Biostage, Inc.		
Form S-3		
August 08, 2016		

As filed with the Securities and Exchange Commission on August 8, 2016

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

BIOSTAGE, INC.

(Exact name of registrant as specified in its charter)

Delaware 45-5210462

(State or other jurisdiction of (I.R.S. Employer incorporation or organization) Identification Number)

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

(774) 233-7300

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

James McGorry President and Chief Executive Officer Biostage, Inc. 84 October Hill Road, Suite 11, Holliston, Massachusetts 01746 (774) 233-7300

(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies to:

Josef B. Volman, Esq.

Chad J. Porter, Esq. Burns & Levinson LLP 125 Summer Street Boston, MA 02110 (617) 345-3000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date hereof.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. "

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated filer"

Accelerated filer

Amount of

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Amount to be Proposed Maximum Maximum

Securities to be Registered

Registered (1) Offering Price Aggregate Registration Fee (4)

Per Unit (2) Offering Price (3)

Common Stock (5)

Preferred Stock (6)

Warrants (7)

Units (8)

Preferred Stock Purchase Rights (9)

Total \$20,000,000 N.A. \$20,000,000 \$ 1,400

The amount to be registered consists of up to \$20,000,000 of an indeterminate amount of common stock, preferred stock, warrants and/or units. There is also being registered hereunder such currently indeterminate number of (i) shares of common stock or other securities of the registrant as may be issued upon conversion of, or in exchange for, preferred stock registered hereby, or (ii) shares of preferred stock, common stock or units as may be issued upon exercise of warrants registered hereby, as the case may be. Any securities registered hereunder may be sold separately or as units with the other securities registered hereunder.

The proposed maximum aggregate offering price per unit will be determined from time to time by the registrant in (2) connection with the issuance by the registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act.

Estimated solely for purposes of computing the registration fee. No separate consideration will be received for (i) common stock or other securities of the registrant that may be issued upon conversion of, or in exchange for, preferred stock registered hereby, or (ii) preferred stock, common stock or units that may be issued upon exercise of warrants registered hereby, as the case may be.

The registration fee has been calculated in accordance with Rule 457(o) under the Securities Act. As discussed below, pursuant to Rule 415(a)(6) under the Securities Act, this Registration Statement includes a total of \$5,288,750 of unsold securities that had been previously registered and for which the registration fee had been previously paid. Accordingly, the amount of the registration fee that remains payable at the time of filing is \$1,400, because the registrant paid a total registration fee of \$614 for such unsold securities, which fee will continue to be applied to such unsold securities.

Including such indeterminate amount of common stock as may be issued from time to time at indeterminate prices (5) or upon conversion of preferred stock registered hereby, or upon exercise of warrants registered hereby, as the case may be.

Including such indeterminate amount of preferred stock as may be issued from time to time at indeterminate prices (6) or upon conversion of preferred stock registered hereby, or upon exercise of warrants registered hereby, as the case may be.

- (7) Including such indeterminate number of warrants or other rights, including without limitation share purchase or subscription rights, as may be issued from time to time at indeterminate prices.
- (8) Each unit will be issued under a unit agreement and will represent an interest in two or more securities, which may or may not be separable from one another.

The common stock currently includes certain preferred stock purchase rights (collectively, the "Rights") issued pursuant to that certain Shareholder Rights Agreement, dated as of October 31, 2013 (filed on Exhibit 4.1 to the registrant's Registration Statement on Form 8-A dated October 31, 2013) (the "Rights Agreement"), between the registrant and Registrar and Transfer Company, as rights agent. Until the occurrence of certain events specified in the Rights Agreement, none of which have occurred, the Rights are not exercisable, are evidenced by the certificate for the common stock and will be transferred along with and only with, and are not severable from, the common stock. The value attributable to the Rights, if any, is reflected in the market price of the common stock. No separate consideration will be payable for the Rights.

Pursuant to Rule 415(a)(6) under the Securities Act, the securities registered pursuant to this Registration Statement include unsold securities consisting of \$5,288,750 of unsold common stock, preferred stock, warrants and units of Biostage, Inc. (formerly known as Harvard Apparatus Regenerative Technology, Inc.) that had been previously registered on the Registration Statement of Biostage, Inc. on Form S-3 (Registration No. 333-200926), which we refer to as the "Prior Registration Statement". The registration fees with respect to such securities, totaling \$614, were

previously paid in connection with the filing of the Prior Registration Statement and will continue to be applied to such unsold securities. Pursuant to Rule 415(a)(6), the offerings of the unsold securities registered under the Prior Registration Statement will be deemed terminated as of the date of effectiveness of this Registration Statement. If the registrant sells any of such unsold securities pursuant to the Prior Registration Statement after the date of this filing, and prior to the date of effectiveness of this registration statement, the registrant will file a pre-effective amendment to this registration statement which will reduce the number of such unsold securities included on this registration statement and increase the additional securities registered hereon so that the total amount of securities registered hereon will equal \$20,000,000, as reflected in footnote 1 to the table above, and will pay the additional registration fee resulting therefrom.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

SUBJECT TO COMPLETION, DATED AUGUST 8, 2016

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PROSPECTUS	
\$20,000,000	
BIOSTAGE, INC.	
Common Stock	
Preferred Stock	
Warrants	
Units	

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 "BSTG." On August 5, 2016, the closing price for our common stock, as reported on the NASDAQ Capital Market, was \$1.14 per share. As of August 5, 2016, the aggregate market value of our outstanding common stock held by non-affiliates (the public float) was approximately \$19.7 million, which was calculated based on 16,109,818 shares of outstanding common stock held by non-affiliates and on a price per share of \$1.22, the closing price of our common stock on June 13, 2016. We have sold \$5,000,001 of securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar month period that ends on, and includes, the date of this prospectus. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of the aggregate market value of the voting and non-voting common equity in any 12 month period so long as our public float remains below \$75 million.

On March 31, 2016, we changed our name from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc. Prior to our name change on March 31, 2016, our common stock was listed on the NASDAQ Capital Market under the symbol "HART."

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 7 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 , 2016.

TABLE OF CONTENTS

	Page
ABOUT THIS PROSPECTUS	1
PROSPECTUS SUMMARY	3
RISK FACTORS	7
NOTE REGARDING FORWARD-LOOKING STATEMENTS	8
USE OF PROCEEDS	9
PLAN OF DISTRIBUTION	9
SECURITIES WE MAY OFFER	12
LEGAL MATTERS	21
<u>EXPERTS</u>	21
WHERE YOU CAN FIND MORE INFORMATION	21
INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE	22

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.

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.

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 Biostage, Inc. and its subsidiaries and not to the persons who manage us or sit on our Board of Directors (the "Board").

About Biostage, Inc.

We are a biotechnology company developing bioengineered organ implants based on our novel CellframeTM technology. Our Cellframe technology is comprised of a biocompatible scaffold that is seeded with the recipient's own stem cells. It is being developed to treat life-threatening conditions of the esophagus, trachea or bronchus with the objective of dramatically improving the treatment paradigm for those patients.

We believe that our Cellframe technology will provide surgeons with new ways to address damage to the esophagus, bronchi, and trachea due to cancer, infection, trauma or congenital abnormalities. Products being developed based on our Cellframe technology for those indications are called CellspanTM products.

A portion of all patients diagnosed with esophageal cancer are treated via a surgical procedure known as an esophagectomy. The current standard of care for an esophagectomy requires a complex surgical procedure that involves moving the patient's stomach or a portion of their colon into the chest to replace the portion of esophagus resected by the removal of the tumor. These current procedures have high rates of complications, and can lead to a severely diminished quality of life and require costly ongoing care. Our Cellspan esophageal implants aim to simplify the procedure, reduce complications, result in a better quality of life and reduce the overall cost of these patients to the healthcare system.

We announced favorable preliminary preclinical results of large-animal studies for the esophagus, trachea and bronchus in November 2015. Based on our preclinical testing to date, the Cellspan esophageal implant product will be our lead development product.

On May 12, 2016, we reported an update of recent results from pre-clinical large-animal studies. We disclosed that the study has demonstrated in a predictive large-animal model the ability of Biostage Cellspan organ implants to successfully stimulate the regeneration of sections of esophagus that had been surgically removed for the study. Cellspan esophageal implants, consisting of a proprietary biocompatible synthetic scaffold seeded with the recipient animal's own stem cells, were surgically implanted in place of the esophagus section that had been removed.

Study animals were returned to a solid diet two weeks after implantation surgery. The scaffolds, which are intended to be in place only temporarily, were later retrieved via the animal's mouth in a non-surgical endoscopic procedure. After 2.5 months, a complete epithelium and other specialized esophagus tissue layers were fully regenerated. Animals in the study demonstrated weight gain and appear healthy and free of any significant side effects, including a few that are now more than 120 days post implantation, and are receiving no specialized care.

We have applied for orphan drug designation for our Cellspan esophageal implant in the U.S., and plan to apply for such designation in Europe. Orphan drug status provides market exclusivity in the U.S. for seven years from the date of the product's approval for marketing. This exclusivity is in addition to any exclusivity we may obtain due to our patents. Additionally, orphan designation provides a waiver of the BLA application fee of \$672,000. Orphan drug status in Europe provides market exclusivity there for ten years from the date of the product's approval for marketing.

We believe that our recent studies provided sufficient data for us to initiate Good Laboratory Practice (GLP) studies to demonstrate that our technology, personnel, systems and practices are sufficient for advancing into clinical trials. GLP studies are required to advance to an Investigational New Drug (IND) application with the U.S. FDA, which would seek approval to initiate clinical trials for Biostage Cellspan esophageal implants in humans. Our goal is to complete an IND filing by year-end 2016.

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

We have incurred substantial operating losses since our Company's inception, and as of March 31, 2016, we have an accumulated deficit of approximately \$27.2 million. We expect to continue to incur operating losses and negative cash flows from operations in 2016 and for the foreseeable future. We believe that our cash on hand at March 31, 2016 will not be sufficient to meet our obligations through December 31, 2016. We will need to raise additional funds in 2016 and in future years to fund our operations, and we may seek to raise necessary funds through a combination public or private equity offerings, debt financings, and other financing mechanisms or strategic collaborations and licensing arrangements.

Corporate Information

We were incorporated under the laws of the State of Delaware on May 3, 2012 by Harvard Bioscience, Inc. ("Harvard Bioscience") to provide a means for separating its regenerative medicine business from its other businesses. On March 31, 2016, we changed our name from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc. 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.biostage.com. The reference to our web site is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our web site is not a part of this prospectus.

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 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.

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

In some cases, you can identify forward-looking statements by terms such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "could," "would," "target," "seek," "aim," "believe," "predicts," "think," "objectives," "optim "strategy," "potential," "is likely," "will," "expect," "plan" "project," "permit" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" in our SEC filings, and under the caption "Risk Factors" in this prospectus.

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

We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information. We qualify all of the information presented in this prospectus and any accompanying prospectus supplement, and particularly our forward-looking statements, by these cautionary statements.

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 CellframeTM technology, 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."

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 Capital 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.
9

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.

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 second 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 60,000,000 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 August 5, 2016, there were 17,108,968 shares of common stock outstanding and no shares of preferred stock outstanding.

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. To the extent our Shareholder Rights Agreement remains in effect at the time we sell any shares of common stock under this prospectus, such shares of common stock would also be accompanied by certain preferred stock purchase rights. See "Description of Capital Stock - Provisions of our Certificate of Incorporation and Bylaws and Delaware Anti-Takeover Law" for additional details regarding our Shareholder Rights Agreement.

Listing
Our common stock is listed on the NASDAQ Capital Market under the symbol "BSTG." On August 5, 2016, the closing price for our common stock, as reported on the NASDAQ Capital Market, was \$1.14 per share. As of the close of business on August 5, 2016, there were 180 stockholders of record of our common stock. Prior to our name change on March 31, 2016 from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc., our common stock was listed on the NASDAQ Capital Market under the symbol "HART."
Transfer Agent and Registrar
The transfer agent and registrar for our common stock is Computershare.
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.

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;