

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 "

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Unit (2)	Proposed Maximum Aggregate Offering Price (3)	Amount of Registration Fee (4)
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
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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

(1) (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
- (3) (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
- (4) \$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
- (9) 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.

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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.

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 Cellframe™ 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 Cellspan™ 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 Cellspan™ 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,” “optimism,” “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 Cellframe™ 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.

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 reallocated 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;

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.

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 5,960,000 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 of which 58,638 were issued as of August 5, 2016.

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;

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;

- 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;

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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;

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.

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.

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.

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 Biostage, Inc. as of December 31, 2015 and 2014, and for each of the years in the two-year period ended December 31, 2015, 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.

The audit report covering the December 31, 2015 consolidated financial statements contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and will require additional financing to fund future operations which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

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 Biostage, 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.biostage.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.

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, 2015;

• Our Quarterly Report on Form 10-Q for the three months ended March 31, 2016;

• Our Current Reports on Form 8-K filed with the SEC on January 7, 2016, March 10, 2016, March 17, 2016, March 24, 2016, March 31, 2016, May 16, 2016, May 20, 2016 and May 26, 2016 (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:

Biostage, 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.

\$20,000,000

Common Stock

Preferred Stock

Warrants

Units

PROSPECTUS

, 2016

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus. You must not rely on any unauthorized information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not offer to sell any securities in any jurisdiction where it is unlawful. Neither the delivery of this prospectus, nor any sale made hereunder, shall create any implication that the information in this prospectus is correct after the date hereof.

Part II—INFORMATION NOT REQUIRED IN PROSPECTUS**Item 14. Other Expenses of Issuance and Distribution**

The expenses payable by Biostage, Inc. (the “Registrant” or the “Company”) in connection with the issuance and distribution of the securities being registered (other than underwriting discounts and commissions, if any) are set forth below. Each item listed is estimated, except for the Securities and Exchange Commission (the “SEC”) registration fee.

Securities and Exchange Commission registration fee	\$ 1,400
FINRA filing fee	*
Legal fees and expenses	*
Accounting fees and expenses	*
Printing fees and expenses	*
Transfer agent and trustee fees	*
Miscellaneous	*
Total	\$ 1,400

*Estimated expenses not presently known.

Item 15. Indemnification of Directors and Officers

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our Amended and Restated Certificate of Incorporation, or our Charter, and Second Amended and Restated Bylaws, or our Bylaws, that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

any breach of the director’s duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or

any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our Charter also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

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As permitted by Section 145 of the Delaware General Corporation Law, our Charter and Bylaws provide that we will indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding by reason of the fact that such person, or a person of whom he or she is the legal representative, is or was our director or officer, or by reason of the fact that our director or officer is or was serving, at our request, as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans maintained or sponsored by us. We will indemnify such persons against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action if such person acted in good faith and in a manner reasonably believed to be in our best interests and, with respect to any criminal proceeding, had no reason to believe such person's conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification only extends to expenses (including attorneys' fees) incurred in connection with the defense or settlement of such actions, and court approval is required before there can be any indemnification where the person seeking indemnification has been found liable to us. Any amendment of this provision will not reduce our indemnification obligations relating to actions taken before an amendment.

Our Charter, filed as an exhibit to our Registration Statement on Form 10-12B filed with the SEC on July 31, 2013, and our Bylaws, filed as an exhibit to our Current Report on Form 8-K filed with the SEC on March 31, 2016, provide for the indemnification provisions described above and elsewhere herein. In addition, we have entered into separate indemnification agreements, a form of which is attached as Exhibit 10.7 to our Registration Statement on Form 10-12B, filed with the Securities and Exchange Commission on July 31, 2013, with our directors and officers which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law.

These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, subject to certain exceptions and limitations. These indemnification agreements also require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. In addition, we have obtained policies that insure our directors and officers and those of our subsidiaries against certain liabilities they may incur in their capacity as directors and officers. Under these policies, the insurer, on our behalf, may also pay amounts for which we have granted indemnification to the directors or officers. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.

Item 16. Exhibits

A list of exhibits filed with this registration statement on Form S-3 is set forth on the Exhibit Index and is incorporated herein by reference.

Item 17. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering;

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof; *provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date;

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser;

(6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof; and

(7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue;

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Holliston, Commonwealth of Massachusetts, on August 8, 2016.

BIOSTAGE, INC.

By: /s/ James J. McGorry

Name: James J.

McGorry

Title: President and

Chief Executive

Officer

POWER OF ATTORNEY

KNOW ALL BE THESE PRESENTS, that each person whose signature appears below hereby severally constitutes and appoints James McGorry and Thomas McNaughton, and each of them singly, as such person's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any or all amendments (including, without limitation, post-effective amendments) to this registration statement (or any registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature

Title

Date

/s/ James J. McGorry

President and Chief Executive Officer and Director

James J. McGorry	(Principal Executive Officer)	August 8, 2016
/s/ Thomas McNaughton Thomas McNaughton	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	August 8, 2016
/s/ John F. Kennedy John F. Kennedy	Chairman	August 8, 2016
/s/ John J. Canepa John J. Canepa	Director	August 8, 2016
/s/ Blaine H. McKee Blaine H. McKee	Director	August 8, 2016
/s/ Thomas Robinson Thomas Robinson	Director	August 8, 2016

EXHIBIT INDEX

Exhibit No.	Description
1.1*	Form of underwriting agreement
3.1(1)	Amended and Restated Certificate of Incorporation of Biostage, Inc.
3.2(2)	Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc.
3.3(2)	Second Amended and Restated Bylaws of Biostage, Inc.
3.4(3)	Certificate of Designations, Preferences and Rights of Series A Preferred Stock of Biostage, Inc. classifying and designating the Series A Junior Participating Cumulative Preferred Stock.
3.5(4)	Certificate of Designation of Series B Convertible Preferred Stock of Biostage, Inc. classifying and designating the Series B Convertible Preferred Stock.
4.1(1)	Specimen Common Stock Certificate
4.2(3)	Shareholder Rights Agreement, dated as of October 31, 2013, between Biostage, Inc. and Registrar and Transfer Company, as Rights Agent.
4.3(4)	Amendment to Shareholder Rights Agreement, dated as of February 12, 2015 between Biostage, Inc. and Computershare Trust Company, N.A., as successor to Registrar and Transfer Company.
4.4(5)	Registration Rights Agreement, dated as of December 15, 2015 between Biostage, Inc. and Aspire Capital Fund, LLC.
4.5*	Form of Certificate of Designations
4.6*	Form of Warrant and Warrant Agreement
4.7*	Form of Unit Agreement
5.1	Opinion of Burns & Levinson LLP
23.1	Consent of Burns & Levinson LLP (included in Exhibit 5.1)
23.2	Consent of KPMG LLP
24.1	Power of Attorney (included in signature page)

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- * To be filed, if necessary, by amendment or as an exhibit to a document to be incorporated or deemed to be incorporated by reference in this registration statement, including a Current Report on Form 8-K.
- (1) Incorporated by reference from the Company's Registration Statement on Form 10-12B, filed with the SEC on July 31, 2013.
- (2) Incorporated by reference from the Company's Current Report on Form 8-K, filed with the SEC on March 31, 2016.
- (3) Incorporated by reference from the Company's Registration Statement on Form 8-A, filed with the SEC on October 31, 2013.
- (4) Incorporated by reference from the Company's Current Report on Form 8-K, filed with the SEC on February 12, 2015.
- (5) Incorporated by reference from the Company's Current Report on Form 8-K, filed with the SEC on December 15, 2015.