademark application with respect to the InBreath trademark.

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THE OFFERING

Issuer:

Harvard Apparatus Regenerative Technology, Inc.

Offering:

Shares of common stock offered by us:

[ ] shares of common stock.

Underwriter s Option to Purchase Additional Shares:

We have granted the underwriter an option to purchase up to [ ] additional shares of common stock at the public offering price per share, less the underwriting discounts and commissions, to cover over-allotment, if any. This option is exercisable, in whole or in part, for a period of 30 days from the date of this prospectus supplement.

Offering price per share for common stock:

$[ ].

Shares of Series B Convertible Preferred Stock offered by us:

[ ] shares of Series B Convertible Preferred Stock. This prospectus supplement also relates to the offering of the shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock.

Offering price per share for Series B Convertible Preferred Stock:

$[ ].

Common stock to be outstanding after the offering[(1)]:

[ ] (or [ ] shares if the underwriter exercises in full its over-allotment option to purchase additional shares of common stock).

NASDAQ Capital Market listing:

Our common stock is listed on The NASDAQ Capital Market under the symbol HART.

Series B Convertible Preferred Stock:

Conversion:

Each share of Series B Convertible Preferred Stock is convertible into five shares of our common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Convertible Preferred Stock into shares of our common stock if, as a result of such conversion, the holder would own more than 4.98% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock, or such holder, together with its affiliates, would own more than 9.98% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock. In addition, the Series B Convertible Preferred Stock automatically converts into common stock upon the occurrence of certain Fundamental Transactions as described below.

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The conversion rate of the Series B Convertible Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Voting rights:

Except as provided in the Certificate of Designation or as otherwise required by law, the holders of Series B Convertible Preferred Stock are entitled to vote with the holders of outstanding shares of common stock, voting together as a single class, with respect to all matters presented to the stockholders for their action or consideration. In any such vote, each holder is entitled to a number of votes equal to the number of shares of common stock into which the Series B Convertible Preferred Stock held by such holder is convertible, after taking into account the Beneficial Ownership Limitation described below. The Company may not, without the consent of holders of a majority of the outstanding shares of Series B Convertible Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series B Convertible Preferred Stock or alter or amend the Certificate of Designation.

Dividends:

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series B Convertible Preferred Stock are entitled to receive dividends on shares of Series B Convertible Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends are payable on shares of Series B Convertible Preferred Stock.

Liquidation:

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series B Convertible Preferred Stock are entitled to receive, *pari passu* with the holders of common stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series B Convertible Preferred Stock been converted into common stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Beneficial Ownership Limitation, described below.

Beneficial Ownership Limitation:

The Company may not effect any conversion of the Series B Convertible Preferred Stock, and a holder does not have the right to convert any portion of the Series B Convertible Preferred Stock to the extent that, after giving effect to the conversion set forth in a notice of conversion, such holder would beneficially own in excess of the holder Beneficial Ownership Limitation, or such holder, together with such holder s affiliates, and any persons acting as a group together with such holder or

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affiliates, would beneficially own in excess of the Affiliates Beneficial Ownership Limitation. The holder Beneficial Ownership Limitation is 4.98% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion of Series B Convertible Preferred Stock, held by the applicable holder. The affiliates Beneficial Ownership Limitation is 9.98% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion of Series B Convertible Preferred Stock, held by the applicable holder and its affiliates (the holder Beneficial Ownership Limitation together with the affiliates Beneficial Ownership Limitation collectively referred to as the Beneficial Ownership Limitation). The holder has the authority to determine whether the foregoing restrictions will limit any conversion, the extent such limitation applies and to which convertible instrument or part thereof such limitation applies. In addition, a holder may, with 61 days prior notice to the Company, or immediately upon notice from the holder to the Company at any time after the public announcement or other disclosure of a Fundamental Transaction, elect to increase or decrease one or both of the holder Beneficial Ownership Limitation and the affiliates Beneficial Ownership Limitation; provided, however, that in no event may either the holder Beneficial Ownership Limitation or the affiliate Beneficial Ownership Limitation be 20.00% or greater.

Fundamental Transaction:

If, at any time while the Series B Convertible Preferred Stock is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person pursuant to which the shares of capital stock of the Company outstanding immediately prior to such merger or consolidation are converted into or exchanged for shares of another corporation or entity and represent, or are converted into or exchanged for equity securities that represent, immediately following such merger or consolidation, less than a majority, by voting power, of the equity securities of (1) the surviving or resulting party or (2) if the surviving or resulting party is a wholly owned subsidiary of another party immediately following such merger or consolidation, the parent of such surviving or resulting party, (ii) the Company, directly or indirectly, effects any sale of all or substantially all of its assets in one or a series of related transactions, (iii) any tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding common

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stock, or (iv) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of common stock (not including any shares of common stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination) (each a Fundamental Transaction), then the Series B Convertible Preferred Stock automatically converts and the holder will receive, for each conversion share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction (subject to the Beneficial Ownership Limitation), the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the Alternate Consideration) receivable as a result of such Fundamental Transaction by a holder of the number of shares of common stock for which the Series B Convertible Preferred Stock is convertible immediately prior to such Fundamental Transaction (subject to the Beneficial Ownership Limitation). For purposes of any such conversion, the determination of the conversion ratio will be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Fundamental Transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder will be given the same choice as to the Alternate Consideration it receives upon automatic conversion of the Series B Convertible Preferred Stock following such Fundamental Transaction.

Listing:

There is no established public trading market for the Series B Convertible Preferred Stock and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series B Convertible Preferred Stock on any national securities exchange or trading system.

Use of proceeds:

We intend to use the net proceeds from this offering for research and development, including funding pre-clinical and clinical trials relating to the HART-Trachea, business development, sales and marketing, capital expenditures, working capital and other general corporate purposes. See the section entitled Use of Proceeds.

Risk factors:

An investment in our securities, including the Series B Convertible Preferred Stock and our common stock,

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involves a high degree of risk and purchasers of our securities may lose their entire investment. See the information contained in or incorporated by reference under Risk Factors beginning on page S-8 of this prospectus supplement, on page 5 of the accompanying prospectus and in the documents incorporated by reference into this prospectus supplement for a discussion of the risk factors you should carefully consider before deciding to invest in our securities.

Insider Participation:

David Green, our Chief Executive Officer and one of our directors, has agreed to purchase 50,000 shares of our common stock in this offering at the price offered to the public.

(1) The number of shares of common stock to be outstanding after this offering shown above is based on 7,877,377 shares of common stock outstanding as of February 6, 2015. It does not include as of such date:

Shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock being offered hereby.

2,056,980 shares of our common stock issuable upon exercise of stock options outstanding as of February 6, 2015 under our 2013 Equity Incentive Plan, or 2013 Plan, at a weighted average exercise price of $4.69 per share.

4,252 shares of our common stock underlying unvested restricted stock units outstanding as of February 6, 2015 under our 2013 Plan.

1,563,898 shares of our common stock available as of February 6, 2015 for future grant or issuance relating to stock options, restricted stock units, restricted stock, other equity awards, or share purchases that may be issued or made with respect to our 2013 Plan and 2013 Employee Stock Purchase Plan.

Unless otherwise indicated, all information in this prospectus supplement assumes that the underwriter will not exercise its over-allotment option to purchase additional shares of common stock offered and sold hereunder.

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RISK FACTORS

Investing in our securities involves risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties described below. You should also consider the risks, uncertainties and assumptions discussed under the heading Risk Factors included in our most recent annual report on Form 10-K which is on file with the SEC and is incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. If any of these risks actually occurs, our business, business prospects, financial condition or results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Please also read carefully the section below entitled Special Note Regarding Forward-Looking Statements.

Risks Related to this Offering and our Series B Convertible Preferred Stock

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

We currently intend to use the net proceeds from this offering for research and development, business development, sales and marketing, capital expenditures, working capital and other general corporate purposes. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. Our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our common stock to decline.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer immediate dilution in the net tangible book value of the common stock you purchase in this offering. After giving effect to the sale of shares of our common stock in this offering at the offering price of $[ ] per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, you will experience immediate dilution of $[ ] per share, representing the difference between our as adjusted net tangible book value per share as of September 30, 2014 after giving effect to this offering and the offering price. See the section entitled Dilution below for a more detailed discussion of the dilution you will incur if you purchase the common stock in this offering.

You will experience immediate and substantial dilution in the net tangible book value per share of the Series B Convertible Preferred Stock you purchase.

Since the price per share of our Series B Convertible Preferred Stock being offered is substantially higher than the net tangible book per share of our underlying common stock, you will suffer substantial dilution in the net tangible book value of the shares that you purchase in this offering. Based on an assumed offering price to the public of $[ ] per share, if you purchase Series B Convertible Preferred Stock in this offering, you will suffer immediate and substantial dilution of $[ ] per share in the net tangible book value of the shares of common stock underlying the Series B Convertible Preferred Stock. See the section entitled Dilution below for a more detailed discussion of the dilution you will incur if you purchase Series B Convertible Preferred Stock in this offering.

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A substantial number of shares of our common stock may be sold in this offering, which could cause the price of our common stock to decline.

In this offering, we will sell [ ] shares, or approximately [ ]% of our outstanding common stock as of February 6, 2015. This sale and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

A significant number of additional shares of our common stock may be issued upon the conversion of existing securities, including the Series B Convertible Preferred Stock, which issuances would substantially dilute existing stockholders and may depress the market price of our common stock.

As of February 6, 2015, there are 7,877,377 shares of common stock outstanding. In addition, [ ] shares of common stock can be issued upon conversion of our Series B Convertible Preferred Stock. The issuance of shares of common stock would substantially dilute the proportionate ownership and voting power of existing security holders, and their issuance, or the possibility of their issuance, may depress the market price of our common stock.

If you purchase the securities sold in this offering, you may experience dilution if we issue additional equity securities in future fundraising transactions.

If we issue additional common stock, or securities convertible into or exchangeable or exercisable for common stock, whether in public offerings or private placements, our stockholders, including investors who purchase shares in this offering, will experience dilution, and any such issuances may result in downward pressure on the price of our common stock.

The Series B Convertible Preferred Stock is a new issuance of securities and does not have an established trading market, which may negatively affect its market value and your ability to transfer or sell your shares.

Prior to this offering, there has been no public market for our Series B Convertible Preferred Stock. We are not listing our Series B Convertible Preferred Stock on an exchange or any trading system and we do not expect that a trading market for our Series B Convertible Preferred Stock will develop.

Upon conversion of the Series B Convertible Preferred Stock, holders may receive less valuable consideration than expected because the value of our common stock may decline after such holders exercise their conversion right but before we settle our conversion obligation.

Under the Series B Convertible Preferred Stock, a converting holder will be exposed to fluctuations in the value of our common stock during the period from the date such holder surrenders shares of Series B Convertible Preferred Stock

for conversion until the date we settle our conversion obligation. Upon conversion, we will be required to deliver the shares of our common stock, together with a cash payment for any fractional share (if so elected by the Company), on the third business day following the relevant conversion date. Accordingly, if the price of our common stock decreases during this period, the value of the shares of common stock that you receive will be adversely affected and would be less than the conversion value of the Series B Convertible Preferred Stock on the conversion date.

We may issue additional series of preferred stock that rank equally to the Series B Convertible Preferred Stock as to dividend payments and liquidation preference.

Neither our amended and restated certificate of incorporation nor the Certificate of Designation for the Series B Convertible Preferred Stock prohibits us from issuing additional series of preferred stock that would rank equally to the Series B Convertible Preferred Stock as to dividend payments and liquidation preference. Our amended and restated certificate of incorporation provides that we have the authority to issue up to 2,000,000 shares of preferred stock. The issuances of other series of preferred stock could have the effect of reducing the amounts available to the Series B Convertible Preferred Stock in the event of our liquidation, winding-up or dissolution. It may also reduce cash dividend payments on the Series B Convertible Preferred Stock if we do not have sufficient funds to pay dividends on all Series B Convertible Preferred Stock outstanding and outstanding parity preferred stock.

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Our Series B Convertible Preferred Stock will rank junior to all our liabilities to third party creditors in the event of a bankruptcy, liquidation or winding up of our assets.

In the event of bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Series B Convertible Preferred Stock only after all our liabilities have been paid. Our Series B Convertible Preferred Stock will effectively rank junior to all existing and future liabilities held by third party creditors. The terms of our Series B Convertible Preferred Stock do not restrict our ability to raise additional capital in the future through the issuance of debt. In the event of bankruptcy, liquidation or winding up, there may not be sufficient assets remaining, after paying our liabilities, to pay amounts due on any or all of our Series B Convertible Preferred Stock then outstanding.

Future issuances of preferred stock may adversely affect the market price for our common stock.

Additional issuances and sales of preferred stock, or the perception that such issuances and sales could occur, may cause prevailing market prices for our common stock to decline and may adversely affect our ability to raise additional capital in the financial markets at times and prices favorable to us

Risks Relating to Our Business

Risks Associated with Regulatory Clearances and Approvals

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

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

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

complex and more time consuming than the review of products under the jurisdiction of only one center within the FDA.

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

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

The FDA has informed us that our HART-Trachea product will be viewed bythe FDA as a combination product com

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

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

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

On May 28, 2014, we received notice from the European Medicines Agency that the HART-Trachea would be regulated as a combined advanced therapy medicinal product. Based on such classification, it will be necessary to seek a marketing authorization for these products granted by the European Commission before being marketed in the EU. Other products we may develop may similarly be regulated as advanced therapy medicinal products or combined advanced therapy medicinal products. The regulatory procedures leading to marketing approval of our products vary among jurisdictions and can involve substantial additional testing. Compliance with the FDA requirements does not ensure clearance or approval in other jurisdictions, and the ability to legally market our products in any one foreign country does not ensure clearance, or approval by regulatory authorities in other foreign jurisdictions. The foreign regulatory process leading to the marketing of the products may include all of the risks associated with obtaining FDA approval in addition to other risks. In addition, the time required to comply with foreign regulations and market products may differ from that required to obtain FDA approval, and we may not obtain foreign approval or clearance on a timely basis, if at all.

Risks Associated with Clinical Trials

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

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

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

Clinical trials necessary to support a BLA license, a PMA application, amarketing authorization, or a CE mark for ou

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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 may be reviewed either under the Investigational Device Exemptions, or IDE pathway (for medical devices) or through the Investigational New Drug, or IND, pathway for biologics or combination products. The first regenerated trachea transplant approved in the U.S. using the HART-Trachea was approved under the IND pathway through CBER. Future FDA review under the IDE, IND, or both pathways, depending on the products, proposed study design, and study populations, is possible. In the EU, if the regulatory classification of our products is rejected by the ethics committee or competent authority reviewing our request for a positive opinion, we may be required to prepare a new study protocol reflecting a different classification. This process would be costly and time consuming.

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

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

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

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that the FDA, foreign competent authorities or notified bodies will agree with our conclusions regarding them. Although we have obtained some positive results from the use of our scaffolds and bioreactors for trachea transplants performed to date, we may not see positive results when the bioreactors, or our scaffolds or other technologies undergo clinical testing in humans in the future. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the

results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our products are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Also, patients receiving transplants using our products may experience significant adverse events following the transplants, including serious health complications or death, which may or may not be related to our products, and any such adverse events may cause the delay or termination of our clinical trials. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our products and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects

The results of our clinical trials may not support our product claims or mayresult in the discovery of adverse side eff

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that are not currently part of the product s profile. In addition, our current clinical experience and clinical trial for trachea transplant involves a small patient population. Because of the small sample size, the results may not be indicative of future results.

Risk Associated with Product Marketing

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

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

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
unanticipated expenditures to address or defend such actions;
customer notifications for repair, replacement, refunds;
recall, detention or seizure of our products;
operating restrictions or partial suspension or total shutdown of production;
withdrawing BLA approvals or PMAs that have already been granted;
withdrawal of the marketing authorization granted by the European Commission or delay in obtaining such marketing authorization;
withdrawal of the CE Certificates of Conformity granted by the notified body or delay in obtaining these certificates;
refusal to grant export approval for our products; and
criminal prosecution.

Postmarket enforcement actions can generate adverse commercial consequences.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully

commercialize the product and generate revenue from the product. If the FDA or a foreign regulatory authority determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In

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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.

In the EU, on September 26, 2012, the European Commission proposed a revision of the legislation currently governing medical devices. As of January 23, 2015, these proposals were still under review by the European Parliament and the Council. If adopted by the European Parliament and the Council in their present form, these proposals will impose stricter requirements on medical device manufacturers. Moreover, the supervising competences of the competent authorities of the EU Member States and the notified bodies will be strengthened. The regulation of advanced therapy medicinal products is also in continued development in the EU, with the European Medicines Agency publishing new clinical or safety guidelines concerning advanced therapy medicinal products on a regular basis.

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

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

We have generated insignificant revenues to date and we have generated no revenues from sale of the HART-Trachea. From February 24, 2009, our business s inception, through September 30, 2014, we have incurred losses of approximately $29.4 million. We expect to continue to experience losses in the foreseeable future due to our limited anticipated revenues and significant anticipated expenses. We do not anticipate that we will achieve meaningful revenues for the foreseeable future. In addition, we expect that we will continue to incur significant operating expenses as we continue to focus on additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals of our products and technologies. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

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

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

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

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

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

Our operations will be adversely affected if we are unable to raise or obtain needed funding.

Substantial time, financial and other resources will be required to complete ongoing development and clinical testing of our products. Regulatory efforts and collaborative arrangements will also be necessary for our products that are currently under development and testing in order for them to be marketed. Our revenues from operations and cash may not be sufficient over the next several years for commercialization of all of the technologies and products we are currently developing. Consequently, we may seek strategic partners for

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various phases of development, marketing and commercialization of products employing our technologies. Further, we cannot assure you as to the sufficiency of our resources or the time required to complete any ongoing development and clinical testing, since the extent to which we conduct such testing is dependent on resource allocation decisions that we make from time to time based on numerous financial, scientific, clinical, regulatory and operational conditions.

In addition to development and other costs, we expect to incur capital expenditures from time to time. These capital expenditures will be influenced by our regulatory compliance efforts, our success, if any, at developing collaborative arrangements with strategic partners, our needs for additional facilities and capital equipment and the growth, if any, of our business in general. We may seek to raise necessary funds through public or private equity offerings, debt financings, other financing mechanisms, strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets.

Additional equity financing could result in significant dilution to our stockholders. 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.

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

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

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

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

to discontinue their participation in a particular research program, creating an inability to complete ongoing research in a timely and efficient manner. As a result of these uncertainties, we are unable to control the precise timing and execution of any experiments that may be conducted.

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

If our collaborators do not devote sufficient time and resources tosuccessfully carry out their duties or meet expecte

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Any of these developments could harm or slow our product and technology development efforts. In particular, we depend upon Dr. Paolo Macchiarini, the surgeon who has led all of the clinical surgeries to date using our technology. Dr. Macchiarini s team developed the initial version of our InBreath airway bioreactor, which we have licensed from the inventors. We continue to collaborate with Dr. Macchiarini on grant proposals and product development. If Dr. Macchiarini were not available to continue to collaborate with us or perform surgeries it would materially slow development of our products. On September 27, 2012, Dr. Macchiarini was arrested in Italy for attempted fraud and extortion for allegedly attempting to persuade severely ill patients to choose private hospitals in other countries over less expensive Italian public hospitals. He was temporarily placed under house arrest and on October 15, 2012 was released from house arrest and is free to travel internationally and to perform surgeries. The case is ongoing. Dr. Macchiarini believes these charges are without merit and has, and intends to continue to, vigorously defend these charges. These allegations do not relate to any surgeries involving our products and have not prevented Dr. Macchiarini from performing further surgeries with our products including the April 2013 surgery in the U.S. and the other 2013 surgeries in Sweden and Russia. In November 2014 allegations that Dr. Macchiarini had failed to obtain informed consent (among other things) for surgeries performed at the Karolinska Institutet in Stockholm, Sweden, were made public. One of these three surgeries used a HART-Trachea. The Karolinska Institutet is currently investigating the allegations. If Dr. Macchiarini decides to terminate his collaboration with us, if the case described above consumes a significant amount of his time, or if the case prevents him from performing surgeries, our product development efforts could be adversely affected and it could cause harm to our reputation or business.

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

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

Our products will subject us to liability exposure.

We face an inherent risk of product liability claims, especially with respect to our products that will be used within the human body, including the scaffolds we manufacture. Product liability coverage is expensive and sometimes difficult to obtain. We may not be able to obtain or maintain insurance at a reasonable cost. We may be subject to claims for liabilities for unsuccessful outcomes of surgeries involving our products, which may include claims relating to patient death. We may also be subject to claims for liabilities relating to patients that suffer serious complications or death during or following transplants involving our products. Our current product liability coverage is $15 million per occurrence and in the aggregate. We will need to increase our insurance coverage if and when we begin commercializing any of our products. There can be no assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance

in the future on commercially desirable items, if at all. If claims against us substantially exceed our coverage, then our business could be adversely impacted. Regardless of whether we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in, among others:

- significant awards against us;
- substantial litigation costs;
- injury to our reputation and the reputation of our products;

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withdrawal of clinical trial participants; and
adverse regulatory action.

Any of these results would substantially harm our business.

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

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

We depend upon a single-source supplier for the hardware and software 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 and software 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 software 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.

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

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

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

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

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

In order to protect or enforce our patent rights, we may initiate patent litigation against third parties. We may also become subject to interference proceedings conducted in the patent and trademark offices of various countries to determine the priority of inventions. The defense and prosecution, if necessary, of intellectual property suits, interference proceedings and related legal and administrative proceedings would be costly and divert our technical and management personnel from their normal responsibilities. We may not prevail in any of these suits should they occur. An adverse determination of any litigation or defense proceedings could put our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of being rejected and patents not being issued.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation, there could be public announcements of the

results of hearings, motions or other interim proceedings or developments in the litigation. Securities analysts or investors may perceive these announcements to be negative, which could cause the market price of our stock to decline.

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

Our continued success will depend significantly on our ability to obtain and maintain meaningful patent protection for certain of our products throughout the world. Patent law relating to the scope of claims in the regenerative medicine and medical device fields in which we operate is still evolving. The degree of future

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

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

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

We expect to compete with multiple pharmaceutical, biotechnology, medical device and scientific research product companies. Companies working in competing areas include, among others, Aastrom Biosciences, Advanced Cell Technologies, Aldagen, Athersys, BioTime, Baxter International, Inc., Bose Corporation, Celgene, Cytori Therapeutics, E. I. du Pont de Nemours and Company, Genzyme (acquired by Sanofi-aventis), Harvest Technologies, InVivo Therapeutics, Mesoblast, Miramatrix Medical, Nanofiber Solutions, NeoStem, Neuralstem, Organovo, Osiris Therapeutics, Pleuristem Smiths Medical, Tengion, Tissue Genesis, Inc., Tissue Growth Technologies (acquired by Instron), Transmedics, United Therapeutics and W.L. Gore and Associates. In addition, there are many academic and clinical centers that are developing regenerative technologies that may one day become competitors for us. Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. We cannot, with any accuracy, forecast when or if these companies are likely to bring regenerative medicine medical products to market for indications that we are also pursuing. Many of these potential competitors may be further along in the process of product development and also operate large, company-funded research and development programs.

We expect that other products will compete with our current and future products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include obtaining marketing exclusivity under certain regulations, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage. Our competitors may develop or market products that are more effective or commercially attractive than our current or future products and may also develop competing relationships with our key collaborators. In addition, we may face competition from new entrants into the field. We

may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. The effects of any such actions of our competitors may have a material adverse effect on our business, operating results and financial condition.

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

To manage growth, we will be required to continue to improve existing, and implement additional, operational and financial systems, procedures and controls, and hire, train and manage additional employees. Our current

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

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

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

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

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

Risks Related To Our Separation From Harvard Bioscience

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

Prior to November 1, 2013, our business was operated by Harvard Bioscience as part of its broader corporate organization rather than as a stand-alone company. Harvard Bioscience assisted us by providing financing and certain corporate functions. On November 1, 2013, all of the shares of our common stock were distributed to the Harvard Bioscience stockholders, and we separated from Harvard Bioscience to become a separately traded public company.

Following the separation from Harvard Bioscience, or the Separation, Harvard Bioscience has been under no obligation to provide assistance to us other than certain interim transitional services, such as accounting, benefits administration, payroll and information technology services, which were provided by Harvard Bioscience for the twelve months following the Separation. Because our business has not been operated as an independent company for a significant period of time, we cannot assure you that we will be able to continue to successfully implement the changes necessary to operate independently or that we will not incur additional costs operating independently that would have a negative effect on our business, results of operations or financial condition.

We have limited operating history as an independent company, and we maybe unable to make the changes necess

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

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

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

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

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

Under the tax sharing agreement between Harvard Bioscience and us, we would generally be required to indemnify Harvard Bioscience against any tax resulting from the Distribution to the extent that such tax resulted from (i) an

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

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

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

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entering into certain transactions pursuant to which all or a portion of our stock would be acquired, whether by merger or otherwise;

issuing equity securities beyond certain thresholds;

repurchasing our common stock;

ceasing to actively conduct our regenerative medicine business; and

taking or failing to take any other action that prevents the Separation and Distribution and related transactions from being tax-free.

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

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

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

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

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

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

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

Since the Separation and Distribution, we are also responsible for the additional costs associated with being an independent public company, including costs related to corporate governance and listed and registered securities. Therefore, our historical financial statements may not be indicative of our future performance as an independent company. For additional information about our past financial performance and the basis of presentation of our financial statements, please see Management s Discussion and Analysis of Financial Condition and Results of Operations in our most recent annual report on Form 10-K which is on file with the SEC, and our financial statements and the related notes thereto, as incorporated by reference in this prospectus supplement and the accompanying prospectus.

We may not be able to engage in desirable strategic or capital-raisingtransactions. In addition, under some circums

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

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have resulted from arm s-length negotiations among unaffiliated third parties. The terms of the agreements we negotiated in the context of the Separation related to, among other things, allocation of assets, liabilities, rights, indemnifications and other obligations among Harvard Bioscience and us. We may have received better terms from third parties because third parties may have competed with each other to win our business. Some of the members of our Board of Directors are also members of the Harvard Bioscience Board of Directors.

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

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

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

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

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

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

- intellectual property, technology and business matters, including failure to make required technology transfers and failure to comply with non-compete provisions applicable to Harvard Bioscience and us;
- labor, tax, employee benefit, indemnification and other matters arising from the Separation;
- distribution and supply obligations;

employee retention and recruiting;
business combinations involving us;

Any disputes that arise between us and Harvard Bioscience with respect toour past and ongoing relationships could

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sales or distributions by Harvard Bioscience of all or any portion of its ownership interest in us; and
business opportunities that may be attractive to both Harvard Bioscience and us.

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

Risks Relating To Our Common Stock

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

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

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

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

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

The market price of our shares may fluctuate widely.

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

the success or failure of surgeries and procedures involving the use our products;
the success and costs of preclinical and clinical testing and obtaining regulatory approvals or clearances for our products;
a shift in our investor base;
our quarterly or annual results of operations, or those of other companies in our industry;
actual or anticipated fluctuations in our operating results due to factors related to our business;
changes in accounting standards, policies, guidance, interpretations or principles;
announcements by us or our competitors of significant acquisitions, dispositions or intellectual property developments or issuances;
the failure to maintain our NASDAQ listing or failure of securities analysts to cover our common stock;
changes in earnings estimates by securities analysts or our ability to meet those estimates;

the operating and stock price performance of other comparable companies; our issuance of equity, debt or other financing instruments;

overall market fluctuations; and

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general economic conditions.

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

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

Some Harvard Bioscience stockholders, including possibly some of its large stockholders, have likely sold, and may continue to sell, our common stock received in the Distribution for reasons such as that our business profile or market capitalization as an independent company does not fit their investment objectives. The sales of significant amounts of our common stock, or the perception in the market that this will occur, may result in a decline in the price of our common stock.

Your percentage ownership will be diluted in the future.

Your percentage ownership will be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees. 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.

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.

Our costs will increase significantly as a result of operating as a publiccompany, and our management will be requi

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Provisions of Delaware law, of our amended and restated certificate of incorporation 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 may 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 do not intend to pay cash dividends on our common stock.

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

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

We are and we will remain an emerging growth company until the earliest to occur of (i) the last day of the fiscal year during which our total annual revenues equal or exceed $1 billion (subject to adjustment for inflation), (ii) the last day of the fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement, (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt, or (iv) the date on which we are deemed a large accelerated filer under the

Securities and Exchange Act of 1934, as amended, or the Exchange Act. For so long as we remain an emerging growth company as defined in the JOBS Act, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on some or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. If we avail ourselves of certain exemptions from various reporting requirements, our reduced disclosure may make it more difficult for investors and securities analysts to evaluate us to a level acceptable by them and may result in less investor confidence.

The recently enacted JOBS Act will allow us to postpone the date by which wemust comply with certain laws and re

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this prospectus supplement, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as may, will, should, expect, plan, anticipate, could, intend, target, project, contemplate, believe, estimate, predict, potential or co of these terms or other similar expressions. These forward-looking statements are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. All forward-looking statements speak only as of the date of this prospectus supplement, are expressly qualified in their entirety by the cautionary statements included in this prospectus and are subject to a number of risks, uncertainties and assumptions, including those described under the sections in this prospectus supplement entitled Risk Factors and elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents incorporated by reference thereto.

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Further, any forward-looking statement speaks only as of the date on which it is made. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties, or how they may affect us. Except as required by law, we have no duty to, and do not intend to, update or revise the forward-looking statements in this prospectus supplement after the date of this prospectus supplement, whether as a result of any new information, future events, changed circumstances or otherwise. This prospectus supplement also contains market data related to our business and industry. This market data includes projections that are based on a number of assumptions. If these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may have a material adverse effect on our business, financial condition, results of operations and the market price of our common stock.

USE OF PROCEEDS

We estimate that the net proceeds we will receive from this offering, based on the public offering price of $[ ] per share of common stock and $[ ] per share of Series B Convertible Preferred Stock, will be approximately $[ ], after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, or approximately $[ ] if the underwriter exercises in full its over-allotment option to purchase additional shares of common stock, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering for research and development, including funding preclinical and clinical trials relating to the HART-Trachea, business development, sales and marketing, capital expenditures, working capital and other general corporate purposes.

We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds from this offering. Pending application of the net proceeds as described above, we intend to invest the net proceeds to us from this offering in a variety of capital preservation investments, including short-term, investment-grade and interest-bearing instruments.

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DILUTION

If you purchase our common stock, Series B Convertible Preferred Stock, or both, in this offering, assuming conversion of the Series B Convertible Preferred Stock into shares of our common stock, your interest will be diluted to the extent of the difference between the public offering price per share and the net tangible book value per share of our common stock after this offering. We calculate net tangible book value per share by subtracting our total liabilities from our total tangible assets and dividing the difference by the number of outstanding shares of our common stock.

Our net tangible book value at September 30, 2014 was $8.70 million, or $1.11 per share of common stock.

After giving effect to the sale of [ ] shares of common stock by us at the public offering price and [ ] shares of Series B Convertible Preferred Stock by us at the public offering price (including the [ ] shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock), less the underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value at September 30, 2014 would be $[ ] or $[ ] per share of common stock. This represents an immediate increase in the as adjusted net tangible book value of $[ ] per share to existing stockholders and an immediate dilution of $[ ] per share to investors in this offering. The following table illustrates this per share dilution:

Public offering price per share of common stock		$
Pubic offering price per share of Series B Convertible Preferred Stock (on an as converted basis)		$
Net tangible book value per share as of September 30, 2014	$ 1.11	
Increase per share attributable to this offering	$	
As adjusted net tangible book value per share after this offering		$
Dilution per share to new investors in this offering		$

The above discussion and tables are based on 7,856,607 shares of common stock outstanding as of September 30, 2014 and assumes the conversion of all [ ] shares of Series B Preferred Stock being offered in this offering into an aggregate of [ ] shares of common stock, but does not include, as of such date:

4,100,123 shares of our common stock issuable upon exercise of stock options outstanding as of September 30, 2014 under our 2013 Plan, at a weighted average exercise price of $3.69 per share.
79,537 shares of our common stock underlying unvested restricted stock units outstanding as of September 30, 2014 under our 2013 Plan.
1,383,040 shares of our common stock available as of September 30, 2014 for future grant or issuance relating to stock options, restricted stock units, restricted stock, other equity awards, or share purchases that may be issued or made with respect to our 2013 Plan and 2013 Employee Stock Purchase Plan.

The table above assumes no exercise of options prior to this offering, and no vesting if issued but unvested restricted stock. To the extent that options are exercised or restricted stock vests, there will be further dilution to new investors.

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CAPITALIZATION

The following table presents our total capitalization and cash and cash equivalents as of September 30, 2014:

on an actual basis;

on a pro forma as adjusted basis to reflect the sale of [ ] shares of our common stock at a price of $[ ] per share and [ ] shares of our Series B Convertible Preferred Stock at a price of $[ ] per share, less underwriting discounts and commissions and estimated offering expenses payable by us (assuming no exercise of the underwriters over-allotment option to purchase additional shares of common stock).

This table should be read in conjunction with our consolidated financial statements and related, which are incorporated by reference herein.

	As of September 30, 2014 (in thousands)		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash and cash equivalents	$7,722	$	$
Stockholders equity:			
Preferred stock, $0.01 par value; 2,000,000 shares authorized, actual and pro forma; no shares issued and outstanding as of September 30, 2014, actual; and shares issued and outstanding, pro forma			
Common stock, $0.01 par value; 30,000,000 shares authorized, actual and pro forma; 7,856,607 shares issued and outstanding as of September 30, 2014, actual; and shares issued and outstanding, pro forma	79		
Additional paid-in capital	18,810		
Accumulated deficit	(10,193)		
Total stockholders equity	8,696		
Total capitalization	$8,696	$	$

The number of shares to be outstanding as shown in the above table is based on 7,856,607 shares of common stock outstanding as of September 30, 2014. It does not include as of such date:

Shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock being offered hereby.

4,100,123 shares of our common stock issuable upon exercise of stock options outstanding as of September 30, 2014 under our 2013 Plan, at a weighted average exercise price of $3.69 per share.

79,537 shares of our common stock underlying unvested restricted stock units outstanding as of September 30, 2014 under our 2013 Plan.

1,383,040 shares of our common stock available as of September 30, 2014 for future grant or issuance relating to stock options, restricted stock units, restricted stock, other equity awards, or share purchases that may be issued or made with respect to our 2013 Plan and 2013 Employee Stock Purchase Plan.

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PRICE RANGE OF COMMON STOCK

Our common stock has been listed on The NASDAQ Capital Market under the symbol HART since October 21, 2013. The last reported sale price for our common stock on February 9, 2015 was $2.34 per share.

The table below sets forth closing information on the range of high and low sales prices for our common stock as reported by The NASDAQ Capital Market since October 21, 2013.

	High	Low
Fiscal Year ended December 31, 2013		
Fourth Quarter	$ 6.25	$ 3.54
Fiscal Year ended December 31, 2014		
First Quarter	$ 11.00	$ 3.76
Second Quarter	$ 10.45	$ 6.51
Third Quarter	$ 9.84	$ 6.70
Fourth Quarter	$ 7.32	$ 2.53

DIVIDEND POLICY

We have never declared or paid dividends on our capital stock and we do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on applicable law and then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering shares of our common stock and shares of our Series B Convertible Preferred Stock. The shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock are also being offered pursuant to this prospectus supplement and the accompanying prospectus.

Common Stock

A description of the common stock that we are offering pursuant to this prospectus supplement is set forth under the heading Description of Capital Stock Common Stock beginning on page 9 of the accompanying prospectus. As of September 30, 2014, we had 7,856,607 shares of common stock outstanding.

Series B Convertible Preferred Stock

General.

Our Board of Directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without shareholder approval. Our Board may determine the designations, powers, preferences and the relative, participating, optional or other special rights, and any qualification, limitations and restrictions, of each series of preferred stock.

Our Board of Directors has designated 5,000 shares of preferred stock as Series A Junior Participating Cumulative Preferred Stock and 1,000,000 shares of preferred stock as Series B Convertible Preferred Stock. The Series A Junior Participating Cumulative Preferred Stock is not being registered pursuant to this prospectus supplement. As of February 6, 2015, there were no shares of preferred stock outstanding.

Rank.

The Series B Convertible Preferred Stock ranks (1) on parity with our common stock on an as converted basis, (2) on parity with our Series A Junior Participating Cumulative Preferred Stock, (3) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series B Convertible Preferred Stock, (4) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series B Convertible Preferred Stock, and (5) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series B Convertible Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

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Conversion.

Each share of the Series B Convertible Preferred Stock is convertible into five shares of common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series B Convertible Preferred Stock into shares of our common stock if, as a result of such conversion, the holder would own more than 4.98% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock, or such holder, together with its affiliates, would own more than 9.98% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series B Convertible Preferred Stock. The conversion rate of the Series B Convertible Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions. The Series B Convertible Preferred Stock automatically converts into common stock upon the occurrence of certain Fundamental Transactions, as described below.

Dividends.

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series B Convertible Preferred Stock are entitled to receive dividends on shares of Series B Convertible Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends are payable on shares of Series B Convertible Preferred Stock.

Voting Rights.

Except as provided in the Certificate of Designation or as otherwise required by law, the holders of Series B Convertible Preferred Stock are entitled to vote with the holders of outstanding shares of common stock, voting together as a single class, with respect to all matters presented to the stockholders for their action or consideration. In any such vote, each holder is entitled to a number of votes equal to the number of shares of common stock into which the Series B Convertible Preferred Stock held by such holder is convertible, after taking into account the Beneficial Ownership Limitation described below. The Company may not, without the consent of holders of a majority of the outstanding shares of Series B Convertible Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series B Convertible Preferred Stock or alter or amend the Certificate of Designation.

Liquidation Rights.

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series B Convertible Preferred Stock are entitled to receive, *pari passu* with the holders of common stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series B Convertible Preferred Stock been converted into common stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Beneficial Ownership Limitation, as described below.

Beneficial Ownership Limitation.

The Company may not effect any conversion of the Series B Convertible Preferred Stock, and a holder does not have the right to convert any portion of the Series B Convertible Preferred Stock to the extent that, after giving effect to the

conversion set forth in a notice of conversion such holder would beneficially own in excess of the holder Beneficial Ownership Limitation, or such holder, together with such holder s affiliates, and any persons acting as a group together with such holder or affiliates, would beneficially own in excess of the affiliates Beneficial Ownership Limitation. The holder Beneficial Ownership Limitation is 4.98% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion of Series B Convertible Preferred Stock held by the applicable holder. The affiliates Beneficial Ownership Limitation is 9.98% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion of Series B Convertible Preferred Stock held by the applicable holder and its affiliates (the holder Beneficial Ownership Limitation together with the affiliates Beneficial Ownership Limitation collectively

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referred to as the Beneficial Ownership Limitation). A holder may, with 61 days prior notice to the Company, or immediately upon notice from the holder to the Company at any time after the public announcement or other disclosure of a Fundamental Transaction, elect to increase or decrease one or both of the holder Beneficial Ownership Limitation and the affiliates Beneficial Ownership Limitation; provided, however, that in no event may either the holder Beneficial Ownership Limitation or the affiliate Beneficial Ownership Limitation be 20.00% or greater.

Failure to Deliver Conversion Shares.

If the Company fails to timely deliver shares of common stock upon conversion of the Series B Convertible Preferred Stock (the Conversion Shares) within the time period specified in the Certificate of Designation (within three trading days after delivery of the notice of conversion), and if the holder has not exercised its Buy-In rights as described below with respect to such shares, then the Company is obligated to pay to the holder, as liquidated damages, an amount equal to $100 per business day (increasing to $200 per business day after the tenth business day) for each $10,000 of Conversion Shares for which the Series B Convertible Preferred Stock converted which are not timely delivered. If the Company makes such liquidated damages payments, it is not also obligated to make Buy-In payments with respect to the same Conversion Shares.

Compensation for Buy-In on Failure to Timely Deliver Shares.

If the Company fails to timely deliver the Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by the holder of the Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a Buy-In), then the Company is obligated to (A) pay in cash to the holder the amount, if any, by which (x) the holder s total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased, minus any amounts paid to the holder by the Company as liquidated damages for late delivery of such shares, exceeds (y) the amount obtained by multiplying (1) the number of Conversion Shares that the Company was required to deliver times, (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the Series B Convertible Preferred Stock and equivalent number of Conversion Shares for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the holder the number of shares of common stock that would have been issued had the Company timely complied with its conversion and delivery obligations.

Subsequent Rights Offerings; Pro Rata Distributions.

If the Company grants, issues or sells any common stock equivalents pro rata to the record holders of any class of shares of common stock (the Purchase Rights), then a holder of Series B Convertible Preferred Stock will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon conversion of the Series B Convertible Preferred Stock (without regard to any limitations on conversion). If the Company declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of common stock, then a holder of Series B Convertible Preferred Stock is entitled to participate in such distribution to the same extent as if the holder had held the number of shares of common stock acquirable upon complete conversion of the Series B Convertible Preferred Stock (without regard to any limitations on conversion).

Fundamental Transaction.

If, at any time while the Series B Convertible Preferred Stock is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person pursuant to which the shares of capital stock of the Company outstanding immediately prior to such merger or consolidation are converted into or exchanged for shares of another corporation or entity and represent, or are converted into or exchanged for equity securities that represent, immediately following such merger or consolidation, less than a majority, by voting power, of the equity securities of (1) the surviving or resulting party or (2) if the surviving or resulting party is a wholly owned subsidiary of another party immediately following such merger or consolidation, the parent of such surviving or resulting party, (ii) the

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Company, directly or indirectly, effects any sale of all or substantially all of its assets in one or a series of related transactions, (iii) any tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding common stock, or (iv) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of common stock (not including any shares of common stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination) (each a Fundamental Transaction), then the Series B Convertible Preferred Stock automatically converts and the holder will receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Fundamental Transaction (subject to the Beneficial Ownership Limitation), the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the Alternate Consideration) receivable as a result of such Fundamental Transaction by a holder of the number of shares of common stock for which the Series B Convertible Preferred Stock is convertible immediately prior to such Fundamental Transaction (subject to the Beneficial Ownership Limitation). For purposes of any such conversion, the determination of the conversion ratio will be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Fundamental Transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder will be given the same choice as to the Alternate Consideration it receives upon automatic conversion of the Series B Convertible Preferred Stock following such Fundamental Transaction.

UNDERWRITING

We have entered into an underwriting agreement with National Securities Corporation, (the underwriter) pursuant to which the underwriter has agreed to purchase from us [ ] shares of our common stock to be sold in this offering and [ ] shares of our Series B Convertible Preferred Stock to be sold in this offering, each, at the public offering price set forth on the cover page of this prospectus supplement, less the underwriting discount.

Underwriter	Shares of Common Stock	Shares of Series B Convertible Preferred Stock
National Securities Corporation		
Summer Street Research Partners		

We have agreed to indemnify the underwriter and its officers, directors, principals, employees, affiliates and shareholders against certain liabilities, including civil liabilities under the Securities Act of 1933, as amended (the Securities Act), resulting from this offering and to contribute to payments the underwriter may be required to make in respect of such liabilities.

The underwriter is offering the shares subject to prior sale, when, as and if issued to and accepted by it, subject to approval of legal matters by its counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriter of officer s certificates and legal opinions. The underwriter reserves the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The underwriter has advised us that it proposes to initially offer the shares of common stock to the public at $[ ] per share and shares of the Series B Convertible Preferred Stock to the public at $[ ] per share. The underwriter proposes to offer the shares to certain dealers at the same price less a concession of not more than $[ ] per share of common stock and $[ ] per share of Series B Convertible Preferred Stock. After the initial offering of the shares, the underwriter may from time to time vary the offering prices and other selling terms.

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David Green, our Chief Executive Officer and one of our directors, has agreed to purchase 50,000 shares of our common stock in this offering at the price offered to the public.

Over-allotment Option to Purchase Additional Shares

We have granted to the underwriter an option to purchase up to [ ] additional shares of common stock from us at the same price to the public, less the same underwriting discount, as set forth in the table below. The underwriter may exercise this option any time during the 30-day period after the date of this prospectus supplement, but only to cover over-allotments, if any, including as described below.

Lock-Up

Our officers and directors have agreed to a 180-day lock-up with respect to shares of our common stock and other of our securities that they beneficially own, including securities that are convertible into shares of common stock and securities that are exchangeable or exercisable for shares of common stock. This means that, subject to certain exceptions, for a period of 180 days following the date of this prospectus supplement, such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of National Securities Corporation. We agreed, subject to certain exceptions, for a period of 180 days following the date of this prospectus supplement, not to offer, sell, pledge or otherwise dispose of shares of our common stock and other of our securities, including securities that are convertible into shares of common stock and securities that are exchangeable or exercisable for shares of common stock, without the prior written consent of National Securities Corporation.

Underwriter Discount and Expenses

The following table summarizes the public offering price, underwriting discount and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the over-allotment option. We have also agreed to pay up to $60,000 of the out-of-pocket fees and expenses of the underwriter, which include the fees and expenses of counsel to the underwriter. The fees and expenses of the underwriter that we have agreed to reimburse are not included in the underwriting discount set forth in the table below. The underwriting discount was determined through arms length negotiations between us and the underwriter.

	Per Share Underwriting Discount	Total Fees Without Exercise of Option to Purchase Additional Common Shares	Total Fees With Exercise of Option to Purchase Additional Common Shares
Underwriting discount for common stock to be paid by us	$		
Underwriting discount for Series B Convertible Preferred Stock to be paid by us	$		
Total Fees		$	$

We estimate that the total expenses of the offering, excluding the underwriting discount, will be approximately $[ ]. This includes $60,000 of fees and expenses of the underwriter, as well as $35,000 of expenses of certain institutional investors we have agreed to reimburse in connection with the offering. These expenses are payable by us.

After deducting fees due to the underwriter and our estimated offering expenses, we expect the net proceeds from this offering to be approximately $[ ].

Stabilization

To facilitate the offering, the underwriter may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock during and after the offering. Specifically, the underwriter may over-allot or otherwise create a short position in the common stock for its own account by selling more shares of common stock than have been sold to it by us. The underwriter may elect to cover any such short position by purchasing shares of common stock in the open market or by exercising the over-allotment option granted to the underwriter. In addition, the underwriter may stabilize or maintain the price of the common stock by

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bidding for or purchasing shares of common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to broker-dealers participating in the offering are reclaimed if shares of common stock previously distributed in the offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of the common stock at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also affect the price of the common stock to the extent that it discourages resales of the common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on the NASDAQ Capital Market, or otherwise and, if commenced, may be discontinued at any time. Neither we nor the underwriter make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock.

The underwriter has informed us that it will not engage in over-allotment, stabilizing or syndicate covering transactions in connection with the offering of our Series B Convertible Preferred Stock.

Passive Market Making

In connection with this offering, the underwriter (and any dealers that are members of the selling group) may also engage in passive market making transactions in our common stock. Passive market making consists of displaying bids limited by the prices of independent market makers and effecting purchases limited by those prices in response to order flow. Rule 103 of Regulation M promulgated by the SEC limits the amount of net purchases that each passive market maker may make and the displayed size of each bid. Passive market making may stabilize the market price of our common stock at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Electronic Offer, Sale and Distribution of Shares

A prospectus supplement in electronic format may be made available on the websites maintained by the underwriter and the underwriter may distribute prospectuses electronically. In those cases, prospective investors may view offering terms and a prospectus online and place orders online or through their financial advisors. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus supplement, the accompanying prospectus or the registration statement of which this prospectus supplement and the accompanying prospectus form a part, has not been approved or endorsed by us or the underwriter, and should not be relied upon by investors.

Right of Participation

Subject to certain conditions, we have granted the underwriter in this offering, for a period of twelve months after the date of the consummation of this offering, a right of participation to act as an additional underwriter or manager in any future registered public equity offering, in an amount not less than 10% of the amount sold in such offering.

Other Relationships with the Underwriter

From time to time in the ordinary course of business, the underwriter and its respective affiliates may in the future perform various commercial banking, financial advisory, investment banking and other financial services for us for which it will receive customary fees and reimbursement of expenses.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus supplement in any jurisdiction where action for that purpose is required. The securities offered by this prospectus supplement may not be offered or sold, directly or indirectly, nor may this prospectus supplement or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus supplement comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus supplement. This prospectus supplement does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus supplement in any jurisdiction in which such an offer or a solicitation is unlawful.

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LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Burns & Levinson LLP, Boston, Massachusetts. Duane Morris LLP, Philadelphia, Pennsylvania, is counsel to the underwriter in connection with this offering.

EXPERTS

The consolidated financial statements of Harvard Apparatus Regenerative Technology, Inc. as of December 31, 2013 and 2012 and for each of the years in the two-year period ended December 31, 2013, and for the period from February 24, 2009 (inception) to December 31, 2013, 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 are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act), and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC s public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC s web site at *http://www.sec.gov*.

This prospectus supplement and the accompanying prospectus are only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus supplement and the accompanying prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

We also maintain a website at *http://www.hartregen.com*, through which you can access our SEC filings. The information contained on our website is not incorporated by reference into, and does not form any part of, this prospectus supplement or the accompanying prospectus. We have included our website address as a factual reference and do not intend it to be an active link to our website.

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INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus supplement, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act with the SEC with respect to the securities being offered pursuant to this prospectus supplement. This prospectus supplement and the accompanying prospectus omit certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement and any prospectus supplement filed hereafter, including the exhibits, for further information about us and the securities we may offer pursuant to this prospectus. Statements in this prospectus supplement and the accompanying prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in Where You Can Find More Information. The documents we are incorporating by reference are:

Our Annual Report on Form 10-K for the year ended December 31, 2013;

Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014;

Item 7.01 of our Current Reports on Form 8-K filed with the SEC on March 7, 2014, December 23, 2014 and December 24, 2014;

Our Current Reports on Form 8-K filed with the SEC on May 28, 2014, and October 17, 2014;

Item 8.01 of our Current Reports on Form 8-K filed with the SEC on October 17, 2014, November 26, 2014, December 1, 2014 and January 30, 2014;

Our Definitive Proxy Statement relating to our 2014 annual meeting of stockholders filed on April 10, 2014;

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; and

All reports and other documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date of this prospectus and prior to the termination or completion of the offering of securities under this prospectus shall be deemed to be incorporated by reference in this prospectus and to be a part hereof from the date of filing such reports and other documents;

Any statement contained in this prospectus supplement, the accompanying prospectus or in a document incorporated or deemed to be incorporated by reference herein or therein will be deemed to be modified or superseded for purposes of this prospectus supplement and the accompanying prospectus to the extent that a statement contained in this prospectus supplement, the accompanying prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus supplement or the accompanying prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement or the accompanying prospectus.

You may request, orally or in writing, a copy of any or all of the documents incorporated herein by reference. These documents will be provided to you at no cost, by contacting: Harvard Apparatus Regenerative Technology, Inc., 84 October Hill Road, Holliston, Massachusetts 01746-1371 or call (774) 233-7300.

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You should rely only on information contained in, or incorporated by reference into, this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus supplement, the accompanying prospectus or incorporated by reference herein or therein. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

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PROSPECTUS

$20,000,000

HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

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Warrants
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We may from time to time issue, in one or more series or classes, up to $20,000,000 in aggregate principal amount of our common stock, preferred stock, warrants and/or units. We may offer these securities separately or together in units. We will specify in the accompanying prospectus supplement the terms of the securities being offered. We may sell these securities to or through underwriters and also to other purchasers or through agents. We will set forth the names of any underwriters or agents, and any fees, conversions, or discount arrangements, in the accompanying prospectus supplement. We may not sell any securities under this prospectus without delivery of the applicable prospectus supplement.

You should read this document and any prospectus supplement or amendment carefully before you invest in our securities.

Our common stock is listed on the NASDAQ Capital Market under the symbol HART. On December 11, 2014, the closing price for our common stock, as reported on the NASDAQ Capital Market, was $3.53 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading Risk Factors contained in this prospectus beginning on page 5 and any applicable prospectus supplement, and under similar headings in the other documents that are incorporated by reference into this prospectus.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS ACCURATE, TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus is December 29, 2014.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a shelf registration process. Under the shelf registration process, we may offer shares of our common stock and preferred stock, warrants to purchase any of such securities, and units comprised of any such securities with a total value of up to $20,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

designation or classification;
aggregate offering price;
rates and times of payment of dividends or other payments, if any;
redemption, conversion, exchange, settlement or sinking fund terms, if any;
conversion, exchange or settlement prices or rates, if any, and, if applicable, any provisions for changes to or adjustments in the conversion, exchange or settlement prices or rates and in the securities or other property receivable upon conversion, exchange or settlement;
ranking;
restrictive covenants, if any;
voting or other rights, if any; and
important federal income tax considerations.

A prospectus supplement may include a discussion of risks or other special considerations applicable to us or the offered securities. A prospectus supplement may also add, update or change information in this prospectus. If there is any inconsistency between the information in this prospectus and any applicable prospectus supplement, you must rely on the information in the prospectus supplement. Please carefully read both this prospectus and any applicable prospectus supplement together with the additional information described under the heading Where You Can Find More Information.

The registration statement containing this prospectus, including exhibits to the registration statement, provides additional information about us and the securities offered under this prospectus. The registration statement can be read at the SEC s website (*www.sec.gov*) or at the SEC s Public Reference Room mentioned under the heading Where You Can Find More Information.

We have not authorized any broker-dealer, salesperson or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and an accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or an accompanying prospectus supplement. This prospectus and an accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy securities, nor do this prospectus and an accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation. The information contained in this prospectus and an accompanying prospectus supplement speaks only as of the date set forth on the applicable cover page and may not reflect subsequent changes in our business, financial condition, results of operations and prospects even though this prospectus and any accompanying prospectus supplement is delivered or securities are sold on a later date.

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We may sell the securities directly to or through underwriters, dealers or agents. We, and our underwriters or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities through underwriters, dealers or agents, we will include in any applicable prospectus supplement:

- the names of those underwriters, dealers or agents;
- applicable fees, discounts, and commissions to be paid to them;
- details regarding over-allotment options, if any; and
- the net proceeds to us.

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PROSPECTUS SUMMARY

The following summary highlights information contained elsewhere in this prospectus. It may not contain all of the information that is important to you. You should read the entire prospectus carefully, especially the discussion regarding the risks of investing in our securities under the heading Risk Factors, before investing in our securities. All references to Company we, our or us refer solely to Harvard Apparatus Regenerative Technology, Inc. and its subsidiaries and not to the persons who manage us or sit on our Board of Directors (the Board).

About Harvard Apparatus Regenerative Technology

We are a clinical stage biotechnology company making regenerated organs for transplant. Our first product, the HART-Trachea, is intended to be used to restore the structure and/or function of a severely damaged trachea (windpipe). The HART-Trachea is comprised of the patient s own bone marrow cells seeded on our proprietary InBreath porous plastic scaffold in our proprietary InBreath organ bioreactor. The HART-Trachea has received orphan drug designation from the U.S. Food and Drug Administration, or FDA, for trachea transplant. Orphan drug designation will provide us with 7 years of market exclusivity from the date of FDA approval of the HART-Trachea.

We are currently engaged in pre-clinical development of our Hart-Trachea. The Hart-Trachea and our other transplant products are currently in development and have not yet received regulatory approval for sale anywhere in the world.

We believe our HART-Trachea could enable surgeons to treat nearly all life-threatening constrictions of the airway. Our HART-Trachea addresses both of the critical challenges to trachea transplant: the shortage of suitable donor tracheas and the risk and expense of lifelong anti-rejection drug therapy. Because the scaffolds are synthetic, they can be made in large quantities and therefore will eliminate the need to wait for suitable donor tracheas. Because the cells are from the patient, the patient s body does not reject the HART-Trachea and therefore the patients do not need to take anti-rejection drugs. In addition, to date, patients with trachea cancer treated using our products have not required either chemotherapy or radiation therapy after the transplant, thus potentially eliminating the significant side effects and expense of such therapies. Because these substantial costs and risks can be reduced or even eliminated with our technology, we believe our products can both help save lives and reduce overall healthcare costs.

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 *http://www. hartregen.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 information statement.

The name Harvard Apparatus is used under a license agreement between Harvard Bioscience, Inc. 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. We have filed a trademark application with respect to the InBreath trademark.

Common Stock

As discussed below under the heading Securities We May Offer, we may issue shares of our common stock from time to time. Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders; provided that Holders of common stock are not entitled to vote on any amendment to our amended and restated certificate of incorporation, or our Charter, that changes the powers, preferences, rights or other terms of one or more series of undesignated preferred stock if the holders of the affected series are entitled to vote, separately or together, with the holders of one or more other such series, on such amendment pursuant to the Charter or Delaware General Corporation Law. Our Board currently has five (5) members. Our Charter provides that the number of directors shall be fixed from time to time by resolution adopted by the vote of the Board. Our Charter provides that our Board shall be divided into three classes, each consisting as nearly as reasonably may be possible of one-third of the total number of

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directors constituting the entire Board, with each class s term expiring on a staggered basis. Newly-created directorships and vacancies on our Board may only be filled by a majority of the members of the incumbent board then in office, though less than a quorum, and not by our stockholders. Directors may be removed from office only for cause by the affirmative vote of the holders of at least seventy-five percent (75%) of the outstanding shares entitled to be cast on the election of directors by the then-outstanding shares of all classes and series of capital stock, voting together as a single class. Holders of common stock have no preemptive, redemption or conversion rights and are not subject to future calls or assessments. No sinking fund provisions apply to our common stock. All outstanding shares are fully-paid and non-assessable. In the event of any liquidation, dissolution or winding up of our company, after the satisfaction in full of the liquidation preferences of holders of any preferred stock, holders of common stock are entitled to ratable distribution of the remaining assets available for distribution to stockholders. Holders of common stock are entitled to receive proportionately any such dividends declared by our Board, out of legally available funds for dividends, subject to any preferences that may be applicable to any shares of preferred stock that may be outstanding at that time.

Preferred Stock

As discussed below under the heading Securities We May Offer, we may issue shares of our preferred stock from time to time, in one or more series. Under our Charter, our Board has the authority to issue, without further action by our stockholders, up to 2,000,000 shares of undesignated preferred stock in one or more series and to fix the designations, powers, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualification, limitations and restrictions thereon, any or all of which may be greater than the rights of our common stock.

If we issue preferred stock, we will fix the designations, powers, preferences and the relative, participating, optional or other special rights, and any qualification, limitations and restrictions of the shares of each series that we sell under this prospectus and applicable prospectus supplements in the certificate of designations relating to that series. If we issue preferred stock, we will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designations that describes the terms of such series of preferred stock before the issuance thereof. We urge you to read any prospectus supplement related to any series of preferred stock we may offer, as well as the complete certificate of designations that contains the terms of the applicable series of preferred stock.

Warrants

As discussed below under the heading Securities We May Offer, we may issue warrants for the purchase of common stock, preferred stock and/or units (as described below) in one or more series, from time to time. We may issue warrants independently or together with common stock and/or preferred stock, and the warrants may be attached to or separate from those securities.

If we issue warrants, they will be evidenced by warrant agreements or warrant certificates issued under one or more warrant agreements, which are contracts between us and an agent for the holders of the warrants. We urge you to read any prospectus supplement related to any series of warrants we may offer, as well as the complete warrant agreement and warrant certificate that contain the terms of the warrants. If we issue warrants, forms of warrant agreements and warrant certificates relating to such warrants will be incorporated by reference into the registration statement of which this prospectus is a part from other filings we would make with the SEC.

Units

As discussed below under the heading Securities We May Offer, we may issue units comprised of shares of common stock, shares of preferred stock and warrants in any combination. We may issue units in such amounts and in as many distinct series as we wish.

If we issue units, they will be issued under one or more unit agreements to be entered into between us and a bank or other financial institution, as unit agent. We urge you to read any prospectus supplement related to any series of units we may offer, as well as the complete unit agreement and unit certificate that contain the terms of the units. If we issue units, forms of unit agreements and unit certificates relating to such units will be incorporated by reference into the registration statement of which this prospectus is a part from other filings we would make with the SEC.

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RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described herein and in the documents incorporated by reference in this prospectus and any prospectus supplement, as well as other information we include or incorporate by reference into this prospectus and any applicable prospectus supplement, before making an investment decision. Our business, financial condition or results of operations could be materially adversely affected by the materialization of any of these risks. The trading price of our securities could decline due to the materialization of any of these risks, and you may lose all or part of your investment. This prospectus and the documents incorporated herein by reference also contain forward-looking statements that involve risks and uncertainties. Actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks described herein and in the documents incorporated herein by reference, including (i) our most recent annual report on Form 10-K which is on file with the SEC and is incorporated herein by reference and (ii) other documents we file with the SEC that are deemed incorporated by reference into this prospectus.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains, and the documents incorporated by reference herein include, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). 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 the HART-Trachea or any other HART products, by the FDA, EMA, MHRA or otherwise, which such approvals may not be obtained on a timely basis or at all; any continued benefits of our spin-off from Harvard Bioscience; 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; commercialization efforts and marketing approvals of HART s products as well as the success thereof, including our HART-Trachea product; the continued availability of a market for the HART 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; our inability to operate effectively as a stand-alone, publicly traded company; the actual costs of separation may be higher than expected; 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 statement by terms such as believe, may, estimate, continue, anticipate, intend, should, could, would, target, seek, aim, believe, predicts, think, objective

strategy potential, is likely, will, expect, plan project, permit and similar expressions intended to
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. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement. You should read this prospectus, the registration statement of which this prospectus is a part, and the exhibits and documents incorporated by reference herein and therein completely and with the

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understanding that our actual future results may be materially different from those described in forward-looking statements. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

You should assume that information contained in or incorporated by reference into this prospectus is accurate only as of the date on the front cover of this prospectus or the date of the document incorporated by reference, as applicable. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

USE OF PROCEEDS

We cannot guarantee that we will receive any proceeds in connection with this offering because we may be unable or choose not to issue and sell any securities covered by this prospectus.

Unless otherwise provided in a supplement or amendment to this prospectus, we intend to use any net proceeds from this offering, together with other available funds, for research and development, including funding preclinical and clinical trials relating to the HART-Trachea, business development, sales and marketing, capital expenditures, working capital and other general corporate purposes.

Pending these uses, we intend to invest the net proceeds to us from this offering in a variety of capital preservation investments, including short-term, investment-grade and interest-bearing instruments. The precise amounts and timing of the application of proceeds will depend upon our funding requirements and the availability of other funds. Except as mentioned in any prospectus supplement, specific allocations of the proceeds to such purposes will not have been made at the date of that prospectus supplement.

Based upon our historical and anticipated future growth and our financial needs, we may engage in additional financings of a character and amount that we determine as the need arises. We may raise additional capital through additional public or private financings, the incurrence of debt and other available sources. Please see the discussion of the risks associated with our liquidity in the section Risk Factors.

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PLAN OF DISTRIBUTION

The securities being offered may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market prices, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected at various times in one or more of the following transactions, or in other kinds of transactions:

through underwriters for resale to the public or investors;

transactions on the Nasdaq Stock Market or on any national securities exchange or U.S. inter-dealer system of a registered national securities association on which our common stock may be listed or quoted at the time of sale;

in the over-the-counter market;

in private transactions and transactions otherwise than on these exchanges or systems or in the over-the-counter market;

in at the market offerings, within the meaning of Rule 415(a)(4) of the Securities Act of 1933, as amended, or the Securities Act, to or through a market maker or into an existing trading market, on an exchange or otherwise;

in connection with short sales of the shares;

by pledge to secure debt and other obligations;

through the writing of options, whether the options are listed on an options exchange or otherwise;

in connection with the writing of non-traded and exchange-traded call options, in hedge transactions and in settlement of other transactions in standardized or over-the-counter options;

through a combination of any of the above transactions; or

any other method permitted by law.

We may sell our securities directly to one or more purchasers, or to or through underwriters, dealers or agents or through a combination of those methods. The related prospectus supplement will set forth the terms of each offering, including:

the name or names of any agents, dealers, underwriters or investors who purchase the securities;

the purchase price of the securities being offered and the proceeds we will receive from the sale;

the amount of any compensation, discounts, commissions or fees to be received by the underwriters, dealer or agents;

any over-allotment options under which underwriters may purchase additional securities from us;

any discounts or concessions allowed or reallowed or paid to dealers;

any securities exchanges on which such securities may be listed;

the terms of any indemnification provisions, including indemnification from liabilities under the federal securities laws; and

the nature of any transaction by an underwriter, dealer or agent during the offering that is intended to stabilize or maintain the market price of the securities.

With respect to any at the market offerings, unless we inform you otherwise in the prospectus supplement, the sales agent with respect to any such at-the-market offering will make all sales using commercially reasonable efforts consistent with its normal trading and sales practices and applicable laws, rules and regulations, on mutually agreeable terms between the sales agent and us. We will include in the prospectus supplement the amount of any compensation to be received by the sales agent.

In addition, any securities covered by this prospectus that qualify for sale pursuant to Regulation S may be sold pursuant to Regulation S rather than pursuant to this prospectus.

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In connection with the sale of our securities, underwriters may receive compensation from us or from purchasers of our securities in the form of discounts, concessions or commissions. Underwriters, dealers and agents that participate in the distribution of our securities may be deemed to be underwriters. Discounts or commissions they receive and any profit on their resale of our securities may be considered underwriting discounts and commissions under the Securities Act.

In compliance with the guidelines of the Financial Industry Regulatory Authority, or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed eight percent (8.0%) of the aggregate amount of the securities offered to this prospectus.

We may agree to indemnify underwriters, dealers and agents who participate in the distribution of our securities against various liabilities, including liabilities under the Securities Act. We may also agree to contribute to payments that the underwriters, dealers or agents may be required to make in respect of these liabilities. We may authorize dealers or other persons who act as our agents to solicit offers by various institutions to purchase our securities from us under contracts that provide for payment and delivery on a future date. We may enter into these contracts with commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others. If we enter into these agreements concerning any series of our securities, we will indicate that in the prospectus supplement or amendment.

In connection with an offering of our securities, underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our securities. Specifically, underwriters may over-allot in connection with the offering, creating a syndicate short position in our securities for their own account. In addition, underwriters may bid for, and purchase, our securities in the open market to cover short positions or to stabilize the price of our securities. Finally, underwriters may reclaim selling concessions allowed for distributing our securities in the offering if the underwriters repurchase previously distributed securities in transactions to cover short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of our securities above independent market levels. Underwriters are not required to engage in any of these activities and may end any of these activities at any time. Agents and underwriters may engage in transactions with, or perform services for, us and our affiliates in the ordinary course of business.

SECURITIES WE MAY OFFER

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize all the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement the particular terms of the securities offered by that prospectus supplement. If we so indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities and the securities exchange, if any, on which the securities will be listed.

Description of Capital Stock

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the common stock and preferred stock that we may offer under this prospectus. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our Charter and our amended and restated

bylaws, or our Bylaws, which are exhibits to the registration statement of which this prospectus forms a part, and by applicable law. The terms of our common stock and preferred stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 30,000,000 shares of common stock, par value $0.01 per share, and 2,000,000 shares of undesignated preferred stock, par value $0.01 per share. As of November 6, 2014, there were 7,856,607 shares of common stock outstanding and no shares of preferred stock outstanding.

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Common Stock

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders; provided, that, except as otherwise required by law, holders of common stock are not entitled to vote on any amendment to the Charter that changes the powers, preferences, rights or other terms of one or more series of undesignated preferred stock if the holders of the affected series are entitled to vote, separately or together, with the holders of one or more other such series, on such amendment pursuant to the Charter or Delaware General Corporation Law. Our Charter provides that our Board shall be divided into three classes, each consisting as nearly as reasonably may be possible of one-third of the total number of directors constituting the entire Board, with each class s term expiring on a staggered basis. Newly-created directorships and vacancies on our Board may only be filled by a majority of the members of the incumbent board then in office, though less than a quorum, and not by our stockholders. Directors may be removed from office only for cause by the affirmative vote of the holders of at least seventy-five percent (75%) of the outstanding shares entitled to be cast on the election of directors by the then-outstanding shares of all classes and series of capital stock, voting together as a single class. Holders of common stock have no preemptive, redemption or conversion rights and are not subject to future calls or assessments. No sinking fund provisions apply to our common stock. All outstanding shares are fully-paid and non-assessable. In the event of our liquidation, dissolution or winding up, after the satisfaction in full of the liquidation preferences of holders of any preferred stock, holders of common stock are entitled to ratable distribution of the remaining assets available for distribution to stockholders. Holders of common stock are entitled to receive proportionately any such dividends declared by our Board, out of legally available funds for dividends, subject to any preferences that may be applicable to any shares of preferred stock that may be outstanding at that time. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol HART. On December 11, 2014, the closing price for our common stock, as reported on the NASDAQ Capital Market, was $3.53 per share. As of the close of business on December 10, 2014, there were 177 stockholders of record of our common stock.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Registrar & Transfer Company.

Preferred Stock

Our Board is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without shareholder approval. Our Board may determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our Board to issue preferred stock in one or more series and determine the number of shares in the series and its rights and preferences is to eliminate delays associated with a shareholder vote on specific issuances. Examples of rights and preferences that the Board may fix are:

dividend rights;
dividend rates;

conversion rights;
voting rights;
terms of redemption; and
liquidation preferences.

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The existence of authorized but unissued shares of preferred stock may enable our Board to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our Board were to determine that a takeover proposal is not in the best interests of us or our stockholders, our Board could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer, stockholder or stockholder group. The rights of holders of our common stock described above, will be subject to, and may be adversely affected by, the rights of any preferred stock that we may designate and issue in the future. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

We will incorporate by reference as an exhibit to the registration statement, which includes this prospectus, the form of any certificate of designations that describes the terms of the series of preferred stock we are offering. This description and the applicable prospectus supplement will include:

the title and stated value;
the number of shares authorized;
the liquidation preference per share;
the purchase price;
the dividend rate, period and payment date, and method of calculation for dividends;
whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
the procedures for any auction and remarketing, if any;
the provisions for a sinking fund, if any;
the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
any listing of the preferred stock on any securities exchange or market;
whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
voting rights, if any, of the preferred stock;
preemptive rights, if any;
restrictions on transfer, sale or other assignment, if any;
whether interests in the preferred stock will be represented by depositary shares;
a discussion of any material United States federal income tax considerations applicable to the preferred stock;
the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

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When we issue shares of preferred stock under this prospectus, the shares will fully be paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

2013 Equity Incentive Plan

Under our 2013 Equity Incentive Plan, we can grant stock options to employees, directors and consultants. The 2013 Equity Incentive Plan also permits us to make grants of incentive stock options, non-qualified stock options, stock appreciation rights, deferred stock awards, restricted stock awards, unrestricted stock awards, performance shares and dividend equivalent rights. We currently have reserved 3,000,000 shares of common stock for the issuance of awards under the 2013 Equity Incentive Plan.

Employee Stock Purchase Plan

Under our employee stock purchase plan, participating employees can authorize us to withhold a portion of their base pay during consecutive six-month payment periods for the purchase of shares of our common stock. At the conclusion of the period, participating employees can purchase shares of our common stock at eight-five percent (85%) of the lower of the fair market value of our common stock at the beginning or end of the period. Shares are issued under the plan for the six-month periods ending June 30 and December 31. Under this plan, 150,000 shares of common stock are authorized for issuance.

Provisions of our Certificate of Incorporation and Bylaws and Delaware Anti-Takeover Law

Certain provisions of the Delaware General Corporation Law and of our Charter and Bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our Board. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Provisions of our Certificate of Incorporation and Bylaws

Our Charter, our Bylaws and Delaware law contain provisions that could discourage, delay or prevent a third party from acquiring us, even if doing so may be beneficial to our stockholders. In addition, these provisions could limit the price investors would be willing to pay in the future for shares of our common stock. The following are examples of such provisions in our Charter and Bylaws:

only our Board, pursuant to a resolution adopted by a majority of our directors, may call special meetings of our stockholders;

stockholders may not act by written consent and stockholder action must take place at the annual or special meeting of our stockholders;

stockholder proposals and nominations of candidates for election as directors other than nominations made by or at the direction of our Board or a committee of our Board to be brought before any meeting of our stockholders must comply with advance notice procedures;

our Board is classified into three classes, each consisting as nearly as reasonably may be possible of one-third of the total number of directors constituting the entire Board;

our Board will fix the exact number of directors to comprise our Board;

subject to any rights that holders of any series of our undesignated preferred stock may have to elect directors and to fill vacancies on our Board, newly-created directorships and vacancies on our Board may only be filled by a majority of the members of the incumbent board then in office, even if less than a quorum is present, and not by our stockholders;

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a director may be removed from office only for cause by the affirmative vote of holders of shares representing at least seventy-five percent (75%) of the votes entitled to be cast on such matter by the then-outstanding shares of all classes and series of our capital stock, voting together as a single class;

our Charter and Bylaws do not provide for cumulative voting in the election of directors;

our Bylaws may be further amended by either (i) the affirmative vote of at least a majority of our entire Board or (ii) the affirmative vote of the holders of at least seventy-five percent (75%) of the combined voting power of the outstanding shares of all classes and series of our capital stock entitled to vote on such amendment, voting together as a single class; and

our Board is authorized to issue, without further action by our stockholders, up to 2,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board.

We implemented a Stockholder Rights Plan (the Rights Plan) on October 31, 2013. Pursuant to the Rights Plan, one preferred stock purchase right will be issued for each outstanding share of our common stock. Each right issued will be subject to the terms of the Rights Plan. The Rights Plan is intended to protect our stockholders in the event of an unfair or coercive offer to acquire us and to provide the Board with adequate time to evaluate unsolicited offers; however, it may have anti-takeover effects. In general terms, our Rights Plan works by imposing a significant penalty upon any person or group that acquires twenty percent (20%) or more of our outstanding common stock, without the approval of our Board. The Rights Plan, however, should not affect any prospective offer or willingness to make an offer at a fair price as determined by our Board, nor should it interfere with any merger or other business combination approved by our Board. However, because the rights may substantially dilute the stock ownership of a person or group attempting to take us over without the approval of our Board, our Rights Plan could make it more difficult for a third party to acquire us (or a significant percentage of our outstanding capital stock) without first negotiating with our Board regarding that acquisition.

Additionally, as required by the Delaware General Corporation Law, any amendment of our Charter must first be approved by a majority of our Board and, as required by our Charter, thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon, voting together as a single class, except that the amendment of the provisions relating to stockholder action, directors, limitation of liability, the amendment of our Bylaws and Charter, forum and transactions with Harvard Bioscience must be approved by not less than seventy-five percent (75%) of the outstanding shares entitled to vote on the amendment, and not less than seventy-five percent (75%) of the outstanding shares of each class entitled to vote thereon as a class. Our Bylaws may be amended by either (i) a vote of at least a majority of our entire Board or (ii) a vote of the holders of at least seventy-five percent (75%) of the combined voting power of the outstanding shares of all classes and series of our capital stock entitled to vote on such amendment, voting together as a single class.

Delaware Anti-Takeover Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, fifteen percent (15%) or more of the corporation s voting stock. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

before the stockholder became interested, the Board approved either the business combination or the transaction

which resulted in the stockholder becoming an interested stockholder;

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upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least eight-five percent (85%) of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or

at or after the time the stockholder became interested, the business combination was approved by the Board of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Description of Warrants

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement, which includes this prospectus.

General

We may issue warrants for the purchase of common stock and/or preferred stock in one or more series. We may issue warrants independently or together with common stock and/or preferred stock, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we will issue under a separate warrant agreement. We will enter into the warrant agreement with a warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

the offering price and aggregate number of warrants offered;

the currency for which the warrants may be purchased;

if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;

if applicable, the date on and after which the warrants and the related securities will be separately transferable;

in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;

the terms of any rights to redeem or call the warrants;

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the periods during which, and places at which, the warrants are exercisable;

the manner of exercise;

the dates on which the right to exercise the warrants will commence and expire;

the manner in which the warrant agreement and warrants may be modified;

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federal income tax consequences of holding or exercising the warrants;
the terms of the securities issuable upon exercise of the warrants; and
any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Description of Units

We may issue units comprised of shares of common stock, shares of preferred stock and warrants in any combination. We may issue units in such amounts and in as many distinct series as we wish. This section outlines certain provisions of the units that we may issue. If we issue units, they will be issued under one or more unit agreements to be entered into between us and a bank or other financial institution, as unit agent. The information described in this section may not be complete in all respects and is qualified entirely by reference to the unit agreement with respect to the units of any particular series. The specific terms of any series of units offered will be described in the applicable prospectus supplement. If so described in a particular supplement, the specific terms of any series of units may differ from the general description of terms presented below. We urge you to read any prospectus supplement related to any series of units we may offer, as well as the complete unit agreement and unit certificate that contain the terms of the units. If we issue units, forms of unit agreements and unit certificates relating to such units will be incorporated by reference as exhibits to the registration statement, which includes this prospectus.

Each unit that we may issue will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. The applicable prospectus supplement may describe:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
any provisions of the governing unit agreement;
the price or prices at which such units will be issued;
the applicable United States federal income tax considerations relating to the units;
any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
any other terms of the units and of the securities comprising the units.

The provisions described in this section, as well as those described under Description of Capital Stock and Description of Warrants, will apply to the securities included in each unit to the extent relevant and as may be updated in any prospectus supplements.

Issuance in Series

We may issue units in such amounts and in as many distinct series as we wish. This section summarizes terms of the units that apply generally to all series. Most of the financial and other specific terms of your series will be described in the applicable prospectus supplement.

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Unit Agreements

We will issue the units under one or more unit agreements to be entered into between us and a bank or other financial institution, as unit agent. We may add, replace or terminate unit agents from time to time. We will identify the unit agreement under which each series of units will be issued and the unit agent under that agreement in the applicable prospectus supplement. The following provisions will generally apply to all unit agreements unless otherwise stated in the applicable prospectus supplement:

Modification without Consent

We and the applicable unit agent may amend any unit or unit agreement without the consent of any holder:

to cure any ambiguity; any provisions of the governing unit agreement that differ from those described below;
to correct or supplement any defective or inconsistent provision; or
to make any other change that we believe is necessary or desirable and will not adversely affect the interests of the affected holders in any material respect.

We do not need any approval to make changes that affect only units to be issued after the changes take effect. We may also make changes that do not adversely affect a particular unit in any material respect, even if they adversely affect other units in a material respect. In those cases, we do not need to obtain the approval of the holder of the unaffected unit; we need only obtain any required approvals from the holders of the affected units.

Modification with Consent

We may not amend any particular unit or a unit agreement with respect to any particular unit unless we obtain the consent of the holder of that unit, if the amendment would:

impair any right of the holder to exercise or enforce any right under a security included in the unit if the terms of that security require the consent of the holder to any changes that would impair the exercise or enforcement of that right; or
reduce the percentage of outstanding units or any series or class the consent of whose holders is required to amend that series or class, or the applicable unit agreement with respect to that series or class, as described below.

Any other change to a particular unit agreement and the units issued under that agreement would require the following approval:

If the change affects only the units of a particular series issued under that agreement, the change must be approved by the holders of a majority of the outstanding units of that series; or
If the change affects the units of more than one series issued under that agreement, it must be approved by the holders of a majority of all outstanding units of all series affected by the change, with the units of all the affected series voting together as one class for this purpose.

These provisions regarding changes with majority approval also apply to changes affecting any securities issued under a unit agreement, as the governing document.

In each case, the required approval must be given by written consent.

Mergers and Similar Transactions Permitted; No Restrictive Covenants or Events of Default

The unit agreements will not restrict our ability to merge or consolidate with, or sell our assets to, another corporation or other entity or to engage in any other transactions. If at any time we merge or consolidate with, or sell our assets substantially as an entirety to, another corporation or other entity, the successor entity will succeed to and assume our obligations under the unit agreements. We will then be relieved of any further obligation under these agreements.

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The unit agreements will not include any restrictions on our ability to put liens on our assets, including our interests in our subsidiaries, nor will they restrict our ability to sell our assets. The unit agreements also will not provide for any events of default or remedies upon the occurrence of any events of default.

Governing Law

The unit agreements and the units will be governed by Delaware law.

Form, Exchange and Transfer

We will issue each unit in global i.e., book-entry form only. Units in book-entry form will be represented by a global security registered in the name of a depositary, which will be the holder of all the units represented by the global security. Those who own beneficial interests in a unit will do so through participants in the depositary s system, and the rights of these indirect owners will be governed solely by the applicable procedures of the depositary and its participants. We will describe book-entry securities, and other terms regarding the issuance and registration of the units in the applicable prospectus supplement.

Each unit and all securities comprising the unit will be issued in the same form.

If we issue any units in registered, non-global form, the following will apply to them.

The units will be issued in the denominations stated in the applicable prospectus supplement. Holders may exchange their units for units of smaller denominations or combined into fewer units of larger denominations, as long as the total amount is not changed.

Holders may exchange or transfer their units at the office of the unit agent. Holders may also replace lost, stolen, destroyed or mutilated units at that office. We may appoint another entity to perform these functions or perform them ourselves.

Holders will not be required to pay a service charge to transfer or exchange their units, but they may be required to pay for any tax or other governmental charge associated with the transfer or exchange. The transfer or exchange, and any replacement, will be made only if our transfer agent is satisfied with the holder s proof of legal ownership. The transfer agent may also require an indemnity before replacing any units.

If we have the right to redeem, accelerate or settle any units before their maturity, and we exercise our right as to less than all those units or other securities, we may block the exchange or transfer of those units during the period beginning 15 days before the day we mail the notice of exercise and ending on the day of that mailing, in order to freeze the list of holders to prepare the mailing. We may also refuse to register transfers of or exchange any unit selected for early settlement, except that we will continue to permit transfers and exchanges of the unsettled portion of any unit being partially settled. We may also block the transfer or exchange of any unit in this manner if the unit includes securities that are or may be selected for early settlement.

Only the depositary will be entitled to transfer or exchange a unit in global form, since it will be the sole holder of the unit.

Payments and Notices

In making payments and giving notices with respect to our units, we will follow the procedures as described in the applicable prospectus supplement.

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LEGAL MATTERS

Certain legal matters in connection with this offering will be passed upon for us by Burns & Levinson LLP, Boston, Massachusetts. Any underwriters will also be advised about the validity of the securities and other legal matters by their own counsel, which will be named in the prospectus supplement.

EXPERTS

The consolidated financial statements of Harvard Apparatus Regenerative Technology, Inc. as of December 31, 2013 and 2012 and for each of the years in the two-year period ended December 31, 2013, and for the period from February 24, 2009 (inception) to December 31, 2013, 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 are subject to the information requirements of the Exchange Act and, in accordance therewith, file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC s Public Reference Room at 100 F Street, Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room. These documents also may be accessed through the SEC s electronic data gathering, analysis and retrieval system, or EDGAR, via electronic means, including the SEC s home page on the Internet (*www.sec.gov*).

We have the authority to designate and issue more than one class or series of stock having various preferences, conversion and other rights, voting powers, restrictions, limitations as to dividends, qualifications, and terms and conditions of redemption. See Description of Capital Stock. We will furnish a full statement of the relative rights and preferences of each class or series of our stock which has been so designated and any restrictions on the ownership or transfer of our stock to any shareholder upon request and without charge. Written requests for such copies should be directed to Harvard Apparatus Regenerative Technology, Inc., 84 October Hill Road, Suite 11, Holliston, Massachusetts 01746-1371, or by telephone request to (774) 233-7300. Our website is located at *http://www.hartregen.com*. Information contained on our website is not incorporated by reference into this prospectus and, therefore, is not part of this prospectus or any accompanying prospectus supplement.

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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, and information that we file later with the SEC will automatically update and supersede the information already incorporated by reference. We are incorporating by reference the documents listed below, which we have already filed with the SEC, and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except as to any portion of any future report or document that is not deemed filed under such provisions, until we sell all of the securities:

Our Annual Report on Form 10-K for the year ended December 31, 2013;

Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2014, June 30, 2014 and September 30, 2014;

Our Current Reports on Form 8-K filed with the SEC on March 7, 2014, March 31, 2014, May 8, 2014, May 28, 2014, August 8, 2014, October 17, 2014, November 6, 2014, November 26, 2014 and December 1, 2014 (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.

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.

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HARVARD APPARATUS REGENERATIVE TECHNOLOGY, INC.

[_____] Shares of Common Stock

[_____] Shares of Series B Convertible Preferred Stock

National Securities Corporation
Sole Book Runner

Summer Street Research Partners
Co-Manager

Prospectus Supplement dated [_____], 2015