Biostage, Inc.
Form S-1/A
February 06, 2017

As filed with the Securities and Exchange Commission on February 3, 2017

Registration No. 333-215410

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 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 incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. 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
President and Chief Executive Officer
Biostage, Inc.
84 October Hill Road, Suite 11, Holliston, Massachusetts 01746
(774) 233-7300

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

With copies to:

Josef B. Volman, Esq.	**Joseph A. Smith, Esq.**
Chad J. Porter, Esq.	**Ellenoff Grossman & Schole LLP**
Burns & Levinson LLP	**1345 Avenue of the Americas**
125 Summer Street	**New York, NY 10105**
Boston, MA 02110	**(212) 370-1300**
(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. x

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

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

If this Form is a 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 ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price(1)**	**Amount of Registration Fee**	
Common Stock, par value $0.01 per share (2)	$ 5,920,635	—	
Series C Convertible Preferred Stock, par value $0.01 per share (2)	$ 1,973,545	—	
Common Stock issuable upon conversion of Preferred Stock (2)	—	—	
Warrants to purchase Common Stock (2)	$ 105,821	—	
Common Stock issuable upon exercise of Warrants (2)	$ 10,000,001	—	
Placement agent's warrants (3)	—	—	
Common stock issuable upon exercise of placement agent's warrants (3)	$ 500,001	—	
Series A Junior Participating Cumulative Preferred Stock Purchase Rights (4)	—	—	
Total	$ 18,500,003	$ 2,145	(5)

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(3) Represents warrants to purchase a number of shares of common stock equal to 5% of the common stock sold in this offering (including the number of shares of common stock issuable upon conversion of shares of Series C Preferred Stock sold in this offering but excluding any shares of common stock underlying the warrants issued in this offering).

(4) This Registration Statement also relates to the Rights to purchase shares of Series A Junior Participating Cumulative Preferred Stock of the Registrant which are attached to all shares of Common Stock pursuant to the terms of the Registrant's Shareholder Rights Agreement dated October 31, 2008, as amended by Amendment No. 1 dated February 12, 2015. Until the occurrence of certain prescribed events, the Rights are not exercisable, are evidenced by the certificates for the Common Stock and will be transferred only with such stock.

(5) Of this amount, $928 was previously paid. Calculated in accordance with Rule 457(o) of the Securities Act based on an estimate of the proposed maximum aggregate offering price at the statutory rate of $115.90 per $1,000,000 of securities registered.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

SUBJECT TO COMPLETION, DATED FEBRUARY 3, 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.

PRELIMINARY PROSPECTUS

Up to 7,936,508 Shares of Common Stock,
Warrants to Purchase up to 10,582,011 Shares of Common Stock and
Up to 2,000 Shares of Series C Convertible Preferred Stock

(2,645,503 shares of Common Stock underlying the Series C

Convertible Preferred Stock)

We are offering up to 7,936,508 shares of common stock, together with warrants to purchase 10,582,011 shares of common stock (and the shares issuable from time to time upon exercise of the warrants) at a combined purchase price of $ pursuant to this prospectus. The shares and warrants will be separately issued but will be purchased together in this offering. Each warrant will have an exercise price of $ per share, will be exercisable upon issuance and will expire five years from the date on which such warrants were issued.

We are also offering to those purchasers, whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock following the consummation of this offering, the opportunity to purchase, if they so choose, in lieu of the shares of our common stock that would result in ownership in excess of 4.99%, shares of Series C Convertible Preferred Stock ("Series C Preferred Stock"), convertible at any time at the holder's option into a number of shares of common stock equal to $1,000 divided by the combined public offering price per share of common stock and warrant (the "Conversion Price"), at a public offering price of $1,000 per share of Series C Preferred Stock. Each

share of Series C Preferred Stock is being sold together with the same warrants described above being sold with each share of common stock.

Our common stock is listed on the NASDAQ Capital Market under the symbol “BSTG.” On February 2, 2017, the closing price for our common stock, as reported on the NASDAQ Capital Market, was $0.756 per share. The warrants and any shares of Series C Preferred Stock that we issue are not and will not be listed for trading on the NASDAQ Capital Market.

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.

	Per Share of Common Stock and Warrant	Per Share of Series C Preferred Stock and Warrant	Total
Public offering price			
Placement agent fees [(1)]			
Proceeds, before expenses, to us			

(1) We have also agreed to (i) grant warrants to purchase shares of common stock to the placement agent as described under "Plan of Distribution" on page 84 of this prospectus, (ii) pay the placement agent a management fee equal to 1% of the gross proceeds raised in this offering and (iii) pay the placement agent a reimbursement for out-of-pocket expenses in connection with marketing the transaction in the amount of up to $35,000 and a reimbursement for legal fees and expenses of the placement agent in the amount of $100,000. For additional information about the compensation paid to the placement agent, see "Plan of Distribution."

We have retained H.C. Wainwright & Co., LLC as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above.

We expect to deliver the shares and the warrants to purchasers in this offering on or about , 2017.

Rodman & Renshaw

a unit of H.C. Wainwright & Co.

The date of this prospectus is , 2017.

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We have not, and the placement agent has 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.

For investors outside the United States: We have not, and the placement agent has 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.

1

We have conducted large-animal studies to investigate the use of 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 pre-clinical 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. Therefore, no synthetic material remained in the animals after the esophageal tube was reconstituted. Within 2.5 to 3 months, a complete inner epithelium layer and other specialized esophagus tissue layers were regenerated. As of February 1, 2017, two animals in the study have not been sacrificed and are alive at ten and eleven months, respectively. These animals have demonstrated significant weight gain, appear healthy and free of any significant side effects and are receiving no specialized care.

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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 September 30, 2016, we have an accumulated deficit of approximately $33.0 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 30, 2016 included in our Form 10-K for the fiscal year ended December 31, 2015, 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 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 March 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 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.

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.

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

	Up to 7,936,508 shares of our common stock
Securities offered by us	Warrants to purchase up to 10,582,011 shares of our common stock
	Up to 2,000 shares of Series C Preferred Stock that are convertible into an aggregate of up to 2,645,503 shares of common stock, subject to certain adjustments.
Warrants	The warrants will be exercisable at an initial exercise price of $ per share. The warrants are exercisable at any time for a period of five years from the date on which such warrants were issued. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.
Series C Preferred Stock	Each share of Series C Preferred Stock is convertible at any time at the holder's option into a number of shares of common stock equal to $1,000 divided by the Conversion Price. Notwithstanding the foregoing, we shall not effect any conversion of Series C Preferred Stock, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series C Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of our common stock in excess of 4.99% of the shares of our common stock then outstanding after giving effect to such exercise. For additional information, see "Description of Our Capital Stock—Series C Convertible Preferred Stock" on page 77 of this prospectus.
Common stock outstanding before this offering	17,116,570 shares
Common stock outstanding after this offering	27,698,581 shares, assuming that we sell all securities offered pursuant to this prospectus and assuming conversion of all shares of Series C Preferred Stock.
Price per share of common stock and warrant	$
Price per share of Series C	$1,000

Preferred Stock and _____ warrants	
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 30.
NASDAQ Capital Market symbol for common stock	BSTG. We do not plan on applying to list the warrants or the Series C Preferred Stock on NASDAQ, any national securities exchange or any other nationally recognized trading system. Without an active trading market, the liquidity of the warrants and Series C Preferred Stock will be limited.
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 17,116,570 shares of our common stock outstanding as of February 1, 2017 and assumes that no shares of Series C Preferred Stock will be sold in the offering, but does not include, as of such date:

- 3,815,704 shares issuable upon exercise of outstanding stock options;
- 1,560,284 shares issuable upon exercise of outstanding warrants to purchase shares of our common stock;
- 2,092,038 shares available for future grants under our 2013 Equity Incentive Plan and our Employee Stock Purchase Plan;
- 10,582,011 shares of common stock issuable upon the exercise of warrants to be issued to investors in this offering at an exercise price of $ per share; and
- 529,101 shares of common stock issuable upon exercise of warrants to be issued to the placement agent as described in “Plan of Distribution.”

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks described herein, as well as other information we include in this prospectus, before making an investment decision. Our business, financial condition or results of operations could be materially adversely affected by the materialization of any of these risks. The trading price of our securities could decline due to the materialization of any of these risks, and you may lose all or part of your investment. This prospectus also contains 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.

Risks Relating To Our Business

Risks Associated with Clinical Trials and Pre-Clinical Development

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

Even if our pre-clinical development efforts or clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that the FDA, foreign regulatory authorities or notified bodies will agree with our conclusions regarding them. Although we have obtained some positive results from the use of our scaffolds and bioreactors for trachea transplants performed to date, we also discovered that our first generation trachea product design encountered certain body response issues that we have sought to resolve with our ongoing development of our Cellframe ™ implant design. We cannot be certain that our Cellframe implant design or any future modifications or improvements with respect thereto will support our claims, and any such developments may result in the discovery of further adverse side effects. We also may not see positive results when our products undergo clinical testing in humans in the future. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. Our pre-clinical development efforts and any clinical trial process may fail to demonstrate that our products are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Also, patients receiving surgeries using our products under compassionate use or in clinical trials may experience significant adverse events following the surgeries, including serious health complications or death, which may or may not be related to materials provided by us. Our current Cellframe ™ technology has never been used in humans. We provided a previous generation trachea implant that was used in human patients under compassionate use. To date, we believe that at least four of the six patients who received that first generation implant have died. While we believe that none of them have died because of a failure of the first generation implant, these and any other such adverse events have and may cause or contribute to the delay or termination of our clinical trials or pre-clinical development efforts. Any delay or termination of our pre-clinical development efforts or clinical trials will

delay the filing of our product submissions and, ultimately, our ability to commercialize our products and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product's profile.

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

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

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

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA and foreign regulatory authorities may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA and foreign regulatory authorities may not consider our data adequate to demonstrate safety and efficacy. Although FDA regulations allow submission of data from clinical trials outside the U.S., there can be no assurance that such data will be accepted or that the FDA will not apply closer scrutiny to such data. Increased costs and delays necessary to generate appropriate data, or failures in clinical trials could adversely affect our business, operating results and prospects. In the U.S., clinical studies for our products will be reviewed through the Investigational New Drug, or IND, pathway for biologics or combination products. The first bioengineered trachea implant approved in the U.S. using our first-generation trachea implant was approved under the IND pathway through CBER for a compassionate use. Such initial U.S. surgery was led by Professor Paolo Macchiarini, M.D., a surgeon pioneering tracheal replacement techniques. In the second half of 2014, allegations that Dr. Macchiarini had failed to obtain informed consent and accurately report patient conditions, among other things, for surgeries performed at the Karolinska Institutet in Stockholm, Sweden, were made public.

The Karolinska Institutet investigated the allegations and concluded that while in some instances Dr. Macchiarini did act without due care, his actions did not qualify as scientific misconduct. Subsequent to this investigation, further negative publicity and claims continued to be released questioning the conduct of Dr. Macchiarini, the Karolinska Institutet, the Krasnodar Regional Hospital in Krasnodar, Russia as well as our company relating to surgeries performed by Dr. Macchiarini and other surgeons at such facilities. In February 2015, the Karolinska Institutet announced that it would conduct an additional investigation into the allegations made about Dr. Macchiarini and the Karolinska Institutet's response and actions in the earlier investigation. In March 2015, the Karolinska Institutet announced that it was terminating Dr. Macchiarini's employment, and in December 2016 the Karolinska Institutet found Dr. Macchiarini, along with three co-authors, guilty of scientific misconduct. These allegations, the results of the investigation and any further actions that may be taken in connection with these matters, have and may continue to

harm the perception of our products or company and make it difficult to recruit patients for any clinical trials.

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

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

Risks Associated with Regulatory Approvals

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

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

The FDA has informed us that our first generation trachea product and our Cellspan esophageal implant would be viewed by the FDA as a combination product comprised of a biologic (cells) and a medical device component. Nevertheless, we cannot be certain how the FDA will regulate our products. The FDA may require us to obtain marketing clearance and approval from multiple FDA centers. The review of combination products is often more complex and more time consuming than the review of products under the jurisdiction of only one center within the FDA.

While the FDA has informed us that our first generation trachea product and our Cellspan esophageal implant would be regulated by the FDA as a combination product, we cannot be certain that any of our other products would also be regulated by the FDA as a combination product. For a combination product, the Office of Combination Products, or OCP, within FDA can determine which center or centers within the FDA will review the product and under what legal authority the product will be reviewed. Generally, the center within the FDA that has the primary role in regulating a combination product is determined based on the primary mode of action of the product. Generally, if the primary mode of action is as a device, then the Center for Devices and Radiological Health, or CDRH, takes the lead. Alternatively, if the primary mode of action is cellular, then the Center for Biologics Evaluation and Research takes the lead. On August 29, 2013, we received written confirmation from FDA's Office of Combination Products that FDA intends to regulate our first generation trachea product as a combination product under the primary jurisdiction of the Center for Biologics Evaluation and Research, or CBER. On October 18, 2016, we also received written confirmation from FDA's Center for Biologics Evaluation and Research, or CBER, that FDA intends to regulate our Cellspan esophageal implant as a combination product under the primary jurisdiction of CBER. We further understand that CBER may choose to consult or collaborate with CDRH with respect to the characteristics of the synthetic scaffold component of our product based on CBER's determination of need for such assistance.

The process of obtaining FDA marketing approval is lengthy, expensive, and uncertain, and we cannot be certain that our products, including products pertaining to the esophagus, airways, or otherwise, will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often more complex and can be more time consuming than the review of a product under the jurisdiction of only one center within the FDA.

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

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

In the EU, our esophagus product will likely be regulated as a combined advanced therapy medicinal product and our other products, including for the trachea or bronchus, may also be viewed as advanced therapy medicinal products, which could delay approvals and clearances and increase costs of obtaining such approvals and clearances.

On May 28, 2014, we received notice from the European Medicines Agency (EMA) that our first generation trachea product would be regulated as a combined advanced therapy medicinal product. While we have not had any formal interaction with the EMA with respect to our Cellframe implant technology, including pertaining to the esophagus, we believe that such implant technology would likely be regulated as a combined advanced therapy medicinal product. In the event of such classification, it would be necessary to seek a marketing authorization for these products granted by the European Commission before being marketed in the EU.

Other products we may develop, including any products pertaining to the airways or otherwise, may similarly be regulated as advanced therapy medicinal products or combined advanced therapy medicinal products. The regulatory procedures leading to marketing approval of our products vary among jurisdictions and can involve substantial additional testing. Compliance with the FDA requirements does not ensure clearance or approval in other jurisdictions, and the ability to legally market our products in any one foreign country does not ensure clearance, or approval by regulatory authorities in other foreign jurisdictions. The foreign regulatory process leading to the marketing of the products may include all of the risks associated with obtaining FDA approval in addition to other risks. In addition, the time required to comply with foreign regulations and market products may differ from that required to obtain FDA approval, and we may not obtain foreign approval or clearance on a timely basis, if at all.

The United Kingdom’s vote to leave the European Union will have uncertain effects and could adversely affect us.

On June 23, 2016, eligible members of the electorate in the United Kingdom decided by referendum to leave the European Union, commonly referred to as "Brexit". The effects of Brexit will depend on any agreements the U.K. makes to retain access to E.U. markets either during a transitional period or more permanently. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially change the regulatory regime applicable to the approval of any product candidates in the United Kingdom. In addition, since the EMA is located in the U.K., the implications for the regulatory review process in the European Union has not been clarified and could result in relocation of the EMA or a disruption in the EMA review process.

Further, Brexit could adversely affect European and worldwide economic or market conditions and could contribute to instability in global financial markets. Brexit is likely to lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business and financial condition.

Risk Associated with Product Marketing

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

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

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

Post-market enforcement actions can generate adverse commercial consequences.

Even if regulatory approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA or a foreign regulatory authority determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical products reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of

previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Extensive governmental regulations that affect our business are subject to change, and we could be subject to penalties and could be precluded from marketing our products and technologies if we fail to comply with new regulations and requirements.

As a manufacturer and marketer of biotechnology products, we are subject to extensive regulation that is subject to change. In March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, known as the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Affordability Reconciliation Act of 2010, or the PPACA, which may have far-reaching consequences for most healthcare companies, including biotechnology companies. The PPACA could substantially change the structure of the health insurance system and the methodology for reimbursing medical services, laboratory tests, drugs and devices. These structural changes, as well as those relating to proposals that may be made in the future to change the health care system, could entail modifications to the existing system of private payers and government programs, as well as implementation of measures to limit or eliminate payments for some medical procedures and treatments or subject the pricing of medical products to government control. Government and other third-party payers increasingly attempt to contain health care costs by limiting both coverage and the level of payments of newly approved health care products. In some cases, they may also refuse to provide any coverage of uses of approved products for disease indications other than those for which the regulatory authorities have granted marketing approval. Governments may adopt future legislative proposals and federal, state, foreign or private payers for healthcare goods and services may take action to limit their payments for goods and services. In addition, it is possible that changes in administration and policy, including the potential repeal of all or parts of the PPACA, resulting from the recent U.S. presidential election could result in additional proposals and/or changes to health care system legislation.

Any of these regulatory changes and events could limit our ability to form collaborations and our ability to commercialize our products, and if we fail to comply with any such new or modified regulations and requirements it could adversely affect our business, operating results and prospects.

If we fail to complete the required IRS forms for exemptions, make timely semi-monthly payments of collected excise taxes, or submit quarterly reports as required by the Medical Device Excise Tax, we may be subject to penalties, such as Section 6656 penalties for any failure to make timely deposits.

Section 4191 of the Internal Revenue Code, enacted by Section 1405 of the Health Care and Education Reconciliation Act of 2010, Public Law 111-152 (124 Stat. 1029 (2010)), in conjunction with the Patient Protection and Affordable Care Act, Public Law 111-148 (124 Stat. 119 (2010)), imposed as of January 1, 2013, an excise tax on the sale of certain medical devices. The excise tax imposed by Section 4191 is 2.3% of the price for which a taxable medical device is sold within the U.S.

While the provision for a medical device excise tax has been suspended for 2016 and 2017, there is no guarantee that the moratorium will be approved for subsequent years. The excise tax will apply to future sales of any company medical device listed with the FDA under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, unless the device falls within an exemption from the tax, such as the exemption governing direct retail sale of devices to consumers or for foreign sales of these devices. We will need to assess to what extent this excise tax may impact the sales price and distribution agreements under which any of our products are sold in the U.S. We also expect general and administrative expense to increase due to the medical device excise tax. We will need to submit IRS forms applicable to relevant exemptions, make semi-monthly payments of any collected excise taxes, and make timely (quarterly) reports to the IRS regarding the excise tax. To the extent we do not comply with the requirements of the Medical Device Excise Tax we may be subject to penalties.

Financial and Operating Risks

Our audited financial statements for the year ended December 31, 2015 contain a going concern qualification. Our financial status creates doubt whether we will continue as a going concern. We will need additional funds in the near future and our operations will be adversely affected if we are unable to obtain needed funding.

In their audit report dated March 30, 2016 included in this prospectus, 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 early 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 early 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.

Any additional equity financings could result in significant dilution to our stockholders and possible restrictions on subsequent financings. Debt financing, if available, could result in agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or paying dividends. Other financing mechanisms may involve selling intellectual property rights, payment of royalties or participation in our revenue or cash flow. In addition, in order to raise additional funds through strategic collaborations or licensing arrangements, we may be required to relinquish certain rights to some or all of our technologies or products. If we cannot raise funds or engage strategic partners on acceptable terms when needed, we may not be able to continue our research and development activities, develop or enhance our products, take advantage of future opportunities, grow our business or respond to competitive pressures or unanticipated requirements.

We have generated insignificant revenue to date and have an accumulated deficit. We anticipate that we will incur losses for the foreseeable future. We may never achieve or sustain profitability.

We have generated insignificant revenues to date and we have generated no revenues from sales of any clinical products, and as of September 30, 2016, we had an accumulated deficit of approximately $33.0 million. We expect to

continue to experience losses in the foreseeable future due to our limited anticipated revenues and significant anticipated expenses. We do not anticipate that we will achieve meaningful revenues for the foreseeable future. In addition, we expect that we will continue to incur significant operating expenses as we continue to focus on additional research and development, pre-clinical testing, clinical testing and regulatory review and/or approvals of our products and technologies. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

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

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

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

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

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

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

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

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

We are currently collaborating with multiple academic researchers and clinicians at a variety of research and clinical institutions. Our success depends in part on the performance of our collaborators. Some collaborators may not be successful in their research and clinical trials or may not perform their obligations in a timely fashion or in a manner satisfactory to us. Typically, we have limited ability to control the amount of resources or time our collaborators may devote to our programs or potential products that may be developed in collaboration with us. Our collaborators frequently depend on outside sources of funding to conduct or complete research and development, such as grants or other awards. In addition, our academic collaborators may depend on graduate students, medical students, or research assistants to conduct certain work, and such individuals may not be fully trained or experienced in certain areas, or they may elect to discontinue their participation in a particular research program, creating an inability to complete ongoing research in a timely and efficient manner. As a result of these uncertainties, we are unable to control the precise timing and execution of any experiments that may be conducted.

Although we have formal co-development collaboration agreements with Mayo Clinic and Connecticut Children’s Medical Center, we do not have formal agreements in place with other collaborators, and most of our collaborators retain the ability to pursue other research, product development or commercial opportunities that may be directly competitive with our programs. If any of our collaborators elect to prioritize or pursue other programs in lieu of ours, we may not be able to advance product development programs in an efficient or effective manner, if at all. If a collaborator is pursuing a competitive program and encounters unexpected financial or capability limitations, they

may be motivated to reduce the priority placed on our programs or delay certain activities related to our programs. Any of these developments could harm or slow our product and technology development efforts.

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

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

Our products will subject us to liability exposure.

We face an inherent risk of product liability claims, especially with respect to our products that will be used within the human body, including the scaffolds we manufacture. Product liability coverage is expensive and sometimes difficult to obtain. We may not be able to obtain or maintain insurance at a reasonable cost. We may be subject to claims for liabilities for unsuccessful outcomes of surgeries involving our products, which may include claims relating to patient death. We may also be subject to claims for liabilities relating to patients that suffer serious complications or death during or following transplants involving our products, including the patients who had surgeries utilizing our first generation scaffold product or our bioreactor technology, or patients that may have surgeries utilizing any of our products in the future. Our current product liability coverage is $15 million per occurrence and in the aggregate. We will need to increase our insurance coverage if and when we begin commercializing any of our products. There can be no assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. If claims against us substantially exceed our coverage, then our business could be adversely impacted. Regardless of whether we are ultimately successful in any product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources and could result in, among others:

- significant awards against us;
- substantial litigation costs;
- injury to our reputation and the reputation of our products;
- withdrawal of clinical trial participants; and
- adverse regulatory action.

Any of these results would substantially harm our business.

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

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

We depend upon a single-source supplier for the hardware used for our organ bioreactor control and acquisition system. The loss of this supplier, or future single-source suppliers we may rely on, or their failure to provide us with an adequate supply of their products or services on a timely basis, could adversely affect our business.

We currently have a single supplier for certain components that we use for our organ bioreactor control and acquisition systems as well as materials used in scaffolds. We may also rely on other single-source suppliers for critical components of our products in the future. If we were unable to acquire hardware or other products or services from applicable single-source suppliers, we could experience a delay in developing and manufacturing our products.

We use and generate hazardous materials in our business and must comply with environmental laws and regulations, which can be expensive.

Our research, development and manufacturing involve the controlled use of hazardous chemicals, and we may incur significant costs as a result of the need to comply with numerous laws and regulations. For example, certain volatile organic laboratory chemicals we use, such as fluorinated hydrocarbons, must be disposed of as hazardous waste. We are subject to laws and regulations enforced by the FDA, foreign health authorities and other regulatory requirements, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of our products, materials used to develop and manufacture our products, and resulting waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, our operations could be interrupted. Further, we could be held liable for any damages that result and any such liability could exceed our resources.

Our products are novel and will require market acceptance.

Even if we receive regulatory approvals for the commercial use of our products, their commercial success will depend upon acceptance by physicians, patients, third party payers such as health insurance companies and other members of the medical community. Market acceptance of our products is also dependent upon our ability to provide acceptable evidence and the perception of the positive characteristics of our products relative to existing or future treatment methods, including their safety, efficacy and/or other positive advantages. If our products fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. If our products receive only limited market acceptance, our business, financial condition and results of operations would be materially and adversely affected.

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

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

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

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments in the litigation. Securities analysts or investors may perceive these announcements to be negative, which could cause the market price of our stock to decline.

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

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

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

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

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

We expect that other products will compete with our current and future products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include obtaining marketing exclusivity under certain regulations, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage. Our competitors may develop or market products that are more effective or commercially attractive than our current or future products and may also develop competing relationships with our key collaborators. In addition, we may face competition from new entrants into the field. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. The effects of any such actions of our competitors may have a material adverse effect on our business, operating results and financial condition.

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

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

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

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

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

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

Risks Related To Our Separation From Harvard Bioscience

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

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

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

Under the tax sharing agreement between Harvard Bioscience and us, we would generally be required to indemnify Harvard Bioscience against any tax resulting from the Distribution to the extent that such tax resulted from (i) an acquisition of all or a portion of our stock or assets, whether by merger or otherwise, (ii) other actions or failures to act

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

We may have received better terms from unaffiliated third parties than the terms we received in our agreements with Harvard Bioscience.

The agreements related to the Separation, including the separation and distribution agreement, tax sharing agreement, transition services agreement and the other agreements, were negotiated in the context of the Separation while we were still part of Harvard Bioscience and, accordingly, may not reflect terms that would have resulted from arm's-length negotiations among unaffiliated third parties. The terms of the agreements we negotiated in the context of the Separation related to, among other things, allocation of assets, liabilities, rights, indemnifications and other obligations among Harvard Bioscience and us. We may have received better terms from third parties because third parties may have competed with each other to win our business. One of the members of our Board of Directors is also a member of the Harvard Bioscience Board of Directors.

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

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

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

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

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

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

- intellectual property, technology and business matters, including failure to make required technology transfers and failure to comply with non-compete provisions applicable to Harvard Bioscience and us;

- labor, tax, employee benefit, indemnification and other matters arising from the Separation;
- distribution and supply obligations;
- employee retention and recruiting;
- business combinations involving us;
- sales or distributions by Harvard Bioscience of all or any portion of its ownership interest in us; and
- business opportunities that may be attractive to both Harvard Bioscience and us.

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

Risks Relating To Our Common Stock

Substantial sales of common stock have and may continue to occur, or may be anticipated, which have and could continue to cause our stock price to decline.

We expect that we will seek to raise additional capital from time to time in the future, which may involve the issuance of additional shares of common stock, or securities convertible into common stock. Since our February 2015 public offering, the holders of the shares of Series B Convertible Preferred Stock issued in that offering have converted all such shares and have sold substantially all of the common stock they received upon such conversion. We believe that the effect of these conversions and sales contributed, at that time, to a decline in the price of our common stock. Further, we cannot predict the effect, if any, that any additional market sales of common stock, or anticipation of such sales (whether from the Distribution or otherwise), or the availability of those shares of common stock for sale will have on the market price of our common stock. Any future sales of significant amounts of our common stock, or the perception in the market that this will occur, may result in a decline in the price of our common stock.

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

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

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

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

- demand and pricing for our products;
- government or private healthcare reimbursement policies;

- adverse events or publicity related to our products, our research or investigations, or our collaborators or other partners;

- physician and patient acceptance of any of our current or future products;

- manufacturing stoppages or delays;

- introduction of competing products or technologies;

- our operating expenses which fluctuate due to growth of our business; and

- timing and size of any new product or technology acquisitions we may complete.

The market price of our shares may fluctuate widely.

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

- the success and costs of pre-clinical and clinical testing and obtaining regulatory approvals or clearances for our products;

- the success or failure of surgeries and procedures involving the use our products;

- a shift in our investor base;
- our quarterly or annual results of operations, or those of other companies in our industry;
- actual or anticipated fluctuations in our operating results due to factors related to our business;
- changes in accounting standards, policies, guidance, interpretations or principles;
- announcements by us or our competitors of significant acquisitions, dispositions or intellectual property developments or issuances;
- the failure to maintain our NASDAQ listing or failure of securities analysts to cover our common stock;
- changes in earnings estimates by securities analysts or our ability to meet those estimates;
- the operating and stock price performance of other comparable companies; our issuance of equity, debt or other financing instruments;
- overall market fluctuations; and
- general macroeconomic conditions.

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

Your percentage ownership will be diluted in the future.

Your percentage ownership will be diluted in the future because of equity awards that we expect will be granted to our directors, officers and employees, as well as shares of common stock, or securities convertible into common stock, we issue in connection with future capital raising or strategic transactions. Our 2013 Equity Incentive Plan provides for the grant of equity-based awards, including restricted stock, restricted stock units, stock options, stock appreciation rights and other equity-based awards to our directors, officers and other employees, advisors and consultants. In

addition, your percentage ownership will be diluted by our issuance of common stock following the exercise of options, or vesting of restricted stock units, we issued pertaining to the adjustment and conversion of outstanding Harvard Bioscience equity awards as a result of the Separation. The issuance of any shares of our stock would dilute the proportionate ownership and voting power of existing security holders.

Provisions of Delaware law, of our amended and restated charter and amended and restated bylaws and our Shareholder Rights Plan may make a takeover more difficult, which could cause our stock price to decline.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and in the Delaware corporate law may make it difficult and expensive for a third party to pursue a tender offer, change in control or takeover attempt, which is opposed by management and the Board of Directors. Public stockholders who might desire to participate in such a transaction may not have an opportunity to do so. Our Board of Directors has adopted a Shareholder Rights Plan that could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, our company or a large block of our common stock. A third party that acquires 20% or more of our common stock could suffer substantial dilution of its ownership interest under the terms of the Shareholder Rights Plan through the issuance of common stock to all stockholders other than the acquiring person. We also have a staggered Board of Directors that makes it difficult for stockholders to change the composition of the Board of Directors in any one year. Any removal of directors will require a super-majority vote of the holders of at least 75% of the outstanding shares entitled to be cast on the election of directors which may discourage a third party from making a tender offer or otherwise attempting to obtain control of us. These anti-takeover provisions could substantially impede the ability of public stockholders to change our management and Board of Directors. Such provisions may also limit the price that investors might be willing to pay for shares of our common stock in the future.

Any issuance of preferred stock in the future may dilute the rights of our common stockholders.

Our Board of Directors has the authority to issue up to 2,000,000 shares of preferred stock and to determine the price, privileges and other terms of these shares. Our Board of Directors is empowered to exercise this authority without any further approval of stockholders. The rights of the holders of common stock may be adversely affected by the rights of future holders of preferred stock.

We have in the past issued, and in addition to the Series C Preferred Stock we will issue in this offering, we may at any time in the future issue, additional shares of authorized preferred stock. For example, in connection with our February 2015 public offering, we issued 695,857 shares of Series B Convertible Preferred Stock and each preferred share was subsequently converted into 5 shares of our common stock.

We do not intend to pay cash dividends on our common stock.

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

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

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

If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. If we avail ourselves of certain exemptions from various reporting requirements, our reduced disclosure may make it more difficult for investors and securities analysts to evaluate us to a level acceptable by them and may result in less investor confidence.

We have received notices from NASDAQ of non-compliance with its continuing listing rules.

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 non-compliance 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.

The failure to meet continuing compliance standards subjects our common stock to a possible delisting. A delisting of our common stock would have an adverse effect on the market liquidity of our common stock and, as a result, the market price for our common stock could become more volatile. Further, a delisting also could make it more difficult for us to raise additional capital.

Risks Relating to This Offering

We have broad discretion to determine how to use the proceeds raised in this offering, and we may not use the proceeds effectively.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways with which you may not agree or that do not yield a favorable return. 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. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer immediate dilution in the net tangible book value of the common stock you purchase in this offering. Based on an assumed combined public offering price of $0.756 per share of common stock and warrant (the last reported sale price of our common stock on the NASDAQ Capital Market on February 2, 2017), and after deducting the placement agent fees and expenses and estimated offering expenses payable by us, you will experience immediate dilution of $0.34 per share of common stock, representing the difference between our net tangible book value per share as of September 30, 2016 after giving effect to this offering and the offering price. See the section entitled “Dilution” below for a more detailed discussion of the dilution you will incur if you purchase the common stock in this offering.

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

Since the price per share of our Series C Preferred Stock being offered is substantially higher than the net tangible book per share of our underlying common stock, you will suffer substantial dilution in the net tangible book value of the shares that you purchase in this offering. Based on an assumed combined public offering price of $0.756 per share of common stock and warrant (the last reported sale price of our common stock on the NASDAQ Capital Market on February 2, 2017), if you purchase Series C Preferred Stock in this offering, you will suffer immediate and substantial dilution of $0.34 per share in the net tangible book value of the shares of common stock underlying the Series C Preferred Stock. See the section entitled "Dilution" below for a more detailed discussion of the dilution you will incur if you purchase Series C Preferred Stock in this offering.

The issuance of additional equity securities may negatively impact the trading price of our common stock.

We have issued equity securities in the past, will issue equity securities in this offering and expect to continue to issue equity securities to finance our activities in the future. In addition, outstanding options and warrants to purchase our common stock may be exercised and additional options and warrants may be issued, resulting in the issuance of additional shares of common stock. The issuance by us of additional equity securities, including the shares of common stock issuable upon exercise of the warrants issued by us in this offering, would result in dilution to our stockholders, and even the perception that such an issuance may occur could have a negative impact on the trading price of our common stock.

There is no public market for the warrants to purchase shares of our common stock being offered by us in this offering.

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any national securities exchange or other nationally recognized trading system, including the NASDAQ Capital Market. Without an active market, the liquidity of the warrants will be limited.

The warrants are speculative in nature.

The warrants do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of $ per share, subject to certain adjustments, prior to five years from the date on which such warrants were issued, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants, if any, is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their imputed offering price. The warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

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

In this offering, we will sell up to 7,936,508 shares of common stock and shares of Series C Preferred Stock convertible into up to 2,645,503 shares of common stock, collectively representing approximately 61.8% of our outstanding common stock as of February 1, 2017. This sale and any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of those shares of common stock or the availability of those shares of common stock for sale will have on the market price of our common stock.

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

As of February 1, 2017, there were 17,116,570 shares of common stock outstanding. In addition, shares of common stock will be issuable upon conversion of our Series C Preferred Stock. The issuance of any such shares of common stock would substantially dilute the proportionate ownership and voting power of existing security holders, and their issuance, or the possibility of their issuance, may depress the market price of our common stock.

There is no public market for the Series C Preferred Stock being offered by us in this offering.

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

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

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

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

Neither our amended and restated certificate of incorporation nor the Certificate of Designation for the Series C Preferred Stock prohibits us from issuing additional series of preferred stock that would rank senior or equally to the Series C Preferred Stock as to dividend payments and liquidation preference. Our amended and restated certificate of

incorporation provides that we have the authority to issue up to 2,000,000 shares of preferred stock. The issuances of other series of preferred stock could have the effect of reducing the amounts available to the Series C Preferred Stock in the event of our liquidation, winding-up or dissolution. It may also reduce cash dividend payments on the Series C Preferred Stock if we do not have sufficient funds to pay dividends on all Series C Preferred Stock outstanding and outstanding parity preferred stock.

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

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

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

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

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus (including any related prospectus supplement or free writing prospectus) 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," "optim "strategy," "potential," "is likely," "will," "expect," "plan" "project," "permit" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" in our SEC filings, and under the caption "Risk Factors" in this prospectus.

You should read this prospectus and any related prospectus supplement and free writing prospectus 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

We estimate the net proceeds from this offering will be approximately $6.8 million, after deducting placement agent fees and expenses and our estimated offering expenses, and based on the assumed combined public offering price of $0.756 per share of common stock and warrant (the last reported sale price of our common stock on the NASDAQ Capital Market on February 2, 2017) and excluding the proceeds, if any, from the exercise of the warrants issued pursuant to this offering.

A $0.25 increase (decrease) in the assumed combined public offering price of $0.756 per share of common stock and warrant would increase (decrease) the net proceeds to us from this offering by approximately $2.4 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated placement agent fees and expenses and estimated offering expenses payable by us.

Similarly, a one million share increase (decrease) in the number of shares of common stock and in the number of warrants offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us by $0.7 million, assuming the assumed combined public offering price of $0.756 per share of common stock and warrant remains the same, and after deducting estimated placement agent fees and expenses and estimated offering expenses payable by us.

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.

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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 February 2, 2017)	$ 0.95	$ 0.73
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 February 2, 2017 was $0.756 per share. Immediately prior to this offering, we had 17,116,570 shares of common stock outstanding, which were held by approximately 180 stockholders of record as of February 1, 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, Series C Preferred Stock, or both, in this offering, assuming conversion of the Series C Preferred Stock into shares of our common stock, your interest will be diluted to the extent of the difference between the public offering price per share and the net tangible book value per share of our common stock after this offering.

The net tangible book value of our common stock on September 30, 2016 was approximately $4.8 million, or approximately $0.28 per share, based on 17,108,968 shares of our common stock outstanding as of September 30, 2016. 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 new 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.

After giving effect to the sale of 7,936,508 shares of common stock by us at an assumed combined public offering price of $0.756 per share of common stock and warrant (the last reported sale price of our common stock on the NASDAQ Capital Market on February 2, 2017), assuming that all 2,000 shares of Series C Preferred Stock are converted into shares of common stock and after deducting placement agent fees and expenses and estimated offering expenses, our pro forma net tangible book value as of September 30, 2016 would have been approximately $11.6 million, or $0.42 per share of common stock, which excludes the warrants to purchase 10,582,011 shares of our common stock to be issued to investors in this offering. This represents an immediate increase in net tangible book value of $0.14 per share of common stock to existing stockholders and immediate dilution of $0.34 per share of common stock to investors purchasing our common stock in this offering at the assumed public offering price. The following table illustrates this dilution on a per share basis:

Assumed combined public offering price per share of common stock and warrant		$ 0.756
Net tangible book value per share as of September 30, 2016	$ 0.28	
Increase in net tangible book value per share attributable to this offering	$ 0.14	
Pro forma net tangible book value per share as of September 30, 2016 after giving effect to this offering		$ 0.42
Dilution per share of common stock to the new investors in this offering		$ 0.34

A $0.25 increase or decrease in the assumed public offering price of $0.756 per share of common stock and warrant would increase or decrease our pro forma net tangible book value after this offering by approximately $2.4 million, or $0.09 per share of common stock, and increase or decrease net tangible book value per share of common stock to existing investors by approximately $0.09 and increase or decrease dilution per share to new investors by approximately $0.16, assuming that the number of shares offered by us, as set forth on the cover page of this

prospectus, remains the same and after deducting the estimated placement agent fees and expenses and estimated offering expenses payable by us.

Similarly, a one million share increase (decrease) in the number of shares and the number of warrants offered by us, as set forth on the cover page of this prospectus, would increase or decrease our pro forma net tangible book value after this offering by $0.7 million, or $0.01 per share of common stock, and increase or decrease the dilution per share to new investors by approximately $0.01 per share, assuming the assumed combined public offering price of $0.756 per share of common stock and warrant remains the same, and after deducting estimated placement agent fees and expenses and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares of common stock, Series C Preferred Stock and warrants that we offer in this offering, and other terms of this offering determined at pricing.

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 September 30, 2016 and assumes that no shares of Series C Preferred Stock will be sold in the offering, but does not include, as of such date:

- 3,879,033 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 outstanding warrants to purchase shares of our common stock;
- 2,035,775 shares available for future grants under our 2013 Equity Incentive Plan and our Employee Stock Purchase Plan;
- 10,582,011 shares of common stock issuable upon the exercise of warrants to be issued to investors in this offering at an exercise price of $ per share; and
- 529,101 shares of common stock issuable upon exercise of warrants to be issued to the placement agent as described in “Plan of Distribution.”

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.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

AND RESULTS OF OPERATIONS

The following management's discussion and analysis should be read in conjunction with our historical financial statements and the related notes included in this prospectus. Management's discussion and analysis contains forward-looking statements that involve risks and uncertainties, including those we detail under "Risk Factors," "Note Regarding Forward-Looking Statements" and elsewhere in this prospectus, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this prospectus. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this prospectus.

Overview

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

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

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

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

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

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

In June 2016, we submitted our application with the U.S. Food and Drug Administration, or the FDA, seeking orphan drug designation for our Cellspan Esophageal Implants. Orphan drug status would provide market exclusivity in the U.S. for seven years from the date of the product's approval for marketing. This exclusivity is in addition to any exclusivity we may obtain due to our patents. Additionally, orphan designation provides certain incentives, including tax credits and a waiver of the Biologics License Application fee. We also intend to apply for orphan drug designation for our Cellspan esophageal implant in Europe in the near term. Orphan drug status in Europe provides market exclusivity there for ten years from the date of the product's approval for marketing. 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.

We are conducting Good Laboratory Practice (GLP) studies to demonstrate that our technology, personnel, systems and practices are sufficient for advancing into clinical trials. GLP safety studies are required to advance to an Investigational New Drug (IND) application with the FDA, which would seek approval to initiate clinical trials for Biostage Cellspan esophageal implants in humans.

In October 2016, we announced a regulatory update following our planned pre-Investigational New Drug, or pre-IND, meeting with the FDA, for the advancement of our lead product candidate, Cellspan Esophageal Implant, into human clinical studies. We expect to file an IND application with the FDA in the third quarter of 2017 based on our election to extend the duration of our ongoing GLP animal studies following the feedback provided by the FDA.

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

On May 12, 2016, we issued 150,000 shares of common stock under the common stock purchase agreement with Aspire Capital Fund, LLC (the "Aspire Purchase Agreement") in exchange for gross proceeds of $371,000, or $349,000 net of issuance costs. On May 17, 2016, we terminated the Aspire Purchase Agreement. The Aspire Purchase Agreement was terminated without any penalty or cost to us.

On May 19, 2016, we closed on a Securities Purchase Agreement (the "Purchase Agreement") for the sale of 2,836,880 shares of our common stock at a purchase price of $1.7625 per share and the issuance of warrants to purchase 1,418,440 shares of common stock at an exercise price of $1.7625 per warrant for gross proceeds of $5.0 million. Additionally, we issued to the placement agent warrants to purchase 141,844 shares of common stock to the placement agent for the offering at an exercise price of $1.7625 per warrant. The warrants are initially exercisable commencing November 19, 2016 through their expiration date of May 19, 2021.

We have incurred substantial operating losses since our inception, and as of September 30, 2016, we had an accumulated deficit of approximately $33.0 million. We expect to continue to incur operating losses and negative cash flows from operations for the foreseeable future. We believe that our cash on hand at September 30, 2016 will be sufficient to meet our obligations through early 2017. Therefore, these conditions raise substantial doubt about our ability to continue as a going concern.

We will need to raise additional funds in future periods to fund our operations. In the event that we do not raise additional capital from outside sources in the near future, we may be forced to curtail or cease our operations. Cash requirements and cash resource needs will vary significantly depending upon the timing and the financial and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products

as well as regulatory efforts and collaborative arrangements necessary for our products that are currently under development. We will seek to raise necessary funds through a combination of publicly or private equity offerings, debt financings, other financing mechanisms, or strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all.

Results of Operations

Components of Operating Loss

Research and development expense. Research and development expense consists of salaries and related expenses, including stock-based compensation, for personnel and contracted consultants and various materials and other costs to develop our new products, primarily: synthetic organ scaffolds, including investigation and development of materials and investigation and optimization of cellularization, and 3D organ bioreactors. Other research and development expenses include the costs of outside service providers and material costs for prototype and test units and outside laboratories and testing facilities performing cell growth and materials experiments, as well as the costs of all other pre-clinical research and testing including animal studies and expenses related to potential patents. We expense research and development costs as incurred.

Selling, general and administrative expense. Selling, general and administrative expense consists primarily of salaries and other related expenses, including stock-based compensation, for personnel in executive, accounting, information technology and human resources roles. Other costs include professional fees for legal and accounting services, insurance, investor relations and facility costs. Our sales and marketing expenses included salaries and related expenses, including stock-based compensation, for personnel performing sales, marketing, and business development roles through December 31, 2015. In 2016, we expect our sales and marketing expenses to be immaterial given our focus on research and development and moving toward submission of an Investigational New Drug application, or IND.

Changes in fair value of warrant liability, net of issuance costs. Changes in fair value of warrant liability, net of issuance costs, represent the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period and in subsequent quarterly periods, the change in the fair value of common stock warrants from the date of between each reporting period until the liability is settled. We use the Black-Scholes pricing model to value the related warrant liability. The costs associated with the issuance of the warrants have been recorded as an expense upon issuance.

Comparison of the three months ended September 30, 2016 to the three months ended September 30, 2015

Research and Development Expense

Research and development expense increased $0.9 million, to $2.2 million or 75.3% for the three months ended September 30, 2016 compared to $1.3 million for the three months ended September 30, 2015. The increase was primarily due to increased spending on pre-clinical studies of $0.5 million, outsourced laboratory services of $0.1 million and payroll-related and other expenses totaling $0.3 million.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased $0.1 million, or 10.1% to $0.9 million for the three months ended September 30, 2016 compared with $1.0 million for the three months ended September 30, 2015, primarily due to lower sales and marketing compensation costs.

Change in fair value of warrant liability, net of issuance costs

The fair value of the warrant liability decreased $0.1 million for the three months ended September 30, 2016 compared to its fair value at June 30, 2016.

Comparison of the nine months ended September 30, 2016 to the nine months ended September 30, 2015

Research and Development Expense

Research and development expense increased $1.8 million, to $5.3 million, or 50.7%, for the nine months ended September 30, 2016 compared to $3.5 million for the nine months ended September 30, 2015. The increase was primarily due to increased spending on pre-clinical studies of $1.0 million, laboratory services and consulting of $0.3 million, $0.1 million for laboratory supplies and $0.4 million of other research and development expenses.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased $2.7 million, or 45.3% to $3.3 million for the nine months ended September 30, 2016 compared with $6.0 million for the nine months ended September 30, 2015. The decrease was due to a $2.6 million decrease in stock-based compensation costs, related primarily to the departure of our former Chairman and CEO in April 2015.

Change in fair value of warrant liability, net of issuance costs

The fair value of the warrant liability decreased $0.4 million, or $0.3 million net of issuance costs of $0.1 million, for the nine months ended September 30, 2016, after being initially recorded at $1.3 million in connection with our sale of securities in May 2016.

Comparison of the Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Revenues

Revenues increased $25 thousand, or 27%, to $0.12 million for the year ended December 31, 2015 compared with the year ended December 31, 2014. Revenues represent the sale of research bioreactor equipment through our distributor, Harvard Bioscience, to end users working on organ regeneration research.

Cost of revenues

Cost of revenues increased $91 thousand, or 190%, to $0.14 million for the year ended December 31, 2015 compared with the year ended December 31, 2014 due to the provision of a $80 thousand reserve on research bioreactor inventories. Cost of revenues includes labor, materials and allocated overhead for our research bioreactor equipment.

Research and Development Expense

Research and development expense decreased $0.3 million, or 7%, to $4.8 million for the year ended December 31, 2015 compared with $5.1 million for the year ended December 31, 2014. A $0.4 million increase in pre-clinical studies costs in 2015 was more than offset by a $0.3 million decrease in payroll and stock-based compensation, a $0.2 million decrease in research spending at our foreign subsidiaries and a $0.2 million decrease in recruiting costs.

Sales and Marketing Expense

Sales and marketing expense decreased approximately $40 thousand, or 12%, to $289 thousand for the year ended December 31, 2015 compared with $329 thousand for the year ended December 31, 2014. The decrease was primarily due to lower stock-based compensation costs.

General and Administrative Expense

General and administrative expense increased $1.0 million, or 17%, to $6.6 million for the year ended December 31, 2015 compared with $5.7 million for the year ended December 31, 2014. The $1.0 million increase was principally due to a $1.4 million increase in stock-based compensation, primarily related to the resignation of the company's former CEO. This was partially offset by decreases in payroll-related costs of $0.3 million and legal costs of $0.1 million.

Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of September 30, 2016, we had an accumulated deficit of approximately $33.0 million. We are currently investing significant resources in the development and commercialization of our products for use by clinicians and researchers in the field of regenerative medicine. As a result, we expect to incur operating losses and negative operating cash flow for the foreseeable future.

We believe that our cash at September 30, 2016 will be sufficient to meet our obligations into early 2017.

We will need to raise additional funds in future periods to fund our operations. Cash requirements and cash resource needs will vary significantly depending upon the timing and the financial and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for our products that are currently under development. We will seek to raise necessary funds through a combination of public or private equity offerings, debt financings, other financing mechanisms, or strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all.

Operating activities. Net cash used in operating activities of $6.1 million for the nine months ended September 30, 2016 was primarily a result of our $8.2 million net loss offset by $1.0 million of cash provided by working capital and $1.1 million add-back of non-cash expenses of stock-based compensation and depreciation, net of a favorable change in the fair value of warrant liability.

Net cash used in operating activities of $5.6 million for the nine months ended September 30, 2015 reflected our $9.4 million net loss and $0.1 million of cash used for working capital offset by a $3.6 million add-back of non-cash stock-based compensation expense and a $0.3 million add-back for depreciation.

Net cash used in operating activities of $7.2 million for the year ended December 31, 2015 was primarily a result of our $11.7 million net loss, offset by a $4.4 million add-back of non-cash expenses of stock-based compensation and depreciation.

Net cash used in operating activities of $8.0 million for the year ended December 31, 2014 was primarily a result of our $11.0 million net loss, offset by a $2.9 million add-back of non-cash expenses of stock-based compensation and depreciation.

Investing activities. Net cash used in investing activities during each of the nine month periods ended September 30, 2016 and 2015 of $0.2 million reflects cash used for additions to property, plant and equipment.

Net cash used in investing activities for the years ended December 31, 2015 and 2014 totaled $0.2 million and $1.2 million, respectively, and represented additions to property, plant and equipment.

Financing activities. Net cash generated from financing activities during the nine months ended September 30, 2016 of $5.0 million consisted of the net proceeds in the amount of $4.5 million from the issuance of 2,836,880 shares of

the Company's common stock at a purchase price of $1.7625 per share and the issuance of warrants to purchase 1,418,440 shares of common stock at an exercise price of $1.7625 per warrant, as well as net proceeds in the amount of $0.4 million from the issuance of 150,000 shares of common stock under the Aspire Purchase Agreement.

Net cash generated from financing activities during the nine months ended September 30, 2015 of $8.7 million consisted of the net proceeds from the issuance of convertible preferred stock and shares of our common stock.

Cash generated from financing activities of $9.6 million for the year ended December 31, 2015 reflected $4.2 million of net proceeds from the issuance of common stock and $5.4 million in net proceeds from the issuance of convertible preferred stock. All convertible preferred stock issued during 2015 was converted into common stock by December 31, 2015.

Cash generated from financing activities of $0.4 million for the year ended December 31, 2014 was the result of the exercise of employee stock options.

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, " *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,"* to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. This update is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company has adopted ASU 2014-15 and its adoption did not have a significant impact on the Company's consolidated financial statements or related disclosures.

In February 2016, the FASB, issued ASU, 2016-02- *Leases (Topic 842)*. The ASU requires companies to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will be effective for the Company in the first quarter of 2019, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on the Company's consolidated financial statements or related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Stock Compensation - Improvements to Employee Share-Based Payment Accounting,* ("ASU 2016-09"), which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and policy elections on the impact for forfeitures. ASU 2016-09 is effective for fiscal years beginning after December 15, 2017 and interim periods within annual periods beginning after December 15, 2018. The Company has not adopted ASU 2016-09 and does not expect the adoption to have a significant impact on the Company's consolidated financial statements or related disclosures.

In November 2016, the FASB issued ASU 2016-18 *Statement of Cash Flows*, which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company is in the process of evaluating the impact of ASU 2016-17 on its financial statements.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations,* which clarifies the definition of a business and provides a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017. The Company does not expect the impact of ASU 2017-01 to have an impact on its financial statements.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with Generally Accepted Accounting Principles in the United States ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We believe the following policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Share-based Compensation

We account for our share-based compensation in accordance with the fair value recognition provisions of current authoritative guidance. Share-based awards, including stock options, are measured at fair value as of the grant date and recognized as expense over the requisite service period (generally the vesting period), which we have elected to amortize on a straight-line basis. Expense on share-based awards for which vesting is performance or milestone based is recognized on a straight-line basis from the date when we determine the achievement of the milestone is probable to the vesting/ milestone achievement date. Since share-based compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. We estimate forfeitures at the time of grant and revise our estimate, if necessary, in subsequent periods. We estimate the fair value of options granted using the Black-Scholes option valuation model. Significant judgment is required in determining the proper assumptions used in these models. The assumptions used include the risk-free interest rate, expected term, expected volatility and expected dividend yield. We base our assumptions on historical data when available or when not available, on a peer group of companies. However, these assumptions consist of estimates of future market conditions, which are inherently uncertain and subject to our judgment, and therefore any changes in assumptions could significantly impact the future grant date fair value of share-based awards

Warrant Accounting

The Company classifies a warrant to purchase shares of its common stock as a liability on its consolidated balance sheets as this warrant is a free-standing financial instrument that may require the Company to transfer consideration upon exercise. The warrant was initially recorded at fair value on date of grant using the Black-Scholes model and net of issuance costs, and it is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

Off - Balance Sheet Arrangements

We do not have any off - balance sheet arrangements.

Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

BUSINESS

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 Cellspan ™ esophageal implants 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 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 pre-clinical 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. Therefore, no synthetic material remained in the animals after the esophageal tube was reconstituted. Within 2.5 to 3 months, a complete inner epithelium layer and other specialized esophagus tissue layers were regenerated. As of February 1, 2017, two animals in the study have not been sacrificed and are alive at ten and eleven months, 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 safety 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.

Our Mission and Our Strategy

Our mission is to be the leading developer and supplier of bioengineered organ implants for restoring organ function for patients with life-threatening conditions of the esophagus, the bronchus and the trachea. Our business strategy to accomplish this mission includes:

Targeting life-threatening medical conditions. We are focused on creating products to help physicians treat life-threatening conditions like esophageal cancer, central lung cancer and damage to the trachea caused by cancer, trauma or infection. We are also developing products for the treatment of congenital abnormalities of the esophagus and the airways. We are not targeting less severe conditions that have reasonable existing treatment options. Solutions for life-threatening medical conditions present a favorable therapeutic index, or risk/benefit relationship, by providing the opportunity of a significant medical benefit for patients who have poor or no treatment alternatives. We believe that product candidates targeting life-threatening medical conditions may be eligible for review and approval by regulatory authorities under established expedited review programs, which may result in savings of time in the regulatory approval process. Also, we believe that products targeting life-threatening medical conditions may be more likely to receive favorable reimbursement compared with treatments for less critical medical conditions.

Developing products that have a relatively short time to market. Since the number of patients diagnosed with esophageal cancer in the U.S. each year is relatively small, we expect the number of patients that we would likely need to enroll in a clinical trial will also be relatively small. A small number of patients implies a relatively fast enrollment time and a less expensive clinical development program. Therefore, we expect to be able to conduct a clinical trial in a relatively short period of time compared to clinical trials in indications with larger patient populations. We intend to work closely with regulatory agencies and clinical experts to design and size the clinical studies appropriately based on the specific conditions our products are intended to treat.

Using our Cellframe technology as a platform to address multiple organs. We believe that pre-clinical data we have produced to date may suggest that our Cellframe technology is a novel and innovative approach to restoring organ function that may provide an ability to develop products that would address life-threatening conditions impacting organs like the esophagus, bronchus and trachea, and perhaps lower portions of the gastrointestinal (GI) tract. We believe that our Cellframe technology may allow physicians to treat certain life-threatening conditions in ways not currently possible, and in some combination, to save patients' lives, avoid or reduce complications experienced in the current standard of care, and improve the patients' quality of life, while at the same time reducing the overall cost of patient care to the healthcare system.

Supplying the finished organ implant to the surgeon. Our technology includes our proprietary organ bioreactor, as well as our proprietary biocompatible scaffold that is seeded with the patient's own cells. We believe there is considerable value in supplying the final cell-seeded scaffold implant to the surgeon so that the hospital and surgeon may focus solely on performing the implantation.

Collaborating with leading medical and research institutions. We have and will continue to collaborate with leading medical and research institutions. We have a co-development initiative with Mayo Clinic for regenerative medicine organ implant products for the esophagus and airways, and we are currently conducting large-animal studies with Mayo Clinic to develop our Cellframe technology. We are also collaborating with Connecticut Children's Medical Center on a co-development project to research regenerative medicine-based solutions to esophageal atresia. We believe the use of our product candidates by leading surgeons and institutions will increase the likelihood that other

surgeons and institutions will use our products.

Our Technology

Our Cellframe technology is comprised of our proprietary bioengineered organ scaffold seeded with the patient's own stem cells in our proprietary organ bioreactor prior to implantation. We believe that our Cellframe technology combines a highly-engineered, biocompatible scaffold and a robust population of cells that, by tapping into the stem cell niche of the surrounding native tissue after implantation, may potentially enable a tubular organ to remodel or regenerate tissue to close the gap created by a surgical resection of a portion of that organ. This unique combination of technologies, developed through our extensive testing performed during the last two years, may potentially provide solutions to life-threatening conditions for patients with unmet medical needs.

We believe that our new technology is unique, in that its mode of action appears to be different from other tissue engineering organ scaffold products developed previously, of which we are aware. Prior to our development of the Cellframe technology, our approach attempted to implant an organ scaffold that would be incorporated into the patient's body by the surrounding native tissue growing into the scaffold. To our knowledge, all previous research and development efforts by other investigators were based on that same concept. Our Cellframe technology appears to work very differently. We believe that the unique combination of our highly-engineered organ scaffold with a population of the patient's own mesenchymal stem cells enables an organ to develop new native tissue around our scaffold, but not into it, so the scaffold acts as a type of frame or staging for the new tissue. As a result, our scaffold is not incorporated into the body. Instead, it is retrieved from the body via an endoscopic or bronchoscopic procedure, not surgically, after sufficient tissue remodeling and regeneration has occurred to restore the organ's integrity and function.

A Cellframe technology-based organ implant includes two key components: a biocompatible synthetic scaffold and the patient's own stem cells.

Biocompatible Scaffold Component

Our proprietary biocompatible scaffold component of the Cellspan esophageal implant is constructed primarily of polyurethane (PU; a plastic polymer). This material was chosen based on extensive testing of various materials. The scaffold is made using a manufacturing process known as electrospinning. The combination of the electrospinning process, which provides control over the desired microstructure of the scaffold fabric, with the PU results in a scaffold that we believe has favorable biocompatibility characteristics.

The Patient's Cells

Based on current pre-clinical development efforts, the cells we seed onto the scaffold are obtained from the patient's adipose tissue (abdominal fat). This fat tissue is obtained from a standard biopsy before the implant surgery. Mesenchymal stem cells are extracted and isolated from the adipose tissue biopsy. The isolated cells are then expanded, or grown, for a short period prior to surgery in order to derive a sufficient cell population to be seeded on the scaffold. The cells are then seeded on the scaffold in our proprietary organ bioreactor and incubated there before the implant surgery.

We believe the Cellspan esophageal implant has the potential to provide a major advance over the current therapeutic options for treating esophageal cancer, damage from infection or trauma and congenital abnormalities. We believe our Cellframe technology has the potential to overcome the major challenges in restoring organ function for a damaged

esophagus. With our Cellspan esophageal implant we are developing a surgical procedure that has the objective of reconstituting the continuity of the patient's esophagus without having to relocate another organ in its place. In addition, by reducing or eliminating complications that occur in the current standard of care, we expect to reduce the costs of addressing and treating those additional complications. Because these substantial costs can be reduced or even eliminated with our technology, we believe our products, if successfully developed, can help save lives, improve the quality of life for patients and reduce overall healthcare costs.

Further, human embryonic stem cells are not part of any of our implant product candidates. This eliminates both the medical risks and ethical controversy associated with regenerative medicine approaches that use human embryonic stem cells.

Unmet Patient Needs and Cellspan Implant Solutions

Esophageal Cancer

There are approximately 456,000 new diagnoses of esophageal cancer globally each year, according to the World Health Organization's International Agency for Research on Cancer. According to the American Cancer Society, there are approximately 17,000 new diagnoses of esophageal cancer in the U.S. each year, and there are more than 15,000 deaths from esophageal cancer each year. Esophageal cancer is very deadly - the five-year survival rate for people with esophageal cancer is 18% in the U.S. Approximately 5,000 esophagectomy surgeries occur in the U.S. annually to treat esophageal cancer, and approximately 10,000 esophagectomies occur in Europe annually. We believe that our Cellspan esophageal implant, if approved, has the potential to provide a major advance over the current esophagectomy procedures for addressing esophageal cancer, which have high complication and morbidity rates.

The current standard of care for the esophagectomy requires either (A) a gastric pull-up, where the stomach is cut and sutured into a tubular shape, then pulled up through the diaphragm to replace a portion of the esophagus resected by the removal of the cancerous tumor; or (B) a colon interposition, where a portion of the colon is resected and used to replace the portion of the esophagus resected by the removal of the cancerous tumor. Esophagectomies have 90-day mortality rates of up to 19%. Serious complications, such as leakage at the anastomoses, which can lead to infections and sepsis, and pulmonary complications, such as impaired pulmonary function or pneumonia, occur in up to 30% of esophagectomy cases. Other complications from esophagectomies, such as a narrowing of the esophagus post-surgery, gastroesophageal reflux and dumping syndrome (repetitive nausea, dizziness and vomiting) can also pose significant quality of life issues for patients.

We believe that the Cellspan esophageal implant has the potential to provide physicians a new, simpler procedure to restore organ function while significantly reducing complication and morbidity rates compared with the current standard of care, and without creating significant quality of life issues for patients.

Esophageal Atresia

Esophageal Atresia (EA) is a rare congenital abnormality in which a baby is born without part of the esophagus. About 1 in 4,000 babies in the U.S. is born with EA. In some cases, the two sections can be connected surgically. However, in cases where the gap is too great for a simple surgical reconnection, the current standard of care is a gastric pull-up, a colon interposition, or a procedure known as the Foker process. In the Foker process, traction devices are surgically attached to the two ends of the esophagus. Traction is then applied, usually for several weeks during which time the baby remains in an Intensive Care Unit, to stimulate the ends of the esophagus to grow and narrow the gap. If the Foker process is successful in narrowing the gap sufficiently, a second surgery is necessary to connect the two ends of the esophagus. In addition to the Foker process being complex, it is also a very expensive procedure, because the baby will normally be several months in hospital for the process.

We believe that a pediatric Cellspan esophageal implant may provide pediatric surgeons with a better procedure to treat EA that would result in a connected esophagus with higher success rates, lower complications and lower overall costs to the healthcare system.

Central Lung Cancer

Lung cancer is the most common form of cancer and the most common cause of death from cancer worldwide. There are more than 450,000 new lung cancer diagnoses annually in the U.S. and Europe. In approximately 25% of all lung cancer cases, the cancerous tumor resides only in a bronchus and not in the lobes of the lungs, and is known as central

lung cancer. Approximately 33,000 central lung cancer cases diagnosed in the U.S. and Europe are Stage I and II and are considered eligible for surgical resection, often with adjuvant chemotherapy and radiation. Approximately 5,000 of those patients are treated via pneumonectomy, a surgical procedure involving the resection of the cancer tumor, the whole bronchus below the tumor and the entire lung to which it is connected. It is a complex surgery and, due to the removal of a lung, results in a 50% reduction in the patient's respiratory capacity. The procedure has reported rates of post-surgical (in hospital) mortality of 8% to 15%. Complication rates associated with pneumonectomy are reported as high as 50%, and include post-operative pneumonia, supraventricular arrhythmias and anastomotic leakage, placing patients at significant mortality risk post-discharge.

We believe that a Cellspan bronchial implant, once developed and approved for marketing, has the potential to provide physicians a treatment alternative superior to the sleeve pneumonectomy to address central lung cancer, a simpler procedure to restore organ function of the bronchus without sacrificing one of the patient's lungs, resulting in fewer post-surgery complications, improved mortality rates and improved quality of life for the patient.

Life-threatening conditions of the Trachea

There are approximately 8,000 patients per year in the U.S. and Europe who suffer from a condition of the trachea that put the patient at high risk of death. These conditions can be due to tracheal trauma, tracheal stenosis or trachea cancer. There are approximately 40,000 tracheal trauma patients diagnosed each year in the U.S. Of those, approximately 1,000 are severe enough to need surgical resection procedures. Tracheal stenosis is a rare complication from tracheostomies, but may have a devastating impact on respiratory function for patients. Approximately 2,000 patients are diagnosed with stenosis from tracheostomy in the U.S. each year. Trachea cancer is a very rare but extremely deadly cancer. Trachea cancer patients in the U.S. have a median survival of 10 months from diagnosis and a 5-year survival of only 27%. There were approximately 200 cases of primary trachea cancer diagnosed in the U.S. in 2013. Based on these facts, we estimate that there are approximately 8,000 patients in the U.S. and Europe with conditions of the trachea that put them at high risk of death, but for whom there is currently no clinically effective tracheal implant or replacement method currently available.

We believe that a Cellspan tracheal implant may potentially provide physicians a treatment to re-establish the structural integrity and function of a damaged or diseased trachea to address life-threatening conditions due tracheal trauma, stenosis or cancer.

Our History

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. Harvard Bioscience has been designing and manufacturing devices for life science researchers for over 100 years. Harvard Bioscience first explored the regenerative medicine market in 2007 and began focusing on providing devices to scientists involved in regenerative medicine research in 2008. Since early 2009, Harvard Bioscience's regenerative medicine business initiative operated as a division of Harvard Bioscience. During this first phase of development of our company, the business was built on the basis of Harvard Bioscience's expertise in physiology and applying that know-how to developing new organ bioreactors and other equipment to be used in regenerative medicine researchers' laboratories.

Harvard Bioscience decided to separate its regenerative medicine business into our company, a separate corporate entity (the "Separation"), and it spun off its interest in our business to its stockholders in November 2013. Since the Separation we have been a separately-traded public company and Harvard Bioscience has not been a stockholder of our common stock or controlled our operations. Following the Separation, we continued to innovate our bioreactors based on our physiology expertise, we developed our materials science capabilities and we investigated and developed a synthetic tracheal scaffold. In April 2014, our first Chief Medical Officer, Saverio LaFrancesca, M.D., joined our company. By that time we had built and staffed cell biology laboratories at our Holliston facility, to give ourselves the ability to perform and control our scientific investigation and developments internally. At that point, we began the second phase of our company's development.

In mid-2014, under Dr. LaFrancesca's leadership, we increased the pace of our scientifically-based internal analysis and development of our first-generation tracheal implant product, the HART-Trachea. From large-animal studies conducted thereafter we found that the product elicited an unfavorable inflammatory response after implantation, which required additional development and testing. These requirements extended our expectations regarding our regulatory milestones and we announced the additional testing and extended milestone expectations in January 2015. During 2015 we isolated and tested all major variables of the organ scaffold and the cell source and protocols, examining the effects of alternatives against the then-existing product approach. Through extensive *in vitro* pre-clinical studies, and small-animal and large-animal studies, we made dramatic improvements, and discovered that the mechanism of action of this new approach was very different from our hypothesis regarding that of the first-generation product. We call this new implant approach our Cellframe technology. Our Cellframe technology uses a different scaffold material and microstructure, a different source and concentration of the patient's cells and several other changes from our earlier trachea initiative. We believe that our Cellframe technology, although built on learnings from our earlier-generation product initiative, represents a new technology platform resulting from our

rigorous science and development. We see the development of our Cellframe technology platform as the beginning of a new, third phase in our company’s progression.

Leading up to the time of the Separation, we engaged in activities with a surgeon, Dr. Paolo Macchiarini, then employed by the Karolinska Institutet in Sweden, one of the world's most respected medical institutions, and who was at that time considered to be a world-renowned regenerative medicine pioneer. We provided organ bioreactors and organ scaffolds to Dr. Macchiarini's laboratories to conduct cell biology research and in return Dr. Macchiarini was to provide us with scientific data to advance the development of our bioreactors and tracheal scaffold. We also provided bioreactors and tracheal scaffolds in support of several compassionate care human surgeries performed by Dr. Macchiarini. We collaborated with Dr. Macchiarini in an effort to advance our product research and development with the assistance of a highly-acclaimed researcher and a well-respected institution. Regarding compassionate use human surgeries, we relied on the due process that involved a team of physicians and the Institutional Review Boards of the institutions where the surgeries were performed. We developed no part of any clinical protocol in any manner. Further, all surgeries involving any of our products or product candidates were conducted under the compassionate use system governed by the rules and regulations of each institution. Dr. Macchiarini was not employed by or affiliated with our company, and we did not pay him any wages or consulting fees. In June 2014, shortly after our Chief Medical Officer joined our company we ceased support of any human surgeries with Dr. Macchiarini. In addition, in November 2014, we formally announced that we would no longer be supporting or providing products to the human surgeries being performed in Russia, based in part on our belief that, due to the design of the Russian hospital's study and the nature and extent of the follow-up medical data made available to us, additional surgeries in Russia would provide less meaningful product development data than the work being done in our U.S. research and pre-clinical programs at that time.

Since the time we withdrew from involvement with Dr. Macchiarini, his work has become the subject of at least two investigations by the Karolinska Institutet. Many of the claims Dr. Macchiarini made publicly and published in peer-reviewed articles in reputable medical journals about the post-surgery quality of life, or even the necessity, of certain of his compassionate care surgeries where he used either a HART bioreactor or a HART-Trachea scaffold, or both, have been called into question. We discontinued development of our HART-Trachea product initiative in 2014, and that first-generation product approach was significantly different from our new Cellframe technology and Cellspan product candidates currently in development. We have focused our development efforts on our Cellframe technology and Cellspan product candidates, which we have and will continue to develop internally, and with our collaborators, via a rigorous scientific development process. As a result, we believe that prior statements by Dr. Macchiarini or others regarding the patients whose surgeries utilized our HART bioreactor or HART-Trachea scaffold, or such products, are not pertinent to our Cellframe technology or Cellspan products, or their respective future development.

Clinical Trials

In order to market our product candidates, we will need to successfully complete clinical trials. The initial indication for which we intend to seek FDA approval will be to restore the function of the esophagus subsequent to esophageal damage due to cancer, injury or congenital abnormalities.

Because esophageal cancer affects only approximately 17,000 patients per year in the U.S. we anticipate that our clinical trials will involve relatively few patients. Therefore, once commenced, we expect to be able to conduct a clinical trial in a relatively short period of time compared to clinical trials in indications with larger patient populations. We intend to work closely with regulatory agencies and clinical experts to design and size the clinical studies appropriately based on the specific conditions our products are intended to treat. We also intend to request expedited review from the FDA for the Cellspan esophageal implant product. Receipt of expedited review would reduce the overall time through the regulatory approval process.

We intend to pursue regulatory approval for the Cellspan esophageal implant in the U.S., Canada and Europe initially. Following clinical trials in other foreign markets, we expect to pursue regulatory approval for the Cellspan esophageal implant in those foreign markets, as well.

Research and Development

Our primary research and development activities are focused in three areas: materials science, cell biology and engineering. In materials science, we focus on designing and testing biocompatible organ scaffolds, testing the structural integrity and the cellularization capacities of the scaffolds. In cell biology, we focus on developing and testing isolation and expansion protocols, cell characterization and fate studies, investigating the effects of various cell types and concentrations, evaluating the biocompatibility of scaffolds, experimenting with different cell seeding methodologies, and developing protocols for implantation experiments. Our engineering group supports the materials science and cell biology groups across an array of their activities, i.e. designing, engineering and making our proprietary organ bioreactors. All three of our R&D groups combine to plan and execute the in vitro studies. A fundamental part of our R&D effort in developing the Cellframe technology has been dedicated to the discovery and development of small and large animal model studies. The large-animal model employs the use of Yucatan mini-pigs. Our Cellspan scaffolds were implanted in the cervical portion as well as the thoracic portion of the esophagus and the airways in studies to date. As of December 31, 2016, we employed 14 full-time scientists and engineers and we also hire other consultants and part-time employees from time to time.

In addition to our in-house engineering and scientific development team, we collaborate with leaders in the field of regenerative medicine who are performing the fundamental research and surgeries in this field to develop and test new products that will advance and improve the procedures being performed. As these procedures become more common, we will work with our collaborators to further enhance our products to make them more efficient and easier to use by surgeons. In the U.S., our principal collaborations have been with Mayo Clinic and Connecticut Children's Medical center. Collaboration typically involves us developing new technologies specifically to address issues these researchers and clinicians face. In certain instances, we have entered into agreements that govern the ownership of the technologies developed in connection with these collaborations.

We incurred approximately $5.1 million and $4.8 million of research and development expenses in 2014 and 2015, respectively. As we have not yet applied for or received regulatory approval to market any clinical products and sales of our research bioreactor products have not been significant in relation to our operating costs, no significant amount of these research and development costs have been passed on to our customers.

Manufacturing

For our scaffolds we use a process called electrospinning to create the fabric part of the scaffold. Electrospinning is a well-known fabrication process. It is useful for cell culture applications as it can create extremely thin fibers (much thinner than a human hair) that can make a fabric with pores approximately the same size as a cell. The electrospinning process parameters can be tuned to create a structure that is very similar to the natural structure of the collagen fibers in human extracellular matrix. Our Cellspan scaffolds are made from polyurethane, an inert polymer that is not bioresorbable. However, we also perform studies on the use of scaffolds made from bioresorbable materials. While we do not manufacture the cells, as they will come from the patient's adipose tissue, for regulatory purposes we are responsible for the quality control of the cells and the seeding of the cells onto the scaffold in the bioreactor. For this we have, in collaboration with our partners, developed standard operating procedures for the seeding of cells on the scaffold. For U.S. clinical trials we anticipate that the seeding will be performed in an automated version of our bioreactor at a pre-qualified third-party contract manufacturer using current Good Manufacturing Procedures (cGMP) using our proprietary protocol and under the supervision of our staff.

For our scaffolds, our primary materials are medical-grade plastic resins and solvents used to liquefy the resins in our manufacturing process. These materials are readily available from a variety of suppliers and do not currently represent a large proportion of our total costs. For our bioreactors, we perform final assembly and testing of components that we buy from third parties like machine shops, parts distributors, molding facilities and printed circuit board manufacturers. These operations are performed primarily at our Holliston, MA headquarters.

Sales and Marketing

We expect that most surgeries using the Cellspan esophageal implant product will be performed at a relatively small number of major hospitals in the U.S., Canada and European countries that will establish themselves as specialized centers of excellence. We believe that a relatively small number of centers of excellence in each country would be able to treat a very large percentage of that country's patients annually, given the expected number of patients to be treated each year. So, we expect our markets to be served by a concentrated number of treatment centers. Further, our three Cellspan product candidates are for the esophagus, the bronchus and the trachea, three organs all treated by thoracic surgeons. Therefore, all three products, once approved, would be marketed primarily to physicians practicing in a single surgical specialty, so we expect that the total number of physicians using our products will be a much smaller population than if our products were to be used by physicians in multiple areas of surgical specialties. Due to our expectation of a population of physicians in one surgical specialty being the primary users of our products in a concentrated number of centers of excellence in each national market, we expect to be able to support our markets with a fairly small field sales force.

We expect to price the product commensurate with the medical value created for the patient and the costs avoided with the use of our product. We further expect to be paid by the hospital that buys the product from us. Finally, we expect that the hospital would seek reimbursement from payers for the entire transplant procedure, including the use of our products.

Harvard Bioscience is the exclusive distributor for the research versions of our organ bioreactors. Harvard Bioscience can only sell those products to the research markets in accordance with the terms of our distribution agreement. We retain all rights to manufacture and sell all our products for clinical use.

Intellectual Property and Related Agreements

We actively seek to protect our products and proprietary information by means of U.S. and foreign patents, trademarks and contractual arrangements. Our success will depend in part on our ability to obtain and enforce patents on our products, processes and technologies to preserve our trade secrets and other proprietary information and to avoid infringing on the patents or proprietary rights of others.

We have rights in the patent and the patent applications listed below. The patent or patents that may issue based on the patent applications are scheduled to expire as provided below:

Patent/Technology	Jurisdiction	Expiration
Patent application covering aspects of synthetic scaffolds and organ and tissue transplantation	U.S.	2032
Patent application relating to methods and compositions for producing elastic scaffolds for use in tissue engineering	U.S.	2033
Patent application relating to support configurations for tubular tissue scaffolds, and airway scaffold configurations	U.S., Europe	2033
Patent application relating to methods and compositions for promoting the structural integrity of scaffolds for tissue engineering	U.S.	2033
Issued Patent covering methods for analyzing engineered tissues	U.S.	2033
Patent application covering aspects of clinical scale bioreactors and tissue engineering	U.S., Europe	2030
Issued Patent covering aspects of liquid distribution in a rotating bioreactor	Germany	2031
Issued Patent covering aspects of liquid distribution in a rotating bioreactor	Germany	2021
Patent application covering aspects of liquid distribution in a rotating bioreactor	U.S.	2032
Patent application relating to bioreactors with supports to facilitate culturing organs	U.S.	2034
Patent application relating to bioreactor adaptors for tubular tissue scaffolds	U.S.	2034
Patent applications relating to engineered hybrid organs	U.S.	2034
	U.S.	2033

Patent applications relating to infrared-based methods for evaluating tissue health including methods for evaluating burns		
Patent applications relating to methods and compositions for esophageal repair	U.S.	2036

We also rely on unpatented proprietary technologies in the development and commercialization of our products. We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as those of our advisors, consultants and other contractors. To help protect our proprietary know-how that may not be patentable, and our inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require employees, consultants and advisors to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions that arise from their activities for us. Additionally, these confidentiality agreements require that our employees, consultants and advisors do not bring to us, or use without proper authorization, any third party’s proprietary technology.

Exclusive License Agreement and Sponsored Research Agreement - InBreath Bioreactor

We had an exclusive license agreement with Sara Mantero and Maria Adelaide Asnaghi to intellectual property rights relating to our InBreath Bioreactor. Under this agreement, we had worldwide rights to intellectual property (including patents, data, and know-how) relating to the hollow organ bioreactor, related techniques, and improvements thereof. We had exclusive worldwide rights to make, use and sell the hollow organ bioreactor, and the right to grant sublicenses and distribution rights. Under this agreement, we were obligated to pay the licensor royalties at various percentage rates in the low to mid-single digits pertaining to any applicable bioreactors we sell. This agreement terminated on August 6, 2016.

We have entered into a sponsored research agreement with Sara Mantero, Maria Adelaide Asnaghi, and the Department of Bioengineering of the Politecnico Di Milano, or PDM. Under the terms of this agreement, PDM is required to use its facilities and best efforts to conduct a research program relating to the development of bioreactors, clinical applications, and automated seeding processes. We are required to provide engineering support to PDM with respect to bioreactor designs. Intellectual property developed by PDM or its employees, including Dr. Mantero or Ms. Asnaghi, under this sponsored research agreement will be owned by Dr. Mantero or Ms. Asnaghi and covered by our exclusive license agreement described above. In addition, we have an option to an exclusive license for intellectual property relating to new technology that may not be covered by the exclusive license agreement. We will own any inventions and discoveries that we solely develop in connection with the research program and any inventions and discoveries that are jointly developed in connection with the research program will be owned jointly by the parties. The sponsored research agreement will continue until terminated by a party thereto upon 90 days prior written notice.

Sublicense Agreement with Harvard Bioscience

We entered into a sublicense agreement with Harvard Bioscience pursuant to which Harvard Bioscience granted us a perpetual, worldwide, royalty-free, exclusive, except as to Harvard Bioscience and its subsidiaries, license to use the mark “Harvard Apparatus” in the name Harvard Apparatus Regenerative Technology. The mark “Harvard Apparatus” is used under a license agreement between Harvard Bioscience and Harvard University, and we have agreed to be bound by such license agreement in accordance with our sublicense agreement. On March 31, 2016, we changed our name from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc. We currently have no affiliation with Harvard University.

Separation Agreements with Harvard Bioscience

On November 1, 2013, to effect the Separation, Harvard Bioscience distributed all of the shares of our common stock to the Harvard Bioscience stockholders (the “Distribution”). Prior to the Distribution Harvard Bioscience contributed the assets of its regenerative medicine business, and approximately $15 million in cash, to our company to fund our operations following the Distribution.

In connection with the Separation and immediately prior to the Distribution, we entered into a Separation and Distribution Agreement, Intellectual Property Matters Agreement, Product Distribution Agreement, Tax Sharing Agreement, Transition Services Agreement, and Sublicense Agreement with Harvard Bioscience to effect the Separation and Distribution and provide a framework for our relationship with Harvard Bioscience after the Separation. These agreements govern the current relationships among us and Harvard Bioscience and provided for the allocation among us and Harvard Bioscience of Harvard Bioscience’s assets, liabilities and obligations (including employee benefits and tax-related assets and liabilities) attributable to periods prior to the Separation.

Government Regulation

Any product that we may develop based on our Cellframe technology, and any other clinical products that we may develop, will be subject to considerable regulation by governments. We were in the past informed by the FDA that our previous-generation tracheal product candidate would be regulated under the Biologics License Application, or BLA, pathway in the U.S. and we were informed by the European Medicines Agency (EMA) that the previous generation tracheal product would be regulated under the Advanced Therapy Medicinal Products, or ATMP, pathway in the EU. On October 18, 2016, we also received written confirmation from FDA's Center for Biologics Evaluation and Research, or CBER, that FDA intends to regulate our Cellspan esophageal implant as a combination product under the primary jurisdiction of CBER. We further understand that CBER may choose to consult or collaborate with CDRH with respect to the characteristics of the synthetic scaffold component of our product based on CBER's determination of need for such assistance. Although our Cellframe technology differs in design and performance from the first generation product candidate, we expect that Cellframe-based products will be regulated by the FDA and EMA under the same pathways as the first generation tracheal product candidate. This expectation is based on the fact that the Cellframe technology is centered on the delivery of the patient's own cells seeded on an implanted synthetic scaffold in order to restore organ function and our belief that the cells provide the primary mode of action. Of course, it is possible that some of our current and future products may use alternative regulatory pathways.

Combination Product/Biologic

Government Regulation Combination Products/Biologics

We believe that products derived from our Cellframe technology may be defined as combination products consisting of two or more regulated components, a biologic and a medical device. In the U.S., a combination product usually is assigned by the FDA to one of the agency's centers, such as the Center for Biologics Evaluation and Research, or CBER, or the Center for Devices and Radiological Health, or CDRH, with the chosen center to take the lead in pre-marketing review and approval of the combination product. Other FDA centers also may review the product in regard to matters that are within their expertise. The FDA selects the lead center based on an assessment of the combination product's "primary mode of action." Some products also may require approval or clearance from more than one FDA center.

To determine which FDA center or centers will review a combination product submission, companies may submit a Request for Designation to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation. We believe that

regenerative medicine products containing cells will be reviewed by CBER, possibly with CBER's consultation with CDRH.

Domestic Regulation of Our Products and Business

The testing, manufacturing, and potential labeling, advertising, promotion, distribution, import and marketing of our products are subject to extensive regulation by governmental authorities in the U.S. and in other countries. In the U.S., the FDA, under the Public Health Service Act, the Federal Food, Drug and Cosmetic Act, and its implementing regulations, regulates biologics and medical device products.

The labeling, advertising, promotion, marketing and distribution of biopharmaceuticals, or biologics and medical devices also must be in compliance with the FDA and U.S. Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions and criminal prosecution. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. Further, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice.

The FDA has broad post-market and regulatory enforcement powers. Manufacturers of biologics and medical devices are subject to unannounced inspections by the FDA to determine compliance with applicable regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by manufacturers or their suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities. Potential FDA enforcement actions include:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- operating restrictions;
- refusal to grant export approval for our products; or
- criminal prosecution.

In addition, other government authorities influence the success of our business, including the availability of adequate reimbursement from third party payers, including government programs such as Medicare and Medicaid. Medicare and Medicaid reimbursement policies can also influence corresponding policies of private insurers and managed care providers, which can further affect our business.

Biologics Regulation

Biological products must satisfy the requirements of the Public Health Services Act and the Food, Drug and Cosmetics Act and their implementing regulations. In order for a biologic product to be legally marketed in the U.S., the product must have a BLA approved by the FDA.

The BLA Approval Process

The steps for obtaining FDA approval of a BLA to market a biopharmaceutical, or biologic product in the U.S. include:

- completion of pre-clinical laboratory tests, animal studies and formulation studies under the FDA's GLP regulations;
- submission to the FDA of an IND application, for human clinical testing, which must become effective before human clinical trials may begin and which must include Institutional Review Board, or IRB, approval at each clinical site before the trials may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices, or GCP, to establish the safety and efficacy of the product for each indication;

- submission to the FDA of a BLA, which contains detailed information about the chemistry, manufacturing and controls for the product, extensive pre-clinical information, reports of the outcomes of the clinical trials, and proposed labeling and packaging for the product;
- the FDA's acceptance of the BLA for filing;
- satisfactory review of the contents of the BLA by the FDA, including the satisfactory resolution of any questions raised during the review or by the advisory committee, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality and purity; and
- FDA approval of the BLA.

Pre-clinical studies include laboratory evaluations of product toxicity, as well as animal studies.

An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed.

Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to GCP. Adverse events must be reported and investigated in a timely manner. To conduct a clinical trial, a company is also required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. The sponsor, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to trial subjects outweigh the anticipated benefits. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each site at which the trial is conducted must approve the protocol and any amendments. If foreign clinical trials are intended to be considered by the FDA for approval of a product in the U.S. then those foreign clinical trials performed under an IND must meet the same requirements that apply to U.S. studies. The FDA will accept a foreign clinical trial not conducted under an IND only if the trial is well-designed, well-conducted, performed by qualified investigators in accordance with international principles for GCP, or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects. The FDA, however, has substantial discretion in deciding whether to accept data from foreign non-IND clinical trials.

Clinical trials involving biopharmaceutical products are typically conducted in three sequential phases. The phases may overlap or be combined. A fourth, or post-approval, phase may include additional clinical trials. These phases are described generally below. We note, however, that the exact number of study subjects required for each specific intended use, and our intent to combine or "telescope" various study phases together, are both areas where we will actively seek FDA feedback to streamline the clinical evaluation process. Briefly, the phases of clinical development generally include the following:

- Phase I. Phase I clinical trials involve the initial introduction of the product into human subjects to determine the adverse effects associated with increasing doses. Such Phase I studies frequently are highly abbreviated or combined with Phase II studies (as outlined below), when the product involves the patient's own cells.

- Phase II. Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the product for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Products that contain the patient's own cells frequently are studied for initial safety and effectiveness determinations in combined or "telescoped" Phase I/II clinical studies.

- Phase III. If the product is found to be potentially effective and to have an acceptable safety profile in Phase II (or sometimes Phase I) trials, the clinical trial program will be expanded to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites. As noted, the exact number of subjects needed, the duration of clinical follow-up, and the endpoints by which safety and efficacy are demonstrated are based on the condition being treated.

- Post-Approval (Phase IV). Post-approval clinical trials are may be required of or agreed to by a sponsor as a condition of, or subsequent to marketing approval. Further, if the FDA becomes aware of new safety information about an approved product, it is authorized to require post approval trials of the biological product. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as Phase III/IV post approval clinical trials. Failure to promptly conduct Phase IV clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

Clinical testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA or the sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request that additional pre-clinical studies or clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, IRBs have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues.

Certain information about clinical trials, including a description of the trial, participation criteria, location of trial sites, and contact information, is required to be sent to the National Institute of Health, or NIH for inclusion in a publicly-assessable database. Sponsors also are subject to certain state laws imposing requirements to make publicly available certain information on clinical trial results. In addition, the FDA Amendments Act of 2007 directs the FDA to issue regulations that will require sponsors to submit to the NIH the results of certain controlled clinical trials, other than Phase I studies.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical trials, together with other detailed information, including information on the chemistry, manufacture and composition of the product, are submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. In most cases, the BLA must be accompanied by a substantial user fee. The FDA will initially review the BLA for completeness before it accepts the BLA for filing. There can be no assurance that the submission will be accepted for filing or that the FDA may not issue a refusal-to-file, or RTF. If a RTF is issued, there is opportunity for dialogue between the sponsor and the FDA in an effort to resolve all concerns. If the BLA

submission is accepted for filing, the FDA will begin an in-depth review of the BLA to determine, among other things, whether a product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity.

Companies also may seek Fast Track or Breakthrough Therapy designation for their products. Fast Track or Breakthrough Therapy products are those that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs for such a condition. If awarded, the Fast Track or Breakthrough Therapy designation applies to the product only for the indication for which the designation was received.

If the FDA determines after review of preliminary clinical data submitted by the sponsor that a Fast Track or Breakthrough Therapy product may be effective, it may begin review of portions of a BLA before the sponsor submits the complete BLA (rolling review), thereby accelerating the date on which review of a portion of the BLA can begin. There can be no assurance that any of our products will be granted Fast Track or Breakthrough Therapy designation. And even if they are designated as Fast Track or Breakthrough Therapy products, we cannot assure you that our products will be reviewed or approved more expeditiously for their Fast Track or Breakthrough Therapy indications than would otherwise have been the case or will be approved promptly, or at all. Furthermore, the FDA can revoke Fast Track or Breakthrough Therapy designation at any time.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive Accelerated Approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a product receiving Accelerated Approval perform adequate and well-controlled post-approval clinical trials to verify and further define the product's clinical benefit and safety profile. There can be no assurance that any of our products will receive Accelerated Approval. Even if Accelerated Approval is granted, the FDA may withdraw such approval if the sponsor fails to conduct the required post-approval clinical trials, or if the post-approval clinical trials fail to confirm the early benefits seen during the accelerated approval process.

Fast Track or Breakthrough Therapy designation and Accelerated Approval should be distinguished from Priority Review designation although products awarded Fast Track or Breakthrough Therapy designation may also be eligible for Priority Review designation. Products regulated by the CBER may receive Priority Review designation if they provide significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. The agency has agreed to the performance goal of reviewing products awarded Priority Review designation within six months, whereas products under standard review receive a ten-month target. The review process, however, can be significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. Priority Review designation is requested at the time the BLA is submitted, and the FDA makes a decision as part of the agency's review of the application for filing. We intend to seek Priority Review designation for the Cellspan esophageal implant as a biologic through the BLA process. We cannot guarantee that the FDA will grant the designation and cannot predict if awarded, what impact, if any, it will have on the review time for approval of our product.

If granted, Fast Track or Breakthrough Therapy designation, Accelerated Approval and Priority Review designation may expedite the approval process, but they do not change the standards for approval.

Before approving a BLA, the FDA will generally inspect the facility or the facilities at which the finished product and its components are manufactured to ensure compliance with cGMP.

Separate approval is required for each proposed indication. If we want to expand the use of an approved product, we will have to design additional clinical trials, submit the trial designs to the FDA for review and complete those trials successfully.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions, such as post-approval studies, on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

After regulatory approval of a product is obtained, companies are required to comply with a number of post-approval requirements relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution and recordkeeping. For example, as a condition of approval of a BLA, the FDA may require post-approval testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved BLA are required to keep extensive records, to report certain adverse reactions and production deviations and problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions or other setbacks. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Specifically, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death. In addition, the FDA could suspend the marketing of or withdraw a previously approved product from the market upon receipt of newly discovered information regarding the product's safety or effectiveness.

Orphan Drug Designations

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs and biologics for rare diseases and conditions affecting fewer than 200,000 persons in the U.S. at the time of application for orphan drug designation, or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a new drug application, or NDA, or BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. In September 2014 the FDA granted orphan designation to our HART-Trachea product in the U.S. 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 product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. The first developer to receive FDA marketing approval for an orphan biologic is entitled to a seven year exclusive marketing period in the U.S. for that product as well as a waiver of the BLA user fee. The exclusivity prevents FDA approval of another application for the same product for the same indication for a period of seven years, except in limited circumstances where there is a change in formulation in the original product and the second product has been proven to be clinically superior to the first.

International

We plan to seek required regulatory approvals and comply with extensive regulations governing product safety, quality, manufacturing and reimbursement processes in order to market our products in other major foreign markets. The regulation of our products in the EU and in other foreign markets varies significantly from one jurisdiction to another. The classification of the particular products and related approval or CE marking procedures can involve additional product testing and additional administrative review periods. The time required to obtain these foreign approvals or to CE mark our products may be longer or shorter than that required in the U.S., and requirements for approval may differ from the FDA requirements. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

The marketing authorization of products containing viable human tissues or cells in the EU is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC lays down specific rules concerning the authorization, supervision and pharmacovigilance of medicinal products, cell therapy medicinal products and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety and efficacy of their products to the European Medicines Agency which is required to provide an opinion regarding the application for marketing authorization. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the European Medicines Agency. Regulation 1394/2007/EC also applies to combination products which consist of medical devices and advanced therapy medicinal products. In light of Regulation 1394/2007/EC, a medical device which forms part of a combined advanced therapy medicinal product must meet the Essential Requirements laid down in Annex I to Directive 93/42/EEC. The manufacturer of the combination product must include evidence of such compliance in its marketing authorization application. The application for a marketing authorization for a combined advanced therapy medicinal product must also, where available, include the results of the assessment of the medical device part by a notified body in accordance with Directive 93/42/EEC.

Legislation similar to the Orphan Drug Act has been enacted in other jurisdictions, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons. The marketing exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Employees

At December 31, 2016, we had 28 employees working in our business, of whom 27 were full-time and one was part-time. At that date, all of our employees were based in the U.S. None of our employees are unionized. In general, we consider our relations with our employees to be good.

Competition

We are not aware of any companies whose products are directly competitive with our cell-seeded biocompatible synthetic scaffold system. However, in our key markets we may in the future compete with multiple pharmaceutical, biotechnology, and medical device, including, among others, Aldagen, Asterias Biotherapeutics, Athersys, BioTime, Caladrius Biosciences, Celgene, Cytori Therapeutics, E. I. du Pont de Nemours and Company, InVivo Therapeutics, Mesoblast, Miramatrix Medical, Nanofiber Solutions, Neuralstem, Organovo, Osiris Therapeutics, Pluristem, Smiths Medical, Tissue Genesis, Inc., Tissue Growth Technologies, United Therapeutics, Vericel Corporation and W.L. Gore and Associates. In addition, there are many academic and clinical centers that are developing regenerative technologies that may one day become competitors with us.

Many of our potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. We cannot forecast if or when these or other companies may develop competitive products.

We expect that other products will compete with products and potential products based on efficacy, safety, cost, and intellectual property positions. While we believe that these will be the primary competitive factors, other factors include, in certain instances, obtaining marketing exclusivity under the Orphan Drug Act, availability of supply, manufacturing, marketing and sales expertise and capability, and reimbursement coverage.

Properties

On November 1, 2013 we entered into a sublease of approximately 17,000 square feet of mixed use space of the facility located at 84 October Hill Road, Suite 11, Holliston, Massachusetts from Harvard Bioscience, which is our corporate headquarters. Our principal facilities incorporate manufacturing, laboratory, development, sales and marketing, and administration functions. We believe our current facilities are adequate for our needs for the foreseeable future.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings arising in the ordinary course of business. We are not currently a party to any such significant claims or proceedings.

MANAGEMENT

The following table shows information about our executive officers and directors as of February 1, 2017.

Name	Age	Position(s)
Executive Officers		
James McGorry	60	President and Chief Executive Officer and Director
Thomas McNaughton	56	Chief Financial Officer
Saverio LaFrancesca, M.D.	55	Executive Vice President and Chief Medical Officer
Directors		
John F. Kennedy[(1)(2)]	68	Chairman
John J. Canepa[(1)(3)]	61	Director
Blaine H. McKee, Ph.D.[(1)]	52	Director
Thomas H. Robinson[(2)(3)]	58	Director

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Governance Committee

Executive Officers

James McGorry - President and Chief Executive Officer and Director

Mr. McGorry has served as our President and Chief Executive Officer (CEO) since July 6, 2015. He has served as a Member of our Board of Directors since February 2013. Mr. McGorry has more than 30 years of experience as a life science business leader in biologics, personalized medicine and medical devices, including multiple product launches. Prior to becoming President and CEO at Biostage, Mr. McGorry most recently served as Executive Vice President and General Manager, Translational Oncology Solutions for Champions Oncology and previously was Executive Vice President of Commercial Operations at Accellent. During a 12-year tenure at Genzyme, he held leadership positions across several therapeutic areas, including Bio Surgery, Cardiac Surgery, Oncology and Transplant. Mr. McGorry also was President of Clineffect Systems, an electronic medical records company. He began his life sciences career with Baxter Healthcare Corporation, where he spent 11 years in positions of increasing responsibility. Mr. McGorry also served as an officer in the United States Army for six years, including commanding a special operations Green Beret

SCUBA detachment. Mr. McGorry has an MBA with a concentration in healthcare from Duke University, Fuqua School of Business, and a B.S. in engineering from the United States Military Academy at West Point where he was the president of his class. We believe Mr. McGorry's qualifications to sit on our Board of Directors include his extensive executive leadership positions at several biotechnology and healthcare companies over the past 25 years.

Thomas McNaughton - Chief Financial Officer

Mr. McNaughton has served as our Chief Financial Officer since May 3, 2012. Mr. McNaughton joined Harvard Bioscience as its Chief Financial Officer in November 2008, and served in that role until the spin-off of our company from Harvard Bioscience on November 1, 2013. During 2008 and prior to joining Harvard Bioscience, Mr. McNaughton was a consultant providing services primarily to an angel-investing group and a silicon manufacturing start-up. From 2005 to 2007, he served as Vice President of Finance and Chief Financial Officer for Tivoli Audio, LLC, a venture capital-backed global manufacturer of premium audio systems. From 1990 to 2005, Mr. McNaughton served in various managerial positions in the areas of financial reporting, treasury, investor relations, and acquisitions within Cabot Corporation, a global manufacturer of fine particulate products, and served from 2002 to 2005 as Finance Director, Chief Financial Officer of Cabot Supermetals, a $350 million Cabot division that provided high purity tantalum and niobium products to the electronics and semiconductor industries. Mr. McNaughton practiced from 1982 to 1990 as a Certified Public Accountant in the audit services group of Deloitte & Touche, LLP. He holds a B.S. in accounting and finance with distinction from Babson College.

Saverio LaFrancesca, M.D. - Chief Medical Officer

Dr. LaFrancesca has served as our Chief Medical Officer since April 14, 2014. Dr. LaFrancesca has a unique combination of experience that features more than 25 years of academic clinical surgical practice and innovative research, with a foundation in the cardiovascular, thoracic transplantation, cardiac assist device and regenerative medicine fields. He joined our company from the Department of Cardiovascular Surgery and Transplantation at the DeBakey Heart and Vascular Center at the Houston Methodist Hospital, where he developed the current surgical and perfusion techniques for thoracic organ procurement and preservation and where he was also the Director of the Exvivo lung perfusion laboratory. Previously Dr. LaFrancesca was an attending surgeon at the Department of Cardiopulmonary Transplantation at the Texas Heart Institute in Houston, Texas. He also previously held an appointment as Associate Professor of Surgery at the “Sapienza” University of Rome in Rome, Italy. Dr. LaFrancesca received his M.D. in medicine and surgery in 1985 at the University of Palermo. He did his Residency in Cardiovascular Surgery in the Department of Cardiovascular Surgery at the “Sapienza” University of Rome. He then completed his postdoctoral training with fellowships at the Texas Heart Institute under the supervision of pioneer heart surgeon Denton Cooley. He was also a Clinical/ Research fellow at McGill University in Montréal, Québec, Canada and at the Baylor College of Medicine in Houston. He holds UNOS certifications as heart transplant surgeon and lung transplant surgeon. He is also certified as surgeon for the use of the HeartMate and the Jarvik 2000 left ventricular assist devices.

Directors

Class I Director — Term expires 2017

James J. McGorry — President, Chief Executive Officer and Director

Mr. McGorry’s biographical information is provided under the caption “Executive Officers” above.

Class II Directors — Term expires 2018

Thomas H. Robinson — Director

Mr. Robinson has served as a member of our Board of Directors since December 3, 2012. Since September 2011, Mr. Robinson has served as a partner with RobinsonButler, an executive search firm. In 2010, Mr. Robinson served as managing director at Russell Reynolds Associates. From 1998 to 2010, Mr. Robinson served as managing partner of the North American medical technology practice, which includes the medical device, hospital supply/distribution and medical software areas, of Spencer Stuart, Inc., a global executive search firm. From 2002 to 2010, Mr. Robinson was a member of Spencer Stuart's board services practice, which assists corporations to identify and recruit outside directors. From 1998 to 2000, Mr. Robinson headed Spencer Stuart's North American biotechnology specialty practice. From 1993 to 1997, Mr. Robinson served as president of the emerging markets business at Boston Scientific Corporation, a global medical devices manufacturer. From 1991 to 1993, Mr. Robinson also served as president and chief operating officer of Brunswick Biomedical, a cardiology medical device company. Mr. Robinson currently serves on the Board of Directors of Cynosure, Inc. He graduated from Brown University with a B.A. degree in mathematics and economics and holds an M.B.A. degree from Harvard Business School. We believe Mr. Robinson's qualifications to sit on our Board of Directors include his executive leadership experience in, and knowledge of, the medical device and regenerative medicine industries, and his significant expertise in the areas of public company corporate governance and operations.

John J. Canepa — Director

Mr. Canepa has served as a member of our Board of Directors since August 14, 2013. Mr. Canepa is the Chief Operating Officer and Chief Financial Officer of Asterand Bioscience, Inc. (formerly known as Stemgent, Inc.) a leading global provider of high quality, well characterized human tissue and human tissue-based research solutions to drug discovery scientists. From August 2005, Mr. Canepa served as the President and Chief Executive Officer of PathoGenetix, Inc., a venture capital backed life science company focused on commercializing proprietary DNA optical mapping technology for pathogen detection and strain identification. From 2001 to 2003, Mr. Canepa served as the Chief Financial Officer at Winphoria Networks. From 1978 to 2001, Mr. Canepa was a Senior Audit Partner in Arthur Andersen's Boston Office Technology Practice with worldwide responsibility for Life Sciences Practice. Currently, Mr. Canepa is Co-Chairman of the Board of Trustees at Mt. Auburn Hospital and a member of the Board of Trustees and the Audit Committee at CareGroup. He graduated from Denison University with a B.A. degree and holders a Masters Degree in Finance from Michigan State University. We believe Mr. Canepa's qualifications to sit on our Board of Directors include his executive leadership experience, his significant operating, accounting and financial management expertise, including with respect to the life sciences, medical technology and biotechnology industries.

Class III Directors — Term Expiring in 2019

John F. Kennedy — Chairman

Mr. Kennedy has served as a member of our Board of Directors since December 3, 2012. From June 2006 until his retirement in October 2008, Mr. Kennedy served as President and Chief Financial Officer of Nova Ventures Corporation, the management company providing executive management services to the operating companies of Nova Holdings LLC, Nova Analytics Corporation and Nova Technologies Corporation. From 2002 to 2006, Mr. Kennedy served as the President and Chief Financial Officer of Nova Analytics Corporation, a worldwide supplier and integrator of analytical instruments. From 1999 to 2002, Mr. Kennedy served as the Senior Vice President, Finance, Chief Financial Officer and Treasurer of RSA Security Inc., an e-business security company. Prior to joining RSA Security, Mr. Kennedy was Chief Financial Officer of Decalog, NV, a developer of enterprise investment management software, from 1998 to 1999. From 1993 to 1998, Mr. Kennedy served as Vice President of Finance, Chief Financial Officer and Treasurer of Natural MicroSystems Corporation, a telecommunications company. Mr. Kennedy, a former CPA, also practiced as a public accountant at KPMG for six years. Mr. Kennedy currently serves on the Boards of Directors of Harvard Bioscience and Datacom Systems, Inc. Mr. Kennedy holds a B.S. in Mathematics from Lowell Technological Institute, now the University of Massachusetts Lowell, and an M.S.B.A. in Accounting from the University of Massachusetts Amherst. We believe Mr. Kennedy's qualifications to sit on our Board of Directors include his executive leadership experience, his significant operating, accounting and financial management expertise and the knowledge and understanding of our Company and industry that he has acquired over 13 years of service on the Board of Directors of Harvard Bioscience.

Blaine H. McKee, Ph.D. — Director

Dr. McKee has served as a member of our Board of Directors since March 10, 2016. Dr. McKee is the Senior Vice President, Head of Transactions at Shire PLC, a position he has held since July 2014. Prior to joining Shire, Dr. McKee served as Executive Vice President and Chief Business Officer of 480 Biomedical from 2011 to 2014, following 15 years at Genzyme Corporation from 1996 to 2011, where he most recently served as Senior Vice President of Strategic Development, leading global business development for the Organ Transplant, Oncology and Multiple Sclerosis business units. Dr. McKee currently serves on the Boards of ArmaGen, Inc., OrbiMed Israel and the New York Pharma Forum. Dr. McKee holds a B.S. in Chemistry with distinction from Colorado State University, a M.B.A. in Finance from MIT Sloan School of Management and a Ph.D. from Massachusetts Institute of Technology. We believe Dr. McKee's qualifications to sit on our Board of Directors include his extensive background in science, finance and strategy functions, including with respect to the life sciences industry.

Information Regarding the Board of Directors and its Committees

Independence

The Board of Directors has determined that all of our Directors are "independent" as such term is currently defined by applicable NASDAQ rules, except for James J. McGorry, who is our President and Chief Executive Officer. Our director John F. Kennedy is currently a director of Harvard Bioscience, Inc. ("Harvard Bioscience"), our former parent company.

Board Structure

The non-employee Directors meet regularly in executive sessions outside the presence of management. Following the resignation of David Green, our former Chairman, President and Chief Executive Officer, the Board of Directors appointed Mr. Kennedy as the Chairman of the Board in April 2015. Among other things, the Chairman provides feedback to the Chief Executive Officer on executive sessions and facilitates discussion among the independent directors outside of meetings of the Board of Directors. The Chief Executive Officer is responsible for the day-to-day management of our Company and the development and implementation of our Company's strategy. Our Board of Directors currently believes that separating the roles of Chief Executive Officer and Chairman contributes to an efficient and effective board. Our Board of Directors does not have a current requirement that the roles of Chief Executive Officer and Chairman of the Board be either combined or separated, because the Board currently believes it is in the best interests of our Company to make this determination based on the position and direction of our Company and the constitution of the Board and management team. From time to time, the Board will evaluate whether the roles of Chief Executive Officer and Chairman of the Board should be combined or separated. The Board has determined that having separate roles of our Company's Chief Executive Officer and Chairman is in the best interest of our stockholders at this time.

The Board of Directors has established an Audit Committee (the "Audit Committee"), a Compensation Committee (the "Compensation Committee") and a Governance Committee (the "Governance Committee").

Audit Committee

The Audit Committee currently consists of Messrs. Kennedy, Canepa and McKee. Mr. Kennedy serves as the Chairman. Dr. McKee was appointed to the Audit Committee in March 2016, as successor to Mr. McGorry who no

longer could serve on the Audit Committee following his July 2015 appointment as our President and Chief Executive Officer. The Audit Committee is comprised entirely of independent Directors and it operates under a Board-approved charter that sets forth its duties and responsibilities.

Under its charter, the Audit Committee is responsible for, among other things:

- reviewing with the independent registered public accounting firm and management the adequacy and effectiveness of internal controls over financial reporting and related matters;
- reviewing and consulting with management and the independent registered public accounting firm on matters related to the annual audit, the annual and quarterly financial statements and related disclosures, earnings releases and related accounting principles, policies, practices and judgments;
- making a recommendation to the Board as to whether our audited financial statements should be included in our Annual Report on Form 10-K;
- appointing, retaining and terminating, and determining compensation of, the Company's independent auditors;
- assurance of the regular rotation of audit partners, including any lead and concurring partners, in accordance with applicable laws and regulations;
- preparation of the Audit Committee report required to be included in our annual proxy statement;
- reporting matters that arise relating to quality or integrity of our financial statements, legal compliance, performance of the independent auditors and other matters, to the Board and reviewing such matters with the Board; and
- the oversight of the Company's independent auditors and the evaluation of the independent auditors' qualifications, performance and independence, including performance of the lead audit partner, and reporting of such evaluation to the Board.

The Audit Committee is responsible for reviewing and discussing with management our policies with respect to risk assessment and risk management. The Board and the Audit Committee discuss matters relating to risks that arise or may arise.

The Audit Committee is also responsible for, and has established policies and procedures with respect to, the pre-approval of all services provided by the independent auditors. When assessing the independence of our auditors, the Audit Committee considers the independent registered public accounting firm's provision of non-audit services to the Company.

The Audit Committee has also established procedures for the receipt, retention and treatment, on a confidential basis, of complaints received by the Company. The Board of Directors and the Audit Committee adopted a Code of Business Conduct and Ethics, a current copy of which is available on the Corporate Governance page in the Investor section of our website at *www.biostage.com*.

With respect to the Company's independent registered public accounting firm, currently KPMG, in accordance with SEC rules and KPMG policies, audit partners are subject to rotation requirements to limit the number of consecutive years an individual partner may provide service to our Company. For lead and concurring audit partners, the maximum number of consecutive years of service in that capacity is five years. Our Audit Committee is involved in the selection of the lead audit partner. The process for selection of our lead audit partner pursuant to this rotation policy involves a meeting between the Chairman of the Audit Committee and the candidate for the role, as well as discussion by the full Audit Committee and with management.

The Board of Directors has determined that all members of the Audit Committee are "independent" as such term is currently defined by NASDAQ rules, meet the criteria for independence set forth under the rules of the Securities and Exchange Commission, and are able to read and understand fundamental financial statements. The Board of Directors has also determined that each of Messrs. Kennedy and Canepa qualifies as an "audit committee financial expert" under the rules of the Securities and Exchange Commission.

The Audit Committee Charter is available on the Corporate Governance page in the Investors section of our website at *www.biostage.com*. Please note that the information contained on the Company website is not incorporated by reference in, or considered to be a part of, this prospectus.

Compensation Committee

The Compensation Committee currently consists of Messrs. Kennedy and Robinson. Mr. Robinson serves as the Chairman. The Compensation Committee is comprised entirely of independent Directors and it operates under a Board-approved charter that sets forth its duties and responsibilities.

The Compensation Committee determines and oversees the execution of our compensation philosophy and oversees the administration of our executive compensation programs. Its responsibilities also include overseeing the Company's compensation and benefit plans and policies, retaining or terminating committee advisors, independence evaluation of compensation advisors, administering its stock plans (including reviewing and approving equity grants) and reviewing and approving annually all compensation decisions for the Company's executive officers, including the President and Chief Executive Officer and the Chief Financial Officer.

The Board of Directors has determined that all members of the Compensation Committee are "independent" as such term is currently defined by NASDAQ rules.

The Compensation Committee Charter is available on the Corporate Governance page in the Investors section of our website at *www.biostage.com*. Please note that the information contained on the website is not incorporated by reference in, or considered to be a part of, this prospectus.

Governance Committee

The current members of the Governance Committee are Messrs. Robinson and Canepa. Mr. Canepa replaced Mr. McGorry as Chairman of the Governance Committee in July 2015, in connection with Mr. McGorry's appointment as our President and Chief Executive Officer. The Governance Committee is comprised entirely of independent directors and it operates under a Board-approved charter that sets forth its duties and responsibilities.

Under the terms of its charter, the Governance Committee is responsible for identifying individuals qualified to become Board members, consistent with criteria recommended by the Governance Committee and approved by the Board of Directors, and recommending that the Board of Directors select the director nominees for election at each annual meeting of stockholders. Its responsibilities also include recommending to the Board of Directors the criteria for membership on Board Committees. The Governance Committee is also responsible for reviewing all stockholder nominations and proposals submitted to the Company, determining whether such nominations or proposals were timely submitted and assisting the Board of Directors with such corporate governance matters as the Board of Directors may request.

In identifying and evaluating nominees for the Board of Directors, the Governance Committee may solicit recommendations from any or all of the following sources: non-management Directors, including our Chairman, the Chief Executive Officer, other executive officers, third-party search firms or any other source it deems appropriate. In addition, the Governance Committee has established a policy that it will review and consider any Director candidates who have been recommended by securityholders in compliance with certain procedures established by the Governance Committee. The Governance Committee will review and evaluate the qualifications of any such proposed Director candidate and conduct inquiries it deems appropriate.

The Governance Committee will evaluate all such proposed Director candidates, including those recommended by securityholders in compliance with the procedures established by the Governance Committee, in the same manner, with no regard to the source of the initial recommendation of such proposed Director candidate. When considering a potential candidate for membership on the Board of Directors, the Governance Committee may consider, in addition to the minimum qualifications and other criteria for Board membership approved by the Board of Directors, all facts and circumstances that the Governance Committee deems appropriate or advisable, including, among other things, the skills of the proposed Director candidate, his or her availability, depth and breadth of business experience or other background characteristics, his or her independence and the needs of the Board of Directors. At a minimum, each nominee must have high personal and professional integrity, have demonstrated ability and judgment, and be effective, in conjunction with the other Directors and nominees, in collectively serving the long-term interests of the stockholders. In addition, the Governance Committee will recommend that the Board select persons for nomination to help ensure that a majority of the Board shall be "independent" in accordance with NASDAQ rules and each of its Audit, Compensation and Governance Committees shall be comprised entirely of independent directors; provided, however, in accordance with NASDAQ rules, under exceptional and limited circumstances, if a committee has at least three members, the Board may appoint one individual to such committee who does not satisfy the independence

standards. Although there is no specific policy regarding the consideration of diversity in identifying director nominees, the Governance Committee may consider whether the nominee, if elected, assists in achieving a mix of Board members that represents a diversity of background and experience. The Governance Committee also may consider whether the nominee has direct experience in the biotechnology, pharmaceutical and/or life sciences industries or in the markets in which the Company operates.

The Board of Directors has determined that all members of the Governance Committee are “independent” as such term is currently defined by NASDAQ rules.

The Governance Committee Charter is available on the Corporate Governance page in the Investor section of our website at *www.biostage.com*. Please note that the information contained on the website is not incorporated by reference in, or considered to be a part of, this prospectus.

The Board's Role in Risk Oversight

Risks to the Company are discussed by the Board of Directors during the year. Management is responsible for the day-to-day management of risks we face, while the Board, as a whole and through its Committees, oversees risk management. The Audit Committee is responsible for reviewing and discussing with management our policies with respect to risk assessment and risk management. The Board of Directors and the Audit Committee review and discuss, including with management, risks that arise or may arise. For example, the Audit Committee discusses financial risk, including with respect to financial reporting and internal controls, with management and our independent registered public accounting firm and the steps management has taken to minimize those risks. Our Board of Directors also administers its risk oversight function through the required approval by the Board (or a Committee of the Board) of significant transactions and other material decisions.

Code of Business Conduct and Ethics

The Board of Directors has adopted a Code of Business Conduct and Ethics, which applies to all Directors, officers and employees of our Company and its subsidiaries including, without limitation, the Chairman of the Board, the President and Chief Executive Officer, and the Chief Financial Officer. The Code of Business Conduct and Ethics is available on the Corporate Governance page in the Investor section of our website at *www.biostage.com*. We intend to post any amendments to or waivers from this Code of Business Conduct and Ethics at this location on its website. Please note, however, that the information contained on the website is not incorporated by reference in, or considered a part of, this prospectus.

EXECUTIVE COMPENSATION

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act of 2012. As a result, we have elected to comply with the reduced disclosure requirements applicable to emerging growth companies in accordance with SEC rules. We have only three executive officers. James McGorry, our President and Chief Executive Officer, Thomas McNaughton, our Chief Financial Officer and Saverio LaFrancesca, M.D., our Chief Medical Officer, are named executive officers.

Summary Compensation Table

The table below summarizes the total compensation paid or earned by each of the named executive officers for services rendered in all capacities during the fiscal years ended December 31, 2015 and December 31, 2016, excluding the compensation Mr. McGorry received in 2015 as an independent director.

Name and Principal Position	Year	Salary	**Option Awards[(1)]**	All Other Compensation		Total
James McGorry	2016	$ 375,000	$ 168,720	$ 19,208	(2)	$ 562,928
President and Chief Executive Officer	2015	$ 173,077	$ 615,204	$ 4,327	(3)	$ 792,608
Thomas McNaughton	2016	$ 309,000	$ 84,360	$ 15,483	(4)	$ 408,843
Chief Financial Officer	2015	$ 309,000	$ 201,790	$ 15,450	(5)	$ 526,240
Saverio LaFrancesca, M.D.	2016	$ 400,000	$ 84,360	$ —		$ 484,360
Chief Medical Officer	2015	$ 400,000	$ 489,292	$ —		$ 889,292

(1) Based on the aggregate grant date fair value computed in accordance with the provisions of FASB ASC 718, "Compensation — Stock Compensation", excluding the impact of estimated forfeitures. Assumptions used in the calculation of this amount are set forth under 2013 Plan Valuation and Expense Information under Stock-Based-Payment Accounting in Note 13 to our audited financial statements for the fiscal year ended December 31, 2015, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2016.

(2) Amount represents $17,307 for matching contributions made by the Company to Mr. McGorry's tax-qualified 401(k) Savings Plan account and premiums in the amount of $1,901 for a life insurance policy.

(3) Amount represents $4,327 for matching contributions made by the Company to Mr. McGorry's tax-qualified 401(k) Savings Plan account.

(4) Amount represents $15,483 for matching contributions made by the Company to Mr. McNaughton's tax-qualified 401(k) Savings Plan account.

(5) Amount represents $15,450 for matching contributions made by the Company to Mr. McNaughton's tax-qualified 401(k) Savings Plan account.

Discussion of Summary Compensation Table and Related Matters

2016 Executive Compensation

Salary and Bonus

In the first quarter of 2016, the Compensation Committee reviewed the overall executive compensation of the Company's named executive officers. Based on a variety of factors, with respect to the named executive officers, the Compensation Committee elected to not approve any salary increases or cash incentive compensation for 2016.

Long-Term Equity Incentive Compensation

In 2016, the Compensation Committee approved grants of long-term equity incentive awards in the form of stock options to executives as part of our total compensation package. The long-term equity incentive awards were granted in an effort to achieve certain key objectives, including (i) to attract and retain high performing and experienced executives, (ii) motivate and reward executives whose knowledge, skills and performance are critical to our success, and (iii) to align the interests of our executives and our stockholders by providing our executives with strong incentives to increase stockholder value and a significant reward for doing so. Our decisions regarding the amount and type of long-term equity incentive compensation and relative weighting of these awards among total executive compensation have also been based on our understanding of market practices of our peers and take into account additional factors such as level of individual responsibility, experience and performance. The long term incentive grants made to our named executive officers during fiscal 2016 are described in the table below:

	Stock Option Awards (#)	
James McGorry *President and Chief Executive Officer*	150,000	(1)
Thomas McNaughton *Chief Financial Officer*	75,000	(1)
Saverio LaFrancesca, Ph.D. *Chief Medical Officer*	75,000	(1)

(1) These options vest in four equal installments on each of March 22, 2017, 2018, 2019 and 2020 and have a term of ten years from the date of grant, being March 22, 2016.

Employment Agreements and Severance and Change in Control Benefits

Current Named Executive Officers

James McGorry

We entered into an employment agreement with Mr. McGorry dated as of June 23, 2015 and effective as of July 6, 2015, appointing Mr. McGorry as our President and Chief Executive Officer. Mr. McGorry's employment agreement has a term of three years, but will automatically renew for successive one year periods unless either party provides 90 days' notice that it does not wish to extend the agreement. Mr. McGorry's employment agreement provides for an annual base salary in the amount of three hundred seventy-five thousand dollars ($375,000) which will be reevaluated on an annual basis by the Board of Directors or the compensation committee. Mr. McGorry also received an option to purchase 671,400 shares of our common stock upon the commencement of his employment, which vests in four equal installments on January 1 of 2016, 2017, 2018 and 2019. Mr. McGorry is eligible to receive cash incentive compensation as determined by the Board of Directors or the compensation committee, and is also eligible to participate in all of our employee benefit plans, including without limitation, retirement plans, stock option plans, stock purchase plans and medical insurance plans.

Mr. McGorry's employment agreement also provides for payments to be made to Mr. McGorry in the event of his termination under certain circumstances. If Mr. McGorry's employment is terminated by us without "cause" (as such term is defined in Mr. McGorry's employment agreement) or by Mr. McGorry for "good reason" (as such term is defined in Mr. McGorry's employment agreement), we are obligated to pay Mr. McGorry the sum of his average annual base salary for the prior three fiscal years or annual salary for the prior fiscal year, whichever is higher, and his average annual cash incentive compensation for the prior three fiscal years or annual cash incentive compensation for the prior fiscal year, whichever is higher. Such payment is conditioned upon Mr. McGorry's execution of a general release of claims against us. In addition, all of Mr. McGorry's stock options or stock-based awards that would otherwise vest within the 12 month period following such termination shall accelerate and become immediately exercisable. We shall continue to pay health insurance premiums for health insurance coverage for Mr. McGorry and his immediate family for a period of one year following his termination without cause or for good reason.

Mr. McGorry may also be entitled to certain payments in the event of a change in control of our Company. If Mr. McGorry's employment is terminated by us without cause or by Mr. McGorry for good reason within 18 months of a change in control of our Company, Mr. McGorry is entitled to receive a lump sum cash payment in an amount equal to the sum of Mr. McGorry's current or most recent annual salary and his most recent cash incentive compensation. In addition, in the event of a change in control, all of Mr. McGorry's stock options or stock-based awards shall accelerate and become immediately exercisable. We will continue to pay health insurance premiums for health insurance coverage for Mr. McGorry and his immediate family for a period of one year following his termination as a result of a change in control.

Mr. McGorry will not be entitled to severance payments unless mutually agreed upon in writing if Mr. McGorry is terminated for cause, due to death or disability, or he terminates his employment without good reason. In the event Mr. McGorry is terminated due to death or disability, we will continue to pay health insurance premiums for health insurance coverage for Mr. McGorry and his immediate family for a period of one year following his termination.

Pursuant to the terms of his employment agreement, Mr. McGorry is also subject to certain confidentiality, non-solicitation and non-competition obligations. The non-solicitation and non-competition obligations survive during the term of his agreement and for a period of 12 months thereafter.

For purposes of Mr. McGorry's employment agreement, "cause" means: (A) conduct by Mr. McGorry constituting a material act of willful misconduct in connection with the performance of his duties; (B) criminal or civil conviction of Mr. McGorry, a plea of nolo contendere by Mr. McGorry or conduct by Mr. McGorry that would reasonably be expected to result in material injury to our reputation if he were retained in his position with us; (C) continued, willful and deliberate non-performance by Mr. McGorry of his duties; (D) a breach by Mr. McGorry of his confidentiality, non-solicitation and non-competition obligations to us; or (E) a material violation by Mr. McGorry of our employment policies.

For purposes of Mr. McGorry's employment agreement, "good reason" means the occurrence of any of the following events: (A) a substantial diminution or other substantive adverse change, not consented to by Mr. McGorry, in his responsibilities, authorities, powers, functions or duties; (B) any removal of Mr. McGorry's title of President and/or Chief Executive Officer; (C) an involuntary reduction in Mr. McGorry's annual salary except for across-the-board reductions similarly affecting substantially all management employees; (D) a breach by us of any of our other material obligations under Mr. McGorry's employment agreement; (E) the involuntary relocation of our offices at which Mr. McGorry is principally employed to a location more than 30 miles from our current offices; or (F) our failure to obtain the agreement from any successor company to us to assume and agree to perform Mr. McGorry's employment agreement.

Thomas McNaughton

On October 31, 2013, we entered into an Employment Agreement with Mr. McNaughton. The term of this agreement commenced on November 1, 2013. Mr. McNaughton's employment agreement has a term of two years, but will automatically renew for successive two year periods unless either party provides 90 days' notice that it does not wish to extend the agreement. Mr. McNaughton's employment agreement provides for an annual base salary in the amount of three hundred nine thousand dollars ($309,000) which will be reevaluated on an annual basis by the Board of Directors or the compensation committee. Mr. McNaughton is eligible to receive cash incentive compensation as determined by the Board of Directors or the compensation committee, and is also eligible to participate in all of our employee benefit plans, including without limitation, retirement plans, stock option plans, stock purchase plans and medical insurance plans.

Mr. McNaughton's employment agreement also provides for payments to be made to Mr. McNaughton in the event of his termination under certain circumstances. If Mr. McNaughton's employment is terminated by us without "cause" (as such term is defined in Mr. McNaughton's employment agreement) or by Mr. McNaughton for "good reason" (as such term is defined in Mr. McNaughton's employment agreement), we are obligated to pay Mr. McNaughton the sum of his average annual base salary for the prior three fiscal years or annual salary for the prior fiscal year, whichever is higher, and his average annual cash incentive compensation for the prior three fiscal years or annual cash incentive compensation for the prior fiscal year, whichever is higher. Such payment is conditioned upon Mr. McNaughton's execution of a general release of claims against us. In addition, all of Mr. McNaughton's stock options or stock-based awards that would otherwise vest within the 18 month period following such termination shall accelerate and become immediately exercisable. We shall continue to pay health insurance premiums for health insurance coverage for Mr. McNaughton and his immediate family for a period of one year following his termination without cause or for good reason.

Mr. McNaughton may also be entitled to certain payments in the event of a change in control of our Company. If Mr. McNaughton's employment is terminated by us without cause or by Mr. McNaughton for good reason within 18 months of a change in control of our Company, Mr. McNaughton is entitled to receive a lump sum cash payment in an amount equal to the sum of Mr. McNaughton's most recent annual salary and his most recent cash incentive compensation. In addition, in the event of a change in control, all of Mr. McNaughton's stock options or stock-based awards shall accelerate and become immediately exercisable. We will continue to pay health insurance premiums for health insurance coverage for Mr. McNaughton and his immediate family for a period of one year following his termination as a result of a change in control.

Mr. McNaughton will not be entitled to severance payments unless mutually agreed upon in writing if Mr. McNaughton is terminated for cause, due to death or disability, or he terminates his employment without good reason. In the event Mr. McNaughton is terminated due to death or disability, we will continue to pay health insurance premiums for health insurance coverage for Mr. McNaughton and his immediate family for a period of one year following his termination.

Mr. McNaughton is also eligible to receive a gross up payment in the event that any amounts received pursuant to the terms of his employment agreement are subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code"), or any interest or penalties on such excise tax are incurred by Mr. McNaughton. Such payment will be equal to the amount of (i) the excise tax, (ii) any federal, state or local tax resulting from the gross up payment and (iii) any interest and/or penalties assessed with respect to such excise tax. Pursuant to the terms of his employment agreement, Mr. McNaughton is also subject to certain confidentiality, non-solicitation and non-competition obligations. The non-solicitation and non-competition obligations survive during the term of his agreement and for a period of 12 months thereafter.

For purposes of Mr. McNaughton's employment agreement, "cause" means: (A) conduct by Mr. McNaughton constituting a material act of willful misconduct in connection with the performance of his duties; (B) criminal or civil conviction of Mr. McNaughton, a plea of nolo contendere by Mr. McNaughton or conduct by Mr. McNaughton that would reasonably be expected to result in material injury to our reputation if he were retained in his position with us; (C) continued, willful and deliberate non-performance by Mr. McNaughton of his duties; (D) a breach by Mr. McNaughton of his confidentiality, non-solicitation and non-competition obligations to us; or (E) a violation by Mr. McNaughton of our employment policies.

For purposes of Mr. McNaughton's employment agreement, "good reason" means the occurrence of any of the following events: (A) a substantial diminution or other substantive adverse change, not consented to by Mr. McNaughton, in his responsibilities, powers, or duties; (B) any removal of Mr. McNaughton's title of Chief Financial Officer; (C) an involuntary reduction in Mr. McNaughton's annual salary except for across-the-board reductions similarly affecting substantially all management employees; (D) a breach by us of any of our other material obligations under Mr. McNaughton's employment agreement; (E) the involuntary relocation of our offices at which Mr. McNaughton is principally employed to a location more than 30 miles from our current offices; or (F) our failure to obtain the agreement from any successor company to us to assume and agree to perform Mr. McNaughton's employment agreement.

Saverio LaFrancesca, M.D.

We entered into an employment agreement with Dr. LaFrancesca dated as of April 8, 2014 effective as of April 14, 2014, appointing Dr. LaFrancesca as our Chief Medical Officer. We entered into an amendment to Dr. LaFrancesca's employment agreement on March 24, 2016. Dr. LaFrancesca's employment agreement has a term of one year, but will automatically renew for successive one year periods unless either party provides 90 days' notice that it does not wish to extend the agreement. Dr. LaFrancesca's employment agreement provides for an annual base salary in the amount of four hundred thousand dollars ($400,000) which will be reevaluated on an annual basis by the Board of Directors or the compensation committee. Dr. LaFrancesca also received an option to purchase 100,000 shares of our common stock upon the commencement of his employment, which vests in four equal installments on January 1 of 2015, 2016, 2017 and 2018. Dr. LaFrancesca is eligible to receive cash incentive compensation as determined by the Board of Directors or the compensation committee, and is also eligible to participate in all of our employee benefit plans, including without limitation, retirement plans, stock option plans, stock purchase plans and medical insurance plans.

Dr. LaFrancesca's employment agreement also provides for payments to be made to Dr. LaFrancesca in the event of his termination under certain circumstances. If Dr. LaFrancesca's employment is terminated by us without "cause" (as such term is defined in Dr. LaFrancesca's employment agreement) or by Dr. LaFrancesca for "good reason" (as such term is defined in Dr. LaFrancesca's employment agreement), we are obligated to pay Dr. LaFrancesca the sum of his average annual base salary for the prior three fiscal years or annual salary for the prior fiscal year, whichever is higher, and his average annual cash incentive compensation for the prior three fiscal years or annual cash incentive compensation for the prior fiscal year, whichever is higher. Such payment is conditioned upon Dr. LaFrancesca's

execution of a general release of claims against us. In addition, all of Dr. LaFrancesca's stock options or stock-based awards that would otherwise vest within the 12 month period following such termination shall accelerate and become immediately exercisable. We shall continue to pay health insurance premiums for health insurance coverage for Dr. LaFrancesca and his immediate family for a period of one year following his termination without cause or for good reason.

Dr. LaFrancesca may also be entitled to certain payments in the event of a change in control of our Company. If Dr. LaFrancesca's employment is terminated by us without cause or by Dr. LaFrancesca for good reason within 18 months of a change in control of our Company, Dr. LaFrancesca is entitled to receive a lump sum cash payment in an amount equal to the sum of Mr. Dr. LaFrancesca's current or most recent annual salary and his most recent cash incentive compensation. In addition, in the event of a change in control, all of Dr. LaFrancesca's stock options or stock-based awards shall accelerate and become immediately exercisable. We will continue to pay health insurance premiums for health insurance coverage for Dr. LaFrancesca and his immediate family for a period of one year following his termination as a result of a change in control.

Dr. LaFrancesca will not be entitled to severance payments unless mutually agreed upon in writing if Dr. LaFrancesca is terminated for cause, due to death or disability, or he terminates his employment without good reason. In the event Dr. LaFrancesca is terminated due to death or disability, we will continue to pay health insurance premiums for health insurance coverage for Dr. LaFrancesca and his immediate family for a period of one year following his termination.

Pursuant to the terms of his employment agreement, Dr. LaFrancesca is also subject to certain confidentiality, non-solicitation and non-competition obligations. The non-solicitation and non-competition obligations survive during the term of his agreement and for a period of 12 months thereafter.

For purposes of Dr. LaFrancesca's employment agreement, "cause" means: (A) conduct by Dr. LaFrancesca constituting a material act of willful misconduct in connection with the performance of his duties; (B) criminal or civil conviction of Dr. LaFrancesca, a plea of nolo contendere by Dr. LaFrancesca or conduct by Dr. LaFrancesca that would reasonably be expected to result in material injury to our reputation if he were retained in his position with us; (C) continued, willful and deliberate non-performance by Dr. LaFrancesca of his duties; (D) a breach by Dr. LaFrancesca of his confidentiality, non-solicitation and non-competition obligations to us; or (E) a violation by Dr. LaFrancesca of our employment policies.

For purposes of Dr. LaFrancesca's employment agreement, "good reason" means the occurrence of any of the following events: (A) a substantial diminution or other substantive adverse change, not consented to by Dr. LaFrancesca, in his responsibilities, authorities, powers, functions or duties; (B) any removal of Dr. LaFrancesca's title of Chief Medical Officer; (C) an involuntary reduction in Dr. LaFrancesca's annual salary except for across-the-board reductions similarly affecting substantially all management employees; (D) a breach by us of any of our other material obligations under Dr. LaFrancesca's employment agreement; (E) the involuntary relocation of our offices at which Dr. LaFrancesca is principally employed to a location more than 30 miles from our current offices; or (F) our failure to obtain the agreement from any successor company to us to assume and agree to perform Dr. LaFrancesca's employment agreement.

Retirement and Other Benefits

We have established a 401(k) tax-deferred savings plan, which permits participants, including our named executive officers, to make contributions by salary deduction pursuant to Section 401(k) of the Code. We are responsible for administrative costs of the 401(k) plan. We may, in our discretion, make matching contributions to the 401(k) plan. In addition, all full-time employees, including our named executive officers, may participate in our health and welfare benefit programs, including medical coverage, vision coverage, dental coverage, disability insurance, and life insurance.

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DIRECTOR COMPENSATION

We use a combination of cash and stock-based incentive compensation to attract and retain qualified candidates to serve on our Board of Directors. In setting director compensation, the Board of Directors and the Compensation Committee consider the significant amount of time that directors expend in fulfilling their duties to the Company as well as the skill-level required by the Company of members of the Board of Directors.

Directors who are also employees of the Company receive no additional compensation for service as a director.

Each non-employee director that is elected to our Board of Directors will receive a non-qualified stock option to purchase 25,000 shares of our Common Stock vesting one year from the date of grant and granted on the fifth business day following his or her initial election to the Board of Directors. Each non-employee director also receives an annual retainer of $30,000 paid in four equal quarterly installments. Each non-employee director is also entitled to receive a non-qualified stock option to purchase 25,000 shares of our Common Stock vesting one year from the date of grant and granted on the third business day following the issuance of our earnings release for year-end results.

Non-employee directors continue to be reimbursed for their expenses incurred in connection with attending Board of directors and committee meetings.

Director Compensation Table

The following table presents the compensation provided by us to the non-employee directors who served during the fiscal year ended December 31, 2016.

Name[1]	Fees earned or paid in cash	**Option awards** [1][2]	Total
John J. Canepa	$ 30,000	$ 26,513	$ 56,513
John F. Kennedy	$ 30,000	$ 26,513	$ 56,513
Blaine H. McKee	$ 23,736	$ 55,378	$ 79,114
Thomas H. Robinson	$ 30,000	$ 26,513	$ 56,513
David Green	$ 12,115	$ 26,513	$ 38,628

(1) Based on the aggregate grant date fair value computed awards in accordance with the provisions of FASB ASC 718, “Compensation — Stock Compensation” excluding the impact of estimated forfeitures. Assumptions used in the calculation of this amount are included under 2013 Plan Valuation and Expense Information under Share-Based-Payment Accounting in Note 13 to our audited financial statements for the fiscal year ended December 31, 2015, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2016.

(2) The aggregate number of option awards outstanding at our 2016 fiscal year end and held by the non-employee directors were as follows: 75,000 for Mr. Canepa; 80,026 for Mr. Kennedy; 50,000 for Mr. McKee; 75,000 for Mr. Robinson; and 775,627 for Mr. Green. With respect to Mr. Kennedy, these holdings include grants of options to purchase 5,026 shares that were issued by our Company in connection with the required adjustment to the similar outstanding equity awards held by him and issued by Harvard Bioscience resulting from the impact of the spin-off of our Company by Harvard Bioscience.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table sets forth information concerning the number and value of exercisable and unexercisable options to purchase Common Stock, and the number of restricted stock units held by our named executive officers as of December 31, 2016.

	Option Awards					Restricted Stock Units	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		Option Exercise Price ($)	Option Expiration Date	Number of Securities Underlying Restricted Stock Units	
James McGorry	25,000	—		$ 4.29	11/18/2023	—	
	25,000	—		$ 1.84	5/29/2025	—	
	167,850	503,550	(1)	$ 1.38	7/6/2025	—	
		150,000	(2)	$ 1.69	3/22/2026	—	
Thomas McNaughton		75,000	(3)	$ 1.69	3/22/2026	—	
	25,000	75,000	(4)	$ 1.40	9/1/2025	—	
	21,250	63,750	(5)	$ 1.84	5/29/2025	—	
	108,844	36,282	(6)	$ 4.29	11/18/2023	—	
	48,375	24,188	(7)	$ 4.29	11/18/2023	—	
	1,546	515	(8)	$ 5.22	5/31/2023	268	(9)
	4,383			$ 3.67	6/1/2022	—	
	2,769	—		$ 5.79	6/2/2021	—	
	11,108	—		$ 3.27	5/21/2019	—	
	5,544	—		$ 2.90	11/14/2018	—	
Saverio LaFrancesca, M.D.	50,000	50,000	(10)	$ 8.66	5/1/2024	—	
	25,000	75,000	(11)	$ 4.08	3/4/2025	—	
	10,000	30,000	(11)	$ 1.84	5/29/2025	—	
	40,000	120,000	(13)	$ 1.40	8/31/2025	—	
	—	75,000	(14)	$ 1.69	3/22/2026	—	

(1) The option was granted on July 6, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on January 1 of each of 2017, 2018 and 2019.

(2) The option was granted on March 22, 2016 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on March 22 of each of 2017, 2018, 2019 and 2020.

(3) The option was granted on March 22, 2016 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on March 22 of each of 2017, 2018, 2019 and 2020.

(4) The option was granted on August 31, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on August 31 of each of 2017, 2018 and 2019.

(5) The option was granted on May 29, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on May 29 of each of 2017, 2018 and 2019.

(6) The option was granted on November 1, 2013 and, assuming continued employment with our Company, the unvested shares become exercisable on January 1, 2017.

(7) The option was granted on November 18, 2013 and, assuming continued employment with our Company, the unvested shares become exercisable in two equal increments subject to the achievement of certain milestone targets determined by our Board of Directors.

(8) The option was granted on November 1, 2013 and, assuming continued employment with our Company, the unvested shares become exercisable on January 1, 2017.

(9) The restricted stock units were granted on November 1, 2013 and, assuming continued employment with our Company, these restricted stock units vest on January 1, 2017.

(10) The option was granted on May 1, 2014 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on May 1 of each of 2017 and 2018.

(11) The option was granted on March 4, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on March 4 of each of 2017, 2018 and 2019.

(12) The option was granted on May 29, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on May 29 of each of 2017, 2018 and 2019.

(13) The option was granted on August 31, 2015 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on August 31 of each of, 2017, 2018 and 2019.

(14) The option was granted on March 23, 2016 and, assuming continued employment with our Company, the unvested shares become exercisable in equal installments on March 23 of each of 2017, 2018, 2019 and 2020.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS

The following table sets forth information regarding the beneficial ownership of our Common Stock as of February 1, 2017 by: (i) all persons known by us to own beneficially more than 5% of our voting securities; (ii) each of our directors; (iii) each of our named executive officers; and (iv) all of our current directors and executive officers as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC and includes voting or investment power with respect to securities. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power and includes any shares as to which the individual or entity has the right to acquire beneficial ownership within 60 days after February 1, 2017 through the exercise of any warrant, stock option or other right. The inclusion of such shares, however, does not constitute an admission that the named stockholder is a direct or indirect beneficial owner of such shares. Common stock subject to options currently exercisable, or exercisable within 60 days after February 1, 2017, are deemed outstanding for the purpose of computing the percentage ownership of the person holding those options, but are not deemed outstanding for computing the percentage ownership of any other person.

Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of Common Stock, except to the extent spouses share authority under community property laws.

	Common Stock Beneficially Owned				
Name and Address of Beneficial Owner [1]	Shares	**Percent Prior to Offering [2]**		**Percent Following Completion of Offering [2]**	
Greater than 5% Holders					
David Green	1,313,886	7.3	%(3)	4.6	%(3)
First Pecos LLC and affiliates	1,077,018	6.3	%(4)	3.9	%(4)
Named Executive Officers					
James J. McGorry	549,500	3.1	%(5)	2.0	%(5)
Thomas W. McNaughton	466,574	2.7	%(6)	1.7	%(6)
Saverio LaFrancesca, M.D.	212,748	1.2	%(7)		*(7)
Non-Employee Directors					
John J. Canepa	92,241		*(8)		*(8)
John F. Kennedy	138,432		*(9)		*(9)
Thomas H. Robinson	125,000		*(10)		*(10)
Blaine H. McKee	50,000		*(11)		*(11)

All current executive officers and directors, as a group (7 persons)	1,634,495	9.0	%(12)	5.7	%(12)

* Represents less than 1% of all of the outstanding shares of Common Stock.

(1) Unless otherwise indicated, the address for all persons shown is c/o Biostage, Inc., 84 October Hill Road, Suite 11, Holliston, Massachusetts 01746.

(2) Based on 17,116,570 shares of Common Stock outstanding on February 1, 2017, together with the applicable options for each stockholder that become exercisable within 60 days. With respect to percentages following completion of this offering, amounts assume that all shares of Series C Preferred Stock are converted into shares of common stock.

(3) Includes options to acquire 775,627 shares that are exercisable within 60 days of February 1, 2017, and 538,259 shares.

(4) This information is based solely upon an amended Schedule 13D filed jointly by First Pecos LLC (“Pecos”), Banco Panamericano, Inc. ("Banco"), Leslie Jabine (“Jabine”) and Chip Greenblatt (“Greenblatt”) on October 27, 2016 reporting beneficial ownership as of October 20, 2016. Consists of:

(a) 547,000 shares held by Pecos;
(b) 490,018 shares held by Banco; and
(c) 40,000 shares held by Jabine.

Greenblatt, as sole manager of Pecos and sole director of Banco, has voting and investment power with respect to the shares held by those entities.

(5) Includes options to acquire 423,200 shares exercisable within 60 days of February 1, 2017, and 126,300 shares.
(6) Includes options to acquire 260,446 shares exercisable within 60 days of February 1, 2017, and 206,128 shares.
(7) Includes options to acquire 168,750 shares exercisable within 60 days of February 1, 2017, and 43,998 shares.
(8) Includes options to acquire 75,000 shares exercisable within 60 days of February 1, 2017and 17,241 shares.
(9) Includes options to acquire 80,026 shares that are exercisable within 60 days of February 1, 2017, and 58,406 shares.
(10) Includes options to acquire 75,000 shares that are exercisable within 60 days of February 1, 2017, and 50,000 shares.
(11) Includes options to acquire 50,000 shares that are exercisable within 60 days of February 1, 2017.
(12) Includes options to acquire 1,132,422 shares that are exercisable within 60 days of February 1, 2017 and 502,073 shares.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information as of December 31, 2016 concerning the number of shares of Common Stock issuable under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Restricted Stock Units, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights	Number of Securities Remaining Available For Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in

	(a)	(b)	Column (a)) (c)	
Equity compensation plans approved by security holders[1]	3,878,082	$ 2.80	2,036,994	(2)
Equity compensation plans not approved by security holders	—	—	—	
Total	3,878,082	$ 2.80	2,036,994	

(1) Consists of our 2013 Equity Incentive Plan, or 2013 Plan, and our Employee Stock Purchase Plan.

(2) Includes 1,945,632 shares available for future issuance under our 2013 Plan and 91,362 shares available for future issuance under our Employee Stock Purchase Plan.

DESCRIPTION OF OUR CAPITAL STOCK

The following description of our common stock, warrants to purchase our common stock and Series C Convertible Preferred Stock summarizes the material terms and provisions of the securities that we may offer under this prospectus. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our 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. As of February 1, 2017, there were 17,116,570 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 February 2, 2017, the closing price for our common stock, as reported on the NASDAQ Capital Market, was $0.756 per share. As of the close of business on February 1, 2017, there were 180 stockholders of record of our common stock. Prior to our name change on March 31, 2016 from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc., our common stock was listed on the NASDAQ Capital Market under the symbol "HART."

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.

Series C Convertible Preferred Stock

General

Our Board of Directors is authorized to issue up to 2,000,000 shares of preferred stock in one or more series without shareholder approval. Our Board of Directors may determine the designations, powers, preferences and the relative, participating, optional or other special rights, and any qualification, limitations and restrictions, of each series of preferred stock. Our Board of Directors has designated 5,000 shares of preferred stock as Series A Junior Participating Cumulative Preferred Stock, 1,000,000 shares of preferred stock as Series B Convertible Preferred Stock and shares of preferred stock as Series C Convertible Preferred Stock, which we refer to herein as the Series C Preferred Stock. The Series A Junior Participating Cumulative Preferred Stock and Series B Convertible Preferred Stock is not being registered pursuant to the registration statement of which this prospectus forms a part. As of February 1, 2017, there were no shares of preferred stock outstanding.

Rank

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

Conversion

Each share of the Series C Preferred Stock is convertible into shares of common stock at any time at the option of the holder, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of our common stock if, as a result of such conversion, the holder would own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock. The conversion rate of the Series C Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Dividends

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

Voting Rights

Except as provided in the Certificate of Designation or as otherwise required by law, the holders of Series C Preferred Stock will have no voting rights. However, we may not, without the consent of holders of a majority of the outstanding shares of Series C Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series C Preferred Stock, increase the number of authorized shares of Series C Preferred Stock, or enter into any agreement with respect to the foregoing.

Liquidation Rights

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

Beneficial Ownership Limitation

The Company may not effect any conversion of the Series C Preferred Stock, and a holder does not have the right to convert any portion of the Series C Preferred Stock to the extent that, after giving effect to the conversion set forth in a notice of conversion such holder would beneficially own in excess of the Beneficial Ownership Limitation, or such holder, together with such holder's affiliates, and any persons acting as a group together with such holder or affiliates, would beneficially own in excess of the Beneficial Ownership Limitation. The "Beneficial Ownership Limitation" is 4.99% of the number of shares of the common stock outstanding immediately after giving effect to the issuance of

shares of common stock issuable upon conversion of Series C Preferred Stock held by the applicable holder. A holder may, with 61 days prior notice to the Company, elect to increase or decrease the Beneficial Ownership Limitation; provided, however, that in no event may either the holder Beneficial Ownership Limitation or the affiliate Beneficial Ownership Limitation be 9.99% or greater.

Exchange Listing

We do not plan on making an application to list the shares of Series C Preferred Stock on the NASDAQ Capital Market, any national securities exchange or other nationally recognized trading system. Our common stock issuable upon conversion of the Series C Preferred Stock is listed on the NASDAQ Capital Market.

Failure to Deliver Conversion Shares

If the Company fails to timely deliver shares of common stock upon conversion of the Series C Preferred Stock (the "Conversion Shares") within the time period specified in the Certificate of Designation (within three trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), and if the holder has not exercised its Buy-In rights as described below with respect to such shares, then the Company is obligated to pay to the holder, as liquidated damages, an amount equal to $50 per business day (increasing to $100 per business day after the third business day and $200 per business day after the tenth business day) for each $5,000 of Conversion Shares for which the Series C Preferred Stock converted which are not timely delivered. If the Company makes such liquidated damages payments, it is not also obligated to make Buy-In payments with respect to the same Conversion Shares.

Compensation for Buy-In on Failure to Timely Deliver Shares

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

Subsequent Rights Offerings; Pro Rata Distributions

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

shares of common stock acquirable upon complete conversion of the Series C Preferred Stock (without regard to any limitations on conversion).

Fundamental Transaction

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

Warrants

The following is a brief summary of the material terms of the warrants offered pursuant to this prospectus and is subject in all respects to the provisions contained in the warrants, the form of which is filed as an exhibit to this prospectus. As of February 1, 2017, there were warrants to purchase 1,560,284 shares of our common stock outstanding. The previously issued warrants all have an exercise price of $1.7625 per warrant and are exercisable commencing November 19, 2016 through their expiration date of May 19, 2021.

Exercisability

Holders may exercise warrants at any time up to 11:59 p.m., New York time, on the date that is five years after the date on which such warrants were issued. The warrants are exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise discussed below). The holder of warrants does not have the right to exercise any portion of the warrant if the holder would beneficially own in excess of 4.99% of the shares of our common stock outstanding immediately after giving effect to such exercise. This percentage may, however, be raised or lowered to an amount not to exceed 9.99% at the option of the holder upon at least 61 days' prior notice from the holder to us.

Cashless Exercise

At any time when a registration statement covering the issuance of the shares of common stock issuable upon exercise of the warrants is not effective, the holder may, at its option, exercise its warrants on a cashless basis. When exercised on a cashless basis, a portion of the warrant is cancelled in payment of the purchase price payable in respect of the number of shares of our common stock purchasable upon such exercise.

Exercise Price

The exercise price of common stock purchasable upon exercise of the warrants is $ per share. The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications or similar events affecting our common stock. Holders of the warrants are entitled to participate in any subsequent rights offering or distribution of our assets on an as-if-exercised basis.

Transferability

The warrants may be transferred at the option of the holder upon surrender of the warrants with the appropriate instruments of transfer.

Exchange Listing

We do not plan on making an application to list the warrants on the NASDAQ Capital Market, any national securities exchange or other nationally recognized trading system. Our common stock underlying the warrants is listed on the NASDAQ Capital Market.

Fundamental Transactions

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities with cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. In addition, as further described in the form of warrant filed as an exhibit to this registration statement, in the event of any fundamental transaction, the holders of the warrants will have the right at any time concurrently with, or within 30 days after, the consummation of the fundamental transaction to require us or any successor entity to purchase the warrants for an amount in cash equal to the value of the unexercised portion of the warrant using the Black-Scholes Option Pricing Model.

Rights as Stockholder

Except as otherwise provided in the warrants (such as the rights described above of a warrant holder upon our sale or grant of any rights to purchase stock, warrants or securities or other property to our stockholders on a pro rata basis) or by virtue of such holder’s ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the warrants. Rather, the number of shares of common stock to be issued will be rounded down to the nearest whole number.

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 65,972 were issued as of February 1, 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:

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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 publicly policy as expressed in the Securities Act and is therefore unenforceable.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement, we have engaged H.C. Wainwright & Co., LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering of our securities pursuant to this prospectus on a reasonable best efforts basis. The terms of this offering were subject to market conditions and negotiations between us, the placement agent and prospective investors. The engagement agreement does not give rise to any commitment by the placement agent to purchase any of our securities, and the placement agent will have no authority to bind us by virtue of the engagement agreement. Further, the placement agent does not guarantee that it will be able to raise new capital in any prospective offering. The placement agent may engage sub-agents or selected dealers to assist with the offering.

Only certain institutional investors purchasing the securities offered hereby will execute a securities purchase agreement with us, providing such investors with certain representations, warranties and covenants from us, which representations, warranties and covenants will not be available to other investors who will not execute a securities purchase agreement in connection with the purchase of the securities offered pursuant to this prospectus. Therefore, those investors shall rely solely on this prospectus in connection with the purchase of securities in the offering.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about , 2017.

We have agreed to pay the placement agent a total cash fee equal to 7% of the gross proceeds of this offering, except with respect to cash consideration paid to us in this offering by certain investors, in which case we will pay the placement agent a cash fee equal to 4% of the gross proceeds received from such investors. We will also pay the placement agent a management fee equal to 1% of the gross proceeds of this offering, a reimbursement for out-of-pocket expenses in the amount of up to $35,000 and a reimbursement for the placement agent’s legal fees and expenses in the amount of $100,000. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent fees and expenses, will be approximately $550,000.

In addition, we have agreed to issue to the placement agent warrants to purchase up to 5% of the aggregate number of shares of common stock sold in this offering at an exercise price of $ per share (representing 125% of the public offering price for a share of common stock and related warrant to be sold in this offering). The placement agent warrants will have substantially the same terms as the warrants being sold to the investors in this offering. Pursuant to FINRA Rule 5110(g), the placement agent warrants and any shares issued upon exercise of the placement agent warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this

offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the placement agent or related persons do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

We have also agreed to give the placement agent, subject to a successful completion of this offering, a twelve-month right of first refusal to act as our lead underwriter or placement agent for any further capital raising transactions undertaken by us (exclusive for the first six months and with a minimum of 50% of fees for the remaining six months) and, in the event an offering is not completed during the term of the agreement, a twelve-month tail fee equal to the cash and warrant compensation in this offering, if any investor who was contacted by the placement agent provides us with further capital during such twelve-month period following the expiration or termination of our engagement.

We have agreed to indemnify the placement agent and specified other persons against certain liabilities relating to or arising out of the placement agent's activities under the placement agency agreement and to contribute to payments that the placement agent may be required to make in respect of such liabilities.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants by the placement agent acting as principal. Under these rules and regulations, the placement agent:

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Determination of offering price

The public offering price of the securities we are offering was negotiated between us and the investors, in consultation with the placement agent based on the trading of our common stock prior to the offering, among other things. Other factors considered in determining the public offering price of the shares of our common stock we are offering include the history and prospects of the Company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Listing

Our common stock is listed on the NASDAQ Capital Market under the symbol "BSTG."

Transfer Agent and Registrar

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

Other Relationships

From time to time, the placement agent has provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions. However, except as disclosed in this prospectus, we have no present arrangements with the placement agent for any further services.

The placement agent in this offering served as our exclusive placement agent in a securities offering we consummated in May 2016, pursuant to which it received compensation, including warrants to purchase shares of our common stock.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The Audit Committee charter sets forth the standards, policies and procedures that we follow for the review, approval or ratification of any related person transaction that we are required to report pursuant to Item 404(a) of Regulation S-K promulgated by the Securities and Exchange Commission. Under the Audit Committee charter, which is in writing, the Audit Committee must conduct an appropriate review of these related person transactions on an ongoing basis, and the approval of the Audit Committee is required for all such transactions. The Audit Committee relies on management to identify related person transactions and bring them to the attention of the Audit Committee.

During the 2015 and 2016 fiscal years, we were not a participant in any related person transactions that required disclosure under this heading except as it relates to (i) our engagement of, and payment during 2015 of $166,645 to RobinsonButler, an executive recruiting consultancy firm where Thomas Robinson, a member of our Board of Directors, is a partner, to complete the search for our President and Chief Executive Officer, and (ii) our commercial agreements with Harvard Bioscience that were entered into in connection with the spin-off of our Company. Harvard Bioscience remained a related party during a portion of 2015, due in part to Mr. Green, our former Chairman and CEO, also being a director of Harvard Bioscience. Since Mr. Green resigned from the positions of Chairman and CEO of Biostage on April 17, 2015, Harvard Bioscience is no longer considered a related party. These commercial agreements with Harvard Bioscience include: (i) a Separation and Distribution Agreement to effect the separation and spin-off distribution and provide other agreements to govern our relationship with Harvard Bioscience after the spin-off; (ii) an Intellectual Property Matters Agreement, which governs various intellectual property related arrangements between our Company and Harvard Bioscience, including the separation of intellectual property rights between us and Harvard Bioscience, as well as certain related cross-licenses between the two companies; (iii) a Product Distribution Agreement, which provides that each company will become the exclusive distributor for the other party for products such other party develops for sale in the markets served by the other; (iv) a Tax Sharing Agreement, which governs the parties respective rights, responsibilities and obligations with respect to tax liabilities and benefits, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings and other matters regarding taxes for periods before, during and after the spin-off; (v) a Transition Services Agreement, which provided for certain services to be performed on a transitional basis by Harvard Bioscience to facilitate our transition into a separate public reporting company for time frames of limited length, which expired in 2014; and (vi) a Sublease of approximately 17,000 square feet of mixed use space of the facility located at 84 October Hill Road, Suite 11, Holliston, Massachusetts, which is our corporate headquarters.

As part of the Transition Services Agreement, and for up to one year following the spin-off date, Harvard Bioscience provided certain support services to us, including, among others, accounting, payroll, human resources and information technology services, with the charges for the transition services generally intended to allow Harvard Bioscience to fully recover the costs directly associated with providing the services, plus all out-of-pocket costs and expenses. In connection with the spin-off and in accordance with these agreements, Harvard Bioscience contributed capital of approximately $15.0 million to us to fund our operations, and transferred to us approximately $0.8 million in assets, made up primarily of property, plant and equipment. As these agreements evidence ongoing commercial arrangements which may involve varying amounts over time, we are unable to provide an approximate dollar value of the amount involved in the transaction. In fiscal 2015, we paid approximately $0.2 million to Harvard Bioscience with

respect to the Transition Services Agreement, Sublease and related cost, and research and development supplies. With respect to such approximate amount paid during fiscal 2015, approximately $50,000 was paid during the period that Harvard Bioscience continued to be a related party. Neither Mr. Green nor Mr. McNaughton receive any amounts from the transactions with Harvard Bioscience relating to their roles as current or former executive officers, and a director as to Mr. Green, of our Company, and it is our understanding that neither Mr. Green nor Mr. McNaughton receive any direct amounts from such agreements and the transactions in relation to their former roles as executive officers of Harvard Bioscience, and Mr. Green's continued role as a director of such company, and their interest is limited to benefits they may receive solely relating to their ongoing roles as executive officer, as to Mr. McNaughton, and director, as to Mr. Green, and stockholders of our Company. As a non-employee director of Harvard Bioscience, Mr. Green also is entitled to receive director compensation that all non-employee directors are entitled to receive under Harvard Bioscience's director compensation programs.

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

Sale of Restricted Securities

Shares of our common stock beneficially owned by individuals who are our affiliates will be restricted securities under the Securities Act. Individuals who may be considered our affiliates are those individuals who control, are controlled by or are under common control with us, as those terms generally are interpreted for federal securities law purposes. These individuals may include some or all of our directors and executive officers. Individuals who are our affiliates will be permitted to sell their shares of our common stock only pursuant to an effective registration statement under the Securities Act, or an exemption from the registration requirements of the Securities Act, such as those afforded by Section 4(a)(1) of the Securities Act or Rule 144 thereunder.

Rule 144

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including an affiliate, who beneficially owns “restricted securities” of a “reporting company” may not sell these securities until the person has beneficially owned them for at least six months. Thereafter, affiliates may not sell within any three-month period a number of shares in excess of the greater of: (i) 1% of the then outstanding shares of common stock as shown by the most recent report or statement published by the issuer; and (ii) the average weekly reported trading volume in such securities during the four preceding calendar weeks.

Sales under Rule 144 by our affiliates also will be subject to restrictions relating to manner of sale, notice and the availability of current public information about us and may be affected only through unsolicited brokers’ transactions.

Persons not deemed to be affiliates who have beneficially owned “restricted securities” for at least six months but for less than one year may sell these securities, provided that current public information about us is “available,” which means that, on the date of sale, we are current in our Exchange Act filings. After beneficially owning “restricted securities” for one year, our non-affiliates may engage in unlimited re-sales of such securities.

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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. Certain legal matters in connection with this offering will be passed upon for the placement agent by Ellenoff Grossman & Schole LLP, New York, NY.

EXPERTS

The consolidated financial statements of Biostage, Inc. as of December 31, 2015 and 2014, and for each of the years in the two-year period ended December 31, 2015, have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

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

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information requirements of the Exchange Act and, in accordance therewith, file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's Public Reference Room at 100 F Street, Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room. These documents also may be accessed through the SEC's electronic data gathering, analysis and retrieval system, or EDGAR, via electronic means, including the SEC's home page on the Internet (*www.sec.gov*).

We 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.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

BIOSTAGE, INC. AND SUBSIDIARIES

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	September 30, 2016	December 31, 2015
Assets		
Current Assets:		
Cash	$ 6,006	$ 7,456
Accounts receivable	66	21
Inventory	41	75
Prepaid expenses	96	330
Total current assets	6,209	7,882
Property, plant and equipment, net	988	1,074
Total assets	$ 7,197	$ 8,956
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 803	$ 357
Accrued and other current liabilities	762	297
Warrant liability	846	-
Total current liabilities	2,411	654
Total liabilities	$ 2,411	$ 654
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value; 1,000,000 shares authorized; none issued and outstanding	-	-
Series B convertible preferred stock, $0.01 par value: 1,000,000 shares authorized; 695,857 shares issued and none outstanding	-	-
Common stock, $0.01 par value; 30,000,000 shares authorized and 17,108,968 and 14,101,395 shares issued and outstanding, respectively	171	141
Additional paid-in capital	37,599	32,908
Accumulated deficit	(32,976)	(24,739)
Accumulated other comprehensive loss	(8)	(8)
Total stockholders' equity	4,786	8,302
Total liabilities and stockholders' equity	$ 7,197	$ 8,956

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Three Months ended September 30,		Nine Months ended September 30,	
	2016	2015	2016	2015
Revenues	$ 26	$ 37	$ 54	$ 110
Cost of revenues	13	18	57	55
Gross profit (deficit)	13	19	(3)	55
Operating expenses:				
Research and development	2,225	1,269	5,279	3,504
Selling, general and administrative	937	1,042	3,261	5,962
Total operating expenses	3,162	2,311	8,540	9,466
Operating loss	(3,149)	(2,292)	(8,543)	(9,411)
Other income (expense):				
Change in fair value of warrant liability, net of issuance costs of $129	96	-	306	-
Other expense	-	-	-	(3)
	96	-	306	(3)
Loss before income taxes	(3,053)	(2,292)	(8,237)	(9,414)
Income taxes	-	-	-	-
Net loss	$ (3,053)	$ (2,292)	$ (8,237)	$ (9,414)
Basic and diluted net loss per share	$ (0.18)	$ (0.19)	$ (0.53)	$ (0.91)
Weighted average common shares, basic and diluted	17,107	11,974	15,585	10,395
Comprehensive loss:				
Net loss	$ (3,053)	$ (2,292)	$ (8,237)	$ (9,414)
Foreign currency translation adjustments	-	-	-	(8)
Total comprehensive loss	$ (3,053)	$ (2,292)	$ (8,237)	$ (9,422)

See accompanying notes to unaudited consolidated financial statements.

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BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (8,237)	$ (9,414)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Share-based compensation expense	1,027	3,612
Depreciation	340	347
Change in fair value of warrant liability, net of issuance costs of $129	(306)	-
Changes in operating assets and liabilities:		
Related party receivables, net	-	11
Accounts receivable	(45)	(54)
Inventories	34	63
Prepaid expenses	234	235
Accounts payable	418	(150)
Accrued and other current liabilities	465	(212)
Net cash used in operating activities	(6,070)	(5,562)
Cash flows from investing activities		
Additions to property and equipment	(225)	(175)
Net cash used in investing activities	(225)	(175)
Cash flows from financing activities		
Proceeds from issuance of common stock and warrants, net of issuance costs	4,496	-
Proceeds from issuance of common stock, net of issuance costs	349	3,314
Proceeds from issuance of convertible preferred stock, net of issuance costs	-	5,357
Net cash provided by financing activities	4,845	8,671
Effect of foreign exchange rates on cash	-	(8)
Net increase (decrease) in cash	(1,450)	2,926
Cash at beginning of period	7,456	5,272
Cash at end of period	$ 6,006	$ 8,198
Supplemental disclosure of cash flow information and non-cash investing and financing activities:		

Equipment purchases included in accounts payable	$ 28	$ -
Grant date fair value of warrants issued to placement agent	$ 116	$ -

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

Biostage, Inc., formerly Harvard Apparatus Regenerative Technology, Inc. ("Biostage" or the "Company") is a biotechnology company developing bioengineered organ implants based on our novel Cellframe ™ technology. Our Cellframe technology is comprised of a biocompatible scaffold that is seeded with the recipient's own stem cells. We believe that this technology may prove to be effective for treating patients across a number of life-threatening medical indications who currently have unmet medical needs. We are currently developing our Cellframe technology to treat life-threatening conditions of the esophagus, bronchus or trachea with the objective of dramatically improving the treatment paradigm for those patients.

Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and acquiring operating assets.

The Company changed its name from Harvard Apparatus Regenerative Technology, Inc. to Biostage, Inc. on March 31, 2016. All references to the Company have been changed to Biostage in the accompanying consolidated financial statements and notes thereto.

Basis of Presentation

The financial statements reflect the Company's financial position, results of operations and cash flows in conformity with accounting principles generally accepted in the United States ("GAAP").

Earnings per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and warrants and unvested restricted stock.

The Company applied the two-class method to calculate basic and diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2016, as its warrants to purchase common stock are participating securities.

The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company was in a net loss position for the three and nine months ended September 30, 2016 and warrant holders do not participate in losses.

Basic and diluted shares outstanding are the same for each period presented as all common stock equivalents would be antidilutive due to the net losses incurred.

Reclassification

Sales and marketing expenses of $0.1 million and $0.3 million for the three and nine months ended September 30, 2015, respectively, have been reclassified to selling, general and administrative expenses to conform to the 2016 presentation.

Unaudited Interim Financial Information

The accompanying interim balance sheet as of September 30, 2016 and consolidated interim statements of operations and comprehensive loss and cash flows for the nine months ended September 30, 2016 and 2015 are unaudited. The interim unaudited consolidated financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company’s financial position as of September 30, 2016 and its results of operations and cash flows for the nine months ended September 30, 2016 and 2015. The financial data and other information disclosed in these notes related to the three month period ended September 30, 2016 and 2015 are unaudited. The results for the nine months ended September 30, 2016 are not necessarily indicative of results to be expected for the year ending December 31, 2016, any other interim periods or any future year or period.

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BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

2. Summary of Significant Accounting Policies and Recently Issued Accounting Pronouncements

Summary of Significant Accounting Policies

The accounting policies underlying the accompanying unaudited consolidated financial statements are those set forth in Note 2 to the financial statements for the year ended December 31, 2015 included in the Company's Annual Report on Form 10-K, and additionally the following accounting policy for warrants issued during the nine months ended September 30, 2016.

Warrant Accounting

The Company classifies a warrant to purchase shares of its common stock as a liability on its consolidated balance sheets as this warrant is a free-standing financial instrument that may require the Company to transfer consideration upon exercise. Each warrant is initially recorded at fair value on date of grant using the Black-Scholes model and net of issuance costs, and it is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-15, " *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,"* to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. This update is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company has not adopted ASU 2014-15 and does not expect the adoption to have a significant impact on the Company's consolidated financial statements or related disclosures.

In February 2016, the FASB, issued ASU, 2016-02- *Leases (Topic 842)*. The ASU requires companies to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leased assets. ASU 2016-02 will be effective for the Company in the first quarter of 2019, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on the Company's consolidated financial statements or related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Stock Compensation - Improvements to Employee Share-Based Payment Accounting,* ("ASU 2016-09"), which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and policy elections on the impact for forfeitures. ASU 2016-09 is effective for fiscal years beginning after December 15, 2017 and interim periods within annual periods beginning after December 15, 2018. The Company has not adopted ASU 2016-09 and does not expect the adoption to have a significant impact on the Company's consolidated financial statements or related disclosures.

3. Capital Stock, Financing and Liquidity

Capital Stock

On May 19, 2016, the Company closed on a Securities Purchase Agreement (the "Purchase Agreement") for the sale by the Company of 2,836,880 shares of the Company's common stock at a purchase price of $1.7625 per share and the issuance of warrants to purchase 1,418,440 shares of common stock at an exercise price of $1.7625 per warrant for gross proceeds of $5.0 million or $4.6 million, net of issuance costs. Additionally, the Company issued the placement agent warrants to purchase 141,844 shares of common stock to the placement agent for the offering at an exercise price of $1.7625 per warrant. The warrants are initially exercisable commencing November 19, 2016 through their expiration date of May 19, 2021.

On February 18, 2015, the Company closed an underwritten public offering of 2,070,000 registered shares of its common stock, at a price to the public of $1.75 per share, and 695,857 registered shares of its $0.01 par Series B Convertible Preferred Stock ("Series B") at a price to the public of $8.75 per share. Gross proceeds from the offering were $9.7 million and underwriters' fees and issuance costs totaled $1.1 million. Thus, the Company generated net proceeds of $8.6 million from the underwritten public offering.

The Series B was convertible into five shares of common stock at the option of the holder, subject to certain limitations related to the holder's ownership percentage of the Company's outstanding common stock. The Series B voted with the common stock on all matters on an as-converted basis, and had no preference to the common shares in respect of dividends, voting, liquidation or otherwise.

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BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

During 2015, all outstanding shares of Series B were converted to common stock, including 205,279 shares of Series B which were converted into 1,026,395 shares of common stock during the nine months ended September 30, 2015.

3. Capital Stock, Financing and Liquidity (continued)

Aspire Purchase Agreement

On December 15, 2015, the Company entered into a common stock purchase agreement (the "Aspire Purchase Agreement"), with Aspire Capital Fund, LLC, ("Aspire Capital"), under which Aspire Capital is committed to purchase up to an aggregate of $15.0 million of the Company's common stock over the approximately 30-month term of the Purchase Agreement. In consideration for entering into the Aspire Purchase Agreement, concurrently with the execution of the Aspire Purchase Agreement, the Company issued Aspire Capital 150,000 shares of our common stock as a commitment fee (the "Commitment Shares").

Upon execution of the Aspire Purchase Agreement, the Company sold to Aspire Capital 500,000 shares of common stock at $2.00 per share (the "Initial Purchase Shares"), which resulted in net proceeds of approximately $0.9 million. Pursuant to the Aspire Purchase Agreement and Registration Rights Agreement, the Company registered 2,688,933 shares of its common stock. This includes the Commitment Shares and the initial purchase shares issued to Aspire Capital and 2,038,933 shares of common stock which the Company may issue to Aspire Capital in the future.

Under the approximately 30-month term of the Aspire Purchase Agreement, on any trading day on which the closing sale price of the Company's common stock exceeds $0.50, the Company had the right, in its sole discretion, to direct Aspire Capital to purchase up to 150,000 shares of the Company's common stock per trading day, at a per share price calculated by reference to the prevailing market price of the Company's common stock. In addition, the Company had the right, from time to time in its sole discretion, to sell Aspire Capital an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the Nasdaq Capital Market on the next trading day, subject to a maximum number of shares which the Company may determine and a minimum trading price. The purchase price per purchase share pursuant to such purchase notices were calculated by reference to the prevailing market price of the Company's common stock.

There were no trading volume requirements or restrictions under the Aspire Purchase Agreement, and the Company controlled the timing and amount of any sales of our common stock to Aspire Capital. There were no monetary penalties for the Company failing to maintain effectiveness of registration. Aspire Capital had no right to require any sales by the Company, but was obligated to make purchases from us as the Company directs in accordance with the Aspire Purchase Agreement. There were no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Additionally, Aspire Capital could hedge its position in the Company's common stock.

On May 12, 2016, the Company issued 150,000 shares of common stock under this arrangement in exchange for gross proceeds of $371 thousand or $349 thousand, net of issuance costs.

The Company terminated the Aspire Purchase Agreement effective as of May 17, 2016. The agreement was terminated by the Company without any penalty or cost to the Company.

Liquidity

The Company has incurred substantial operating losses since its inception, and as of September 30, 2016 has an accumulated deficit of approximately $33.0 million. The Company expects to continue to incur operating losses and negative cash flows from operations in 2016 and in future years. Management believes that the Company's cash at September 30, 2016 will be sufficient to meet the Company's obligations through December 31, 2016 and into early 2017. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company will need to raise additional funds in future periods to fund its operations. Cash requirements and cash resource needs will vary significantly depending upon the timing and the financial and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for the Company's products that are currently under development. The Company will seek to raise necessary funds through a combination of publicly or private equity offerings, debt financings, other financing mechanisms, or strategic collaborations and licensing arrangements. The Company may not be able to obtain additional financing on terms favorable to us, if at all.

The Company's operations will be adversely affected if it is unable to raise or obtain needed funding and may materially affect the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and therefore, the financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amount and classifications of liabilities that may result from the outcome of this uncertainty.

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BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

4. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

During the year ended December 31, 2015, the Company had no assets or liabilities requiring fair value measurements. As discussed in Note 3, on May 19, 2016, the Company closed on the Purchase Agreement for the sale by the Company of shares of the Company's common stock and the issuance of warrants to purchase 1,418,440 shares of common stock at an exercise price of $1.7625 per warrant. Additionally, the Company issued the placement agent warrants to purchase 141,844 shares of Common Stock at an exercise price of $1.7625 per warrant. The warrants are initially exercisable commencing November 19, 2016 through their expiration date of May 19, 2021. The liability associated with those warrants was initially recorded at fair value in the Company's consolidated balance sheet upon issuance, and subsequently re-measured each fiscal quarter. The changes in the fair value between issuance and September 30, 2016 recorded as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss.

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The Company had no assets or liabilities classified as Level 1 or Level 2. The Company has concluded that the warrants issued in connection with the Purchase Agreement, meet the definition of a liability under *ASC 480 Distinguishing liabilities From Equity* and has classified the liability as Level 3.

The Company has re-measured the liability to estimated fair value at September 30, 2016, using the Black-Scholes option pricing model with the following assumptions:

	September 30, 2016
Risk-free interest rate	1.18 %
Expected volatility	73.8 %
Expected term	5.2 years
Expected dividend yield	0 %

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2016:

	Fair Value Measurement as of September 30, 2016 (In thousands)			
	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 846	$ 846
Total	$ -	$ -	$ 846	$ 846

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2016:

	Warrant Liability (in thousands)
Balance at December 31, 2015	$ -
Issuance of warrants	1,281
Change in fair value upon re-measurement	(435)
Balance at September 30, 2016	$ 846

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

There were no transfers between Level 1 and Level 2 in any of the periods reported.

5. Related Party Transactions

On October 31, 2013, Harvard Bioscience, Inc. ("Harvard Bioscience") contributed its regenerative medicine business assets, plus $15 million of cash, into Biostage (the "Separation"). On November 1, 2013, the spin-off of the Company from Harvard Bioscience was completed. On that date, the Company became an independent company that operates the regenerative medicine business previously owned by Harvard Bioscience. The spin-off was completed through the distribution to Harvard Bioscience stockholders of all the shares of common stock of Biostage (the "Distribution").

At the time of the Separation, the Company entered into a 10-year product distribution agreement with Harvard Bioscience under which each company will become the exclusive distributor for the other party for products such other party develops for sale in the markets served by the other. In addition, Harvard Bioscience has agreed that except for certain existing activities of its German subsidiary, to the extent that any Harvard Bioscience businesses desires to resell or distribute any bioreactor that is then manufactured by the Company, the Company will be the exclusive manufacturer of such bioreactors and Harvard Bioscience will purchase such bioreactors from the Company. Since inception of the Company, sales to Harvard Bioscience accounted for 100% of the Company's revenues and receivables.

From inception through April 17, 2015, Harvard Bioscience was considered to be a related party to the Company because David Green, the Company's former Chairman and CEO, was also a director of Harvard Bioscience. After Mr. Green's April 17, 2015 resignation as Chairman and CEO of the Company, Harvard Bioscience is no longer considered a related party. Mr. Green service on the Company's board of directors ended on May 26, 2016 but Mr. Green remains a member of the Board of Directors of Harvard Bioscience. Related party rent expenses with Harvard Bioscience for the period of January 1, 2015 through September 30, 2015, were $51,000.

During the nine months ended September 30, 2015, the Company recognized $165,000 in recruiting expense related to professional search fees to RobinsonButler, an executive recruiting consultancy firm where Tom Robinson, a member of the Company's Board of Directors, is a partner. RobinsonButler was retained by the Company's Board of Directors to complete the search for the Company's CEO and President.

6. Stock-Based Compensation

Biostage 2013 Equity Incentive Plan

The Company maintains the 2013 Equity Incentive Plan (the "Plan") for the benefit of certain of its officers, employees, non-employee directors, and other key persons (including consultants and advisory board members). All options and awards granted under the Plan consist of the Company's shares of common stock.

The Company also issued equity awards under the Plan at the time of the Distribution to all holders of Harvard Bioscience equity awards as part of an adjustment (the "Adjustment") to prevent a loss of value due to the Distribution.

Compensation expense recognized under the Plan relates to service provided by employees, board members and a non-employee of the Company. There was no required compensation associated with the Adjustment awards to employees who remained at Harvard Bioscience.

The Company has granted options to purchase common stock and restricted stock units under the Plan. Stock option activity during the nine months ended September 30, 2016 was as follows:

	Amount	Weighted-average exercise price
Outstanding at December 31, 2015	3,253,118	$ 3.29
Granted	915,000	1.58
Canceled	(288,817)	3.69
Outstanding at September 30, 2016	3,879,301	$