

Biostage, Inc.
Form POS AM
March 20, 2017

As filed with the Securities and Exchange Commission on March 17, 2017

Registration No. 333-215410

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

POST-EFFECTIVE

AMENDMENT NO. 2 TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Biostage, Inc.

(Exact name of registrant as specified in its Charter)

| | | |
|--|-------------------------------------|-----------------------|
| Delaware | 3841 | 45-5210462 |
| (State or other jurisdiction of | (Primary Standard Industrial | (I.R.S. |
| incorporation or organization) | Classification Code Number) | Employer |
| | | Identification |
| | | No.) |

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 office)

James McGorry

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: As soon as practicable after the effective date of this registration statement.

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, check the following box.

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 post-effective amendment filed pursuant to Rule 462(d) 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.

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 <input type="checkbox"/> | Accelerated filer <input type="checkbox"/> |
| Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company) | Smaller reporting company <input checked="" type="checkbox"/> |

EXPLANATORY NOTE

This Post-Effective Amendment No. 2 constitutes the second post-effective amendment to the Registrant's Registration Statement on Form S-1, File No. 333-215410, which was first filed on January 4, 2017, as amended (the "Registration Statement").

The primary purpose of this Post-Effective Amendment No. 2 is to (i) incorporate the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 into the prospectus forming a part hereof, (ii) provide for the incorporation by reference in the Registration Statement of all documents subsequently filed by the Registrant pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and (iii) make certain other updates to the prospectus forming a part hereof.

On February 10, 2017, the Registrant completed a public offering pursuant to the Registration Statement of 20,000,000 shares of its common stock and the issuance of warrants to purchase 20,000,000 shares of common stock. Additionally, the Registrant issued warrants to purchase 1,000,000 shares of common stock to the placement agent for the offering. This Post-Effective Amendment No. 2 solely relates to the 21,000,000 shares of the Registrant's common stock that may be issued pursuant to exercise of the warrants. No additional securities are being registered under this Post-Effective Amendment No. 2. All applicable filing fees were paid at the time of the original filing of the Registration Statement.

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 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 MARCH 17, 2017

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.

Up to 21,000,000 Shares of Common Stock

We are offering up to 21,000,000 shares of common stock consisting of shares underlying outstanding warrants to purchase common stock. The shares underlie warrants to purchase up to 20,000,000 shares of our common stock at an exercise price of \$0.40 per share that expire on February 15, 2022 and warrants to purchase up to 1,000,000 shares of our common stock at an exercise price of \$0.50 per share that expire on February 9, 2022.

Our common stock is listed on the NASDAQ Capital Market under the symbol “BSTG.” On March 16, 2017, the closing price for our common stock, as reported on the NASDAQ Capital Market, was \$0.39 per share.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “Risk Factors” contained in this prospectus beginning on page 8.

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 _____, 2017.

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We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any prospectus supplement or free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable prospectus supplement or free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

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For investors outside the United States: We have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus and any prospectus supplement or free writing prospectus authorized by us. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The information in this prospectus is accurate only as of the date it is presented. You should read this prospectus and any prospectus supplement or free writing prospectus that we have authorized for use in connection with this offering, in their entirety before investing in our securities.

We are offering to sell, and seeking offers to buy, the securities offered by this prospectus only in jurisdictions where offers and sales are permitted. The distribution of this prospectus and the offering of the securities offered by this prospectus in certain jurisdictions may be restricted by law. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

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 constitute our Board of Directors.

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 seeded with the patient’s own stem cells. Our platform technology is being developed to treat life-threatening conditions of the esophagus, bronchus and trachea. By focusing on these underserved patients, we hope to dramatically improve the treatment paradigm for these patients. Our unique Cellframe technology combines the clinically proven principles of tissue engineering, cell biology and material science.

We believe that our Cellframe technology may provide surgeons a new paradigm to address life-threatening conditions of the esophagus, bronchus, and trachea due to cancer, infection, trauma or congenital abnormalities. Our novel technology harnesses the body’s response and modulates it toward the healing process to restore the continuity and integrity of the organ. We are pursuing the Cellspan™ esophageal implant as our first product candidate to address esophageal atresia and esophageal cancer, and we are also developing our technology’s applications to address conditions of the bronchus and trachea.

In collaboration with world-class institutions, such as Mayo Clinic and Connecticut Children’s Medical Center, we are expecting to transition from a pre-clinical company to a clinical company in 2017. We plan to file an Investigational New Drug application (IND) with the U.S. Food and Drug Administration (FDA) for our Cellspan esophageal implant in the third quarter of 2017 and expect to begin first in human clinical trials in the fourth quarter of 2017.

Our Cellframe technology platform: how it works

Our Cellframe process begins with the collection of an adipose (fat) tissue biopsy from the patient followed by the use of standard tissue culture techniques to isolate and expand the patient's own (autologous) mesenchymal (multipotent) stem cells, or MSC. The cells are seeded onto a biocompatible, synthetic scaffold, produced to mimic the dimensions of the organ to be regenerated, and incubated in a proprietary, organ bioreactor. The scaffold is electrospun from polyurethane (PU) to form a non-woven, hollow tube. The specific microstructures of the Cellspan implants are designed to allow the cultured cells to attach to and cover the scaffold fibers.

We have conducted large-animal studies to investigate the use of the Cellspan implants for the reconstitution of the continuity and integrity of tubular shape organs, such as the esophagus and the large airways, following a full circumferential resection of a clinically relevant segment, just as would occur in a clinical setting. We announced favorable preliminary preclinical results of large-animal studies for the esophagus, bronchus and trachea in November 2015. Based on the results of those studies, we chose the esophagus to be the initial focus for our organ regeneration technology.

Illustration of intersection of Cellspan esophageal implant and native esophagus at time of implant and proposed mechanism of action

In May 2016, we reported an update of results from additional, confirmatory pre-clinical large-animal studies. We disclosed that the studies had demonstrated in a predictive large-animal model the ability of our Cellspan organ implant to successfully stimulate the regeneration of a section of esophagus that had been surgically removed. 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. After the surgical full circumferential resection of a portion of the thoracic esophagus, the Cellspan implant stimulated the reconstitution of full esophageal structural integrity and continuity.

Illustration of esophageal reconstitution over Cellspan esophageal implant following time of implant and proposed mechanism of action

Study animals were returned to a solid diet three weeks after the implantation surgery. The scaffold portions of the Cellspan implants, which are intended to be in place only temporarily, were retrieved approximately three weeks post-surgery via the animal's mouth in a non-surgical endoscopic procedure. Within 2.5 to 3 months, a complete inner epithelium layer and other specialized esophagus tissue layers were regenerated. As of March 1, 2017, two animals in the study have not been sacrificed and are alive at eleven months and one year, respectively. These animals have demonstrated significant weight gain, appear healthy and free of any significant side effects and are receiving no specialized care.

Platform technology in life-threatening orphan indications

In November 2016, we were granted Orphan Drug Designation for our Cellspan esophageal implant by the FDA to restore the structure and function of the esophagus subsequent to esophageal damage due to cancer, injury or congenital abnormalities. Orphan drug designation provides a seven-year marketing exclusivity period against competition in the U.S. from the date of a product's approval for marketing. This exclusivity would be in addition to any exclusivity we may obtain from our patents. Additionally, orphan designation provides certain incentives, including tax credits and a waiver of the Biologics License Application fee. We also plan to apply for orphan drug designation for our Cellspan esophageal implant in Europe. Orphan drug designation in Europe provides market exclusivity in Europe for ten years from the date of the product's approval for marketing.

We are now advancing the development of our Cellframe technology, specifically a Cellspan esophageal implant, in large-animal studies with collaborators. As we believe that our recent studies provided sufficient confirmatory proof of concept data, we have initiated the Good Laboratory Practice (GLP) studies to demonstrate that our technology, personnel, systems and practices are sufficient for advancing into human clinical trials. In order to seek approval for the initiation of clinical trials for Biostage Cellspan esophageal implants in humans, GLP studies to support the safety of the Cellspan esophageal implant are required to submit an Investigational New Drug (IND) application with the FDA.

Our goal is to submit an IND filing in the third quarter of 2017.

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

Changing the surgical treatment of Esophageal Cancer

Illustration of esophageal cancer site *Illustration of potential human application of Cellspan esophageal implant at site of esophageal cancer (depicting implant prior to esophageal tissue reconstitution over implant)*

According to the World Health Organization's International Agency for Research on Cancer, there are approximately 450,000 new cases of esophageal cancer worldwide each year. 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 provide a simpler surgical procedure, with reduced complications, that may result in a better quality of life after the operation and reduce the overall cost of these patients to the healthcare system.

Congenital Abnormalities - Esophageal Atresia: a much needed focus on children

Each year, several thousand children worldwide are born with a congenital abnormality known as esophageal atresia, a condition where the baby is born with an esophagus that does not extend completely from the mouth to the stomach. When a long segment of the esophagus is lacking, the current standard of care is a series of surgical procedures where surgical sutures are applied to both ends of the esophagus in an attempt to stretch them and pull them together so they can be connected at a later date. This process can take weeks and the procedure is plagued by serious complications and may carry high rates of failure. Such approach also requires, in time, at least two separate surgical interventions. Other options include the use of the child's stomach or intestine that would be pulled up into the chest to allow a connection to the mouth. We are working to develop a Cellspan esophageal implant solution to address newborns' esophageal atresia, that could potentially be life-saving or organ-sparing, or both.

Financial Conditions

We have incurred substantial operating losses since our inception, and as of December 31, 2016, we have an accumulated deficit of approximately \$36.3 million. We expect to continue to incur operating losses and negative cash flows from operations in 2017 and for the foreseeable future.

In their audit report dated March 16, 2017 included in our Form 10-K for the fiscal year ended December 31, 2016, our independent registered public accounting firm included a "going concern" qualification as to our ability to continue as a going concern. We believe that if we do not raise additional capital from outside sources in the very near future, we may be forced to curtail or cease our operations. We believe that our existing cash resources will be sufficient to fund our planned operations through the third quarter of 2017. Our cash requirements and cash resources will vary significantly depending upon the timing, financial and other resources that will be required to complete ongoing development and pre-clinical and clinical testing of our products as well as regulatory efforts and collaborative arrangements necessary for our products that are currently under development. In addition to development and other costs, we expect to incur capital expenditures from time to time. These capital expenditures will be influenced by our regulatory compliance efforts, our success, if any, at developing collaborative arrangements with strategic partners, our needs for additional facilities and capital equipment and the growth, if any, of our business in general. We will require additional funding by the third quarter of 2017 to continue our anticipated operations and support our capital needs. We may seek to raise necessary funds through a combination of public or private equity offerings, debt financings, other financing mechanisms, strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. In addition, general market conditions may make it difficult for us to seek financing from the capital markets.

We are and we will remain an “emerging growth company” until the earliest to occur of (i) the last day of the fiscal year during which our total annual revenues equal or exceed \$1 billion (subject to adjustment for inflation), (ii) the last day of the fiscal year following the fifth anniversary of the date of our first sale of common equity securities pursuant to an effective registration statement, (iii) the date on which we have, during the previous three-year period, issued more than \$1 billion in non-convertible debt, or (iv) the date on which we are deemed a “large accelerated filer” under the Securities and Exchange Act of 1934, as amended, or the Exchange Act. For so long as we remain an “emerging growth company” as defined in the JOBS Act, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Recent Developments

On February 10, 2017, we completed a public offering of 20,000,000 shares of common stock at a purchase price of \$0.40 per share and the issuance of warrants to purchase 20,000,000 shares of common stock at an exercise price of \$0.40 per warrant for gross proceeds of \$8.0 million (the “February 2017 Public Offering”). Additionally, we issued to the placement agent warrants to purchase 1,000,000 shares of common stock to the placement agent for the offering at an exercise price of \$0.50 per warrant.

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.

THE OFFERING

Securities offered by us Up to 21,000,000 shares of our common stock consisting of shares underlying outstanding warrants as follows:

warrants to purchase up to 20,000,000 shares of our common stock at an exercise price of \$0.40 per share, expiring on February 15, 2022; and

warrants to purchase up to 1,000,000 shares of our common stock at an exercise price of \$0.50 per share, expiring on February 9, 2022.

Common stock
outstanding before this offering 37,116,570 shares

Common stock
outstanding after this offering 58,116,570 shares.

Use of proceeds We intend to use the net proceeds from this offering for research and development, including funding pre-clinical and clinical trials relating to the Cellframe™ technology, business development, sales and marketing, capital expenditures, working capital and other general corporate purposes. See “Use of Proceeds” on page 10.

NASDAQ Capital
Market symbol for
common stock BSTG.

Risk factors This investment involves a high degree of risk. See the information contained in “Risk Factors” beginning on page 8 of this prospectus.

The number of shares of our common stock to be outstanding after this offering is based on 37,116,570 shares of our common stock outstanding as of March 16, 2017, but does not include, as of such date:

5,410,979 shares issuable upon exercise of outstanding stock options, certain of which may not be exercised until we amend our amended and restated certificate of incorporation to increase the number of authorized shares of our common stock;

405,018 shares issuable pursuant to outstanding deferred stock awards of restricted stock units;

1,560,284 shares issuable upon exercise of additional outstanding warrants to purchase shares of our common stock; and

92,103 shares available for future grants under our 2013 Equity Incentive Plan and our Employee Stock Purchase Plan.

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, as well as other information we include or incorporate by reference into this prospectus, before making an investment decision. In particular, you should consider the risk factors under the heading “Risk Factors” included in our most recent Annual Report on Form 10-K, as may be revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K, each of which are on file with the SEC and are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. 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.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus (including any related prospectus supplement or free writing prospectus 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; our ability to continue as a going concern; 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; our inability to implement our growth strategy; and our liquidity.

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,” “optimistic,” “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 related prospectus supplement and free writing prospectus 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 is accurate as of the date on the cover of this prospectus or 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 related prospectus supplement or free writing prospectus, and particularly our forward-looking statements, by these cautionary statements.

USE OF PROCEEDS

If all of the warrants are exercised in full for cash, we will receive approximately \$8.5 million in proceeds. However, the warrants contain a cashless exercise provision that permit exercise of warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act of 1933, as amended, covering the issuance of the underlying shares.

We intend to use the net proceeds from this offering, together with other available funds, for research and development, including funding pre-clinical 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. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the net proceeds from this offering.

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.

PRICE RANGE OF OUR COMMON EQUITY

Our common stock trades on The NASDAQ Capital Market under the symbol “BSTG.” Prior to April 1, 2016, in connection with our name change, our common stock traded on The NASDAQ Capital Market under the symbol “HART” since October 21, 2013. The following table sets forth, for the quarters shown, the range of high and low sales prices of our common stock on the NASDAQ Capital Market.

| | High | Low |
|--|--------|--------|
| Fiscal Year ending December 31, 2017 | | |
| First Quarter (through March 16, 2017) | \$0.95 | \$0.29 |
| Fiscal Year ended December 31, 2016 | | |
| First Quarter | \$2.60 | \$1.08 |
| Second Quarter | \$2.86 | \$0.92 |
| Third Quarter | \$1.22 | \$0.90 |
| Fourth Quarter | \$1.42 | \$0.73 |
| Fiscal Year ended December 31, 2015 | | |
| First Quarter | \$4.43 | \$1.85 |
| Second Quarter | \$3.83 | \$1.36 |
| Third Quarter | \$1.73 | \$0.56 |
| Fourth Quarter | \$3.47 | \$0.53 |

The closing price of our common stock on the NASDAQ Capital Market on March 16, 2017 was \$0.39 per share. Immediately prior to this offering, we had 37,116,570 shares of common stock outstanding, which were held by approximately 180 stockholders of record as of March 16, 2017.

DIVIDEND POLICY

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

DILUTION

If you purchase our common stock in this offering, your interest will be diluted to the extent of the difference between the purchase price per share and the net tangible book value per share of our common stock after this offering.

The net tangible book value of our common stock on December 31, 2016, as adjusted to give effect to the sales of shares of common stock and warrants on February 15, 2017 pursuant to the February 2017 Public Offering, was approximately \$9.8 million, or approximately \$0.26 per share, based on 17,108,968 shares of our common stock outstanding as of December 31, 2016 and 20,000,000 shares of common stock issued in the February 2017 Public Offering. We calculate net tangible book value per share by subtracting our total liabilities from our total tangible assets and dividing the difference by the number of outstanding shares of our common stock. Dilution in net tangible book value per share to the investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the net tangible book value per share of our common stock immediately afterwards. The following illustrations set forth the per share dilution to investors purchasing the shares of common stock offered hereby underlying each set of warrants under which the shares of common stock are issuable.

Warrants Expiring on February 9, 2022

After giving effect to the sale of 1,000,000 shares of common stock at an exercise price of \$0.50 per share, our pro forma net tangible book value as of December 31, 2016 would have been approximately \$10.3 million, or \$0.27 per share of common stock. This represents an immediate increase in net tangible book value of \$0.01 per share of common stock to existing stockholders and immediate dilution of \$0.23 per share of common stock to investors purchasing our common stock in this offering. The following table illustrates this dilution on a per share basis:

| | |
|--|--------|
| Offering price per share of common stock | \$0.50 |
| Net tangible book value per share as of December 31, 2016 | \$0.26 |
| Increase in net tangible book value per share attributable to this offering | \$0.01 |
| Pro forma net tangible book value per share as of December 31, 2016 after giving effect to this offering | \$0.27 |
| Dilution per share of common stock to investors in this offering | \$0.23 |

Warrants Expiring on February 15, 2022

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After giving effect to the sale of 20,000,000 shares of common stock at an exercise price of \$0.40 per share, our pro forma net tangible book value as of December 31, 2016 would have been approximately \$17.8 million, or \$0.31 per share of common stock. This represents an immediate increase in net tangible book value of \$0.05 per share of common stock to existing stockholders and immediate dilution of \$0.09 per share of common stock to investors purchasing our common stock in this offering. The following table illustrates this dilution on a per share basis:

| | |
|--|--------|
| Offering price per share of common stock | \$0.40 |
| Net tangible book value per share as of December 31, 2016 | \$0.26 |
| Increase in net tangible book value per share attributable to this offering | \$0.05 |
| Pro forma net tangible book value per share as of December 31, 2016 after giving effect to this offering | \$0.31 |
| Dilution per share of common stock to investors in this offering | \$0.09 |

The number of shares of our common stock to be outstanding after this offering is based on 17,108,968 shares of our common stock outstanding as of December 31, 2016 plus the 20,000,000 shares of common stock issued in the February 2017 Public Offering, but does not include, as of such date:

·3,877,681 shares issuable upon exercise of outstanding stock options;

·268 shares issuable pursuant to outstanding deferred stock awards of restricted stock units;

·1,560,284 shares issuable upon exercise of additional outstanding warrants to purchase shares of our common stock;
and

·2,037,485 shares available for future grants under our 2013 Equity Incentive Plan and our Employee Stock Purchase Plan.

To the extent that outstanding options or warrants are exercised, investors purchasing our common stock in this offering will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

DESCRIPTION OF OUR CAPITAL STOCK

The following description of our common stock summarizes the material terms and provisions of the common stock 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 amended and restated certificate of incorporation, or 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 warrants to purchase our common 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, of which 1,000,000 shares were designated as Series B Convertible Preferred Stock . As of March 16, 2017, there were 37,116,570 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 our Charter or Delaware General Corporation Law. Our Charter provides that our Board of Directors 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 of Directors, with each class's term expiring on a staggered basis. Newly-created directorships and vacancies on our Board of Directors 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 of Directors, 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 March 16, 2017, the closing price for our common stock, as reported on the NASDAQ Capital Market, was \$0.39 per share. As of the close of business on March 16, 2017, there were approximately 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.”

On July 16, 2015, we received a notice from NASDAQ of non-compliance with its continuing listing rules, namely that the audit committee of our Board of Directors had two members following James McGorry’s appointment as our President and Chief Executive Officer, instead of the required minimum of three members. In accordance with NASDAQ continued listing rules, we were given until the earlier of our next annual shareholders’ meeting or July 6, 2016 to add a third audit committee member. On March 10, 2016, Blaine McKee, Ph.D. was appointed as a member of the Board of Directors and its audit committee, and we regained compliance with that requirement.

On November 10, 2015, we received a notice from NASDAQ of non-compliance with its listing rules regarding the requirement that the listed securities maintain a minimum bid price of \$1 per share. Based upon the closing bid price for the 30 consecutive business days preceding the notice, the Company no longer met this requirement. However, the NASDAQ rules also provide the Company a period of 180 calendar days in which to regain compliance and, in some circumstances, a second 180-day compliance period. On November 25, 2015, we regained compliance with the minimum bid price requirement when the closing price of our common stock was at least \$1 per share for ten consecutive business days.

On November 18, 2016, we received a notice from NASDAQ of non-compliance with its listing rules regarding the minimum bid price requirement. As noted above, the NASDAQ rules provide the Company a period of 180 calendar days in which to regain compliance and, in some circumstances, a second 180-day compliance period. We are monitoring the closing bid price of our common stock and will consider available options to resolve the noncompliance with the minimum bid price requirement as may be necessary, including the possibility of seeking stockholder approval of a reverse stock split. There can be no assurance that we would be successful in receiving such stockholder approval.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare.

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 65,882 were issued as of March 16, 2017.

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 of Directors. 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 of Directors, 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 of Directors or a committee of our Board of Directors to be brought before any meeting of our stockholders must comply with advance notice procedures;

· our Board of Directors 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 of Directors;

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

· 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 of Directors, newly-created directorships and vacancies on our Board of Directors 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 of Directors 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 of Directors 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 of Directors.

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 of Directors 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 of Directors. 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 of Directors, nor should it interfere with any merger or other business combination approved by our Board of Directors. 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 of Directors, 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 of Directors 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 of Directors 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 of Directors 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 of Directors 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 Directors 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.

Disclosure of SEC Position on Indemnification for Securities Act Liabilities

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

PLAN OF DISTRIBUTION

We are offering up to 21,000,000 shares of common stock consisting of shares underlying outstanding warrants to purchase common stock. The shares of common stock offered under this prospectus will be issued and sold only upon the due exercise of the warrants under which they are issuable, including the payment of the applicable exercise price, to the registered holder of the warrant being exercised. The warrants that the shares underlie consist of warrants to purchase up to 20,000,000 shares of our common stock at an exercise price of \$0.40 per share, expiring on February 15, 2022, and warrants to purchase up to 1,000,000 shares of our common stock at an exercise price of \$0.50 per share, expiring on February 9, 2022.

LEGAL MATTERS

Certain legal matters with respect to the validity of the securities offered by this prospectus will be passed upon for us by Burns & Levinson LLP, Boston, MA.

EXPERTS

The consolidated financial statements of Biostage, Inc. as of December 31, 2016 and 2015, and for each of the years in the two-year period ended December 31, 2016, 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, 2016 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 post on our public website (<http://www.biostage.com>) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained on that site, or connected to that site, are not incorporated into and are not a part of this prospectus.

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.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference the information and reports we file with them under File No. 001-35853, which means that we can disclose important information to you by referring you to those publicly available 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 all documents subsequently filed by us pursuant to 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, prior to the termination of the offering:

- Our Annual Report on Form 10-K for the year ended December 31, 2016; 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.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus is modified or superseded for purposes of the prospectus to the extent that a statement contained in this prospectus or in any other subsequently filed document that also is or is deemed to be incorporated by reference herein modifies or supersedes such statement.

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.

We also incorporate by reference any future filings, other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items, made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, in each case, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules, until the offering of the securities under the registration statement of which this prospectus forms a part is terminated or completed.

Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and later information filed with the SEC may update and supersede some of the information included or incorporated by reference in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded.

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.

Up to 21,000,000 Shares of Common Stock

PROSPECTUS

, 2017

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. 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 placement agent fees and expenses) are set forth below. Each item listed is estimated, except for the Securities and Exchange Commission (the “SEC”) registration fee and FINRA filing fees.

| | |
|---|--------------|
| Securities and Exchange Commission registration fee | \$— |
| Legal fees and expenses | 10,000 |
| Accounting fees and expenses | 5,000 |
| Transfer agent fees and expenses | 5,000 |
| Miscellaneous | — |
| Total | \$20,000 |

Item 14. 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.

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 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding the shares of common stock and preferred stock and the warrants issued, and options granted, by us in the three years preceding the filing of this registration statement that were not registered under the Securities Act. The offers, sales and issuances of the securities described below were exempt from registration under the Securities Act by virtue of Section 4(a)(2) of the Securities Act.

Aspire Capital, LLC Transaction

On December 15, 2015, we entered into a Common Stock Purchase Agreement (the “Purchase Agreement”) with Aspire Capital Fund, LLC, an Illinois limited liability company (“Aspire Capital”), which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of \$15.0 million of shares of our common stock (the “Purchase Shares”) over the 30-month term set forth in the Purchase Agreement.

On December 15, 2015, we issued 150,000 shares of our common stock to Aspire Capital in consideration for entering into the Purchase Agreement (the “Commitment Shares”) and sold 500,000 shares to Aspire Capital for an aggregate purchase price of \$1,000,000 (the “Initial Purchase Shares”). Under the Purchase Agreement, the Purchase Shares could be sold by us to Aspire Capital on any business day in two ways: (1) through a regular purchase of up to 150,000

shares at a known price based on the market price of our common stock prior to the time of each sale, and (2) through a VWAP purchase of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lesser of the closing sale price or 97% of the volume weighted average price for such purchase date.

On May 12, 2016, we issued 150,000 shares of common stock under this arrangement in exchange for gross proceeds of approximately \$371,000. We terminated the Aspire Purchase Agreement effective as of May 17, 2016.

May 2016 Offering

On May 15, 2016, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain investors (the “Investors”) for the sale by us of 2,836,880 registered shares of our common stock at a purchase price of \$1.7625 per share. Concurrently with the sale of the shares of our common stock, pursuant to the Purchase Agreement we also sold unregistered warrants to purchase 1,418,440 shares of our common stock. The aggregate gross proceeds for the sale of the shares of common stock and the warrants was approximately \$5.0 million. Subject to certain ownership limitations, the warrants will be initially exercisable commencing six months from the issuance date at an exercise price equal to \$1.7625 per share of common stock, subject to adjustments as provided under the terms of the warrants. The warrants are exercisable for five years from the initial exercise date. The closing of the sales of these securities under the Purchase Agreement occurred on May 19, 2016.

We entered into an engagement letter (the “Engagement Letter”) H.C. Wainwright & Co., LLC (“Wainwright”), pursuant to which Wainwright agreed to serve as exclusive placement agent for the issuance and sale of our shares of common stock and the warrants. Pursuant to the Engagement Letter, we granted to Wainwright unregistered warrants to purchase up to 5% of the aggregate number of shares sold in the transactions (the “Wainwright Warrants”). The Wainwright Warrants have substantially the same terms as the warrants.

Item 16. Exhibits and Financial Statement Schedules.

A list of exhibits filed with this Post-Effective Amendment No. 2 to Registration Statement on Form S-1 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;

(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 has duly caused this Post-Effective Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Town of Holliston, Commonwealth of Massachusetts, on this 17th day of March, 2017.

BIOSTAGE, INC.

By: /s/ James J. McGorry
 James J. McGorry
 Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Post-Effective Amendment No. 2 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|----------------|
| /s/ James J. McGorry James J. McGorry | Chief Executive Officer and Director (Principal Executive Officer) | March 17, 2017 |
| /s/ Thomas W. McNaughton Thomas W. McNaughton | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | March 17, 2017 |
| * John F. Kennedy | Chairman | March 17, 2017 |
| * John J. Canepa | Director | March 17, 2017 |
| * Blaine H. McKee | Director | March 17, 2017 |
| * Thomas Robinson | Director | March 17, 2017 |

By: /s/ James J. McGorry
 James J. McGorry, Attorney-in-Fact

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EXHIBIT INDEX

| Exhibit Number | Description of Exhibit |
|-----------------------|---|
| 2.1§ (3) | Separation and Distribution Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013. |
| 3.1 (1) | Amended and Restated Certificate of Incorporation of Biostage, Inc. |
| 3.2 (13) | Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc., dated as of March 30, 2016 |
| 3.3 (17) | Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc., dated as of May 26, 2016. |
| 3.4 (13) | Second Amended and Restated By-laws of the Biostage, Inc. |
| 3.5 (2) | 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. |
| 3.6(6) | Certificate of Designation of Series B Convertible Preferred Stock of Biostage, Inc. classifying and designating the Series B Convertible Preferred Stock. |
| 4.1(16) | Form of Warrant. |
| 4.2(16) | Form of Placement Agent Warrant |
| 4.3 (1) | Specimen Stock Certificate evidencing shares of common stock. |
| 4.4 (7) | Specimen Series B Convertible Preferred Stock Certificate. |
| 4.5 (2) | Shareholder Rights Agreement, dated as of October 31, 2013, between Biostage, Inc. and Registrar and Transfer Company, as Rights Agent. |
| 4.6(6) | 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. |
| 4.7 (10) | Registration Rights Agreement, dated December 15, 2015, between Biostage, Inc. and Aspire Capital Fund, LLC. |
| 4.8 (14) | Form of Common Stock Purchase Warrant, dated as of May 2016. |
| 5.1(16) | Opinion of Burns & Levinson LLP |
| 10.1 (3) | Intellectual Property Matters Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013. |
| 10.2 (3) | Product Distribution Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013. |
| 10.3 (3) | Tax Sharing Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013. |
| 10.4 (3) | Transition Services Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013. |
| 10.5 (3) | Sublease by and between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013. |
| 10.6# (3) | Employment Agreement between Biostage, Inc. and David Green dated as of October 31, 2013. |
| 10.7# (3) | Employment Agreement between Biostage, Inc. and Thomas McNaughton dated as of October 31, 2013. |
| 10.8 (1) | Form of Indemnification Agreement for Officers and Directors. |
| 10.9 (1) | 2013 Equity Incentive Plan. |
| 10.10 (1) | Employee Stock Purchase Plan. |
| 10.11 (1) | Form of Incentive Stock Option Agreement. |
| 10.12 (1) | Form of Non-Qualified Stock Option Agreement for executive officers. |
| 10.13 (1) | Form of Non-Qualified Stock Option Agreement for directors. |
| 10.14 (1) | Form of Deferred Stock Award Agreement. Director Compensation Arrangements. |

10.15#

(1)

10.16~~4~~⁽⁴⁾ Sublicense Agreement dated as of December 7, 2012 between Biostage, Inc. and Harvard Bioscience, Inc., and related Trademark License Agreement, dated December 19, 2002, by and between Harvard Bioscience, Inc. and President and Fellows of Harvard College.

10.17⁽¹⁾ Patent Rights Assignment dated December 21, 2012 between Biostage, Inc. and Dr. Paolo Macchiarini.

10.18⁽¹⁾ Sponsored Research Agreement dated August 5, 2009 by and among Biostage, Inc. (as assignee of Harvard Bioscience, Inc.), Sara Mantero, Maria Adelaide Asnaghi, and Department of Bioengineering of the Politecnico Di Milano

10.19~~5~~⁽⁵⁾ Exclusive License Agreement dated August 6, 2009 by and between Biostage, Inc. (as assignee of Harvard Bioscience, Inc.) and Sara Mantero and Maria Adelaide Asnaghi.

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- 10.20⁽¹⁾ Novel Surgery Agreement dated as of May 21, 2012 between Biostage, Inc. and State Budget Institution of Public Health Department Regional Clinical Hospital #1 and Vladimir Alekseevich Porhanov.
- 10.21⁽¹⁾ Novel Surgery Agreement dated as of May 24, 2012 between Biostage, Inc. and OSF Healthcare System, owner and operator of Saint Francis Medical Center and Children’s Hospital of Illinois, and Mark Holterman, M.D.
- 10.22⁽¹⁾ Amendment to Novel Surgery Agreement dated as of April 5, 2013 between Biostage, Inc. and OSF Healthcare System, owner and operator of Saint Francis Medical Center and Children’s Hospital of Illinois, and Mark Holterman, M.D.
- 10.23⁽¹⁾ Amendment to Novel Surgery Agreement dated as of June 26, 2013 between Biostage, Inc. and State Budget Institution of Public Health Department Regional Clinical Hospital #1 and Igor S. Polyakov.
- 10.24⁽⁶⁾ Underwriting Agreement dated as of February 12, 2015, between Biostage, Inc. and National Securities Corporation as representative of the underwriters named therein.
- 10.25^{#(8)} Employment Agreement between Biostage, Inc. and James McGorry dated as of June 23, 2015.
- 10.26^{#(9)} Employment Agreement between Biostage, Inc. and Saverio LaFrancesca, M.D. dated as of April 8, 2014.
- 10.27⁽¹⁰⁾ Common Stock Purchase Agreement, dated December 15, 2015 between Biostage, Inc. and Aspire Capital Fund, LLC.
- 10.28^{#(11)} Amendment to Employment Agreement between Biostage, Inc. and Saverio LaFrancesca, M.D. dated as of March 24, 2016.
- 10.29⁽¹⁴⁾ Form of Securities Purchase Agreement, dated May 15, 2016, between Biostage, Inc. and the Purchasers listed therein.
- 10.30⁽¹⁴⁾ Form of Common Stock Purchase Warrant.
- 10.31⁽¹⁴⁾ Engagement Letter, dated May 15, 2016, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
- 10.32⁽¹⁵⁾ Amendment to Engagement Letter, dated May 18, 2016, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
- 10.33^{#(17)} Letter Agreement, dated as of December 17, 2016, between Biostage, Inc. and Saverio LaFrancesca, M.D.
- 10.34⁽¹⁶⁾ Form of Securities Purchase Agreement.
- 10.35⁽¹⁶⁾ Form of Common Stock Purchase Warrant.
- 10.36⁽¹⁷⁾ Form of Placement Agent Common Stock Purchase Warrant.
- 10.37⁽¹⁶⁾ Engagement Agreement, dated January 3, 2017, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
- 10.38⁽¹⁶⁾ Amendment to Engagement Letter, dated February 7, 2017, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
- 21.1⁽¹⁷⁾ Subsidiaries of the Biostage, Inc.
- 23.1⁽¹⁶⁾ Consent of Burns & Levinson LLP (included in Exhibit 5.1)
- 23.2* Consent of KPMG LLP
- 24.1⁽¹⁸⁾ Power of Attorney (included in signature page)

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

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

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

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

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

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- (6) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on February 12, 2015) and incorporated by reference thereto.
- (7) Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed on March 27, 2015) and incorporated by reference thereto.
- (8) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on July 6, 2015) and incorporated by reference thereto.
- (9) Previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q (filed on August 14, 2015) and incorporated by reference thereto.
- (10) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on December 15, 2015) and incorporated by reference thereto.
- (11) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on March 24, 2016) and incorporated by reference thereto.
- (12) Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed on March 30, 2016) and incorporated by reference thereto.
- (13) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on March 31, 2016) and incorporated by reference thereto.
- (14) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on May 16, 2016) and incorporated by reference thereto.
- (15) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on May 20, 2016) and incorporated by reference thereto.
- (16) Previously filed as an exhibit to the Company's Pre-Effective Amendment No. 2 to Registration Statement on Form S-1 (filed on February 7, 2017) and incorporated by reference thereto.
- (17) Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed on March 17, 2017) and incorporated by reference thereto.

(18) Previously filed as an exhibit to the Company's Registration Statement on Form S-1 (filed on January 4, 2017) and incorporated by reference thereto.

*Filed herewith.

#Management contract or compensatory plan or arrangement.

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

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

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