

Biostage, Inc.  
Form 10-K  
March 29, 2019

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

**x Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the fiscal year ended December 31, 2018**

**or**

**Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from        to**

**Commission File Number 001-35853**

**BIOSTAGE, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**                                  **45-5210462**  
(State or other jurisdiction of        (I.R.S. Employer  
Incorporation or organization)        Identification No.)

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

(Address of Principal Executive Offices, including zip code)

**(774) 233-7300**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$0.01 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

YES  NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

YES  NO

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES  NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

YES  NO

## Edgar Filing: Biostage, Inc. - Form 10-K

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. "

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

Large accelerated filer " Accelerated filer "  
Non-accelerated filer x Smaller reporting company x  
Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.

YES " NO x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2018 was approximately \$12,553,138. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding voting power of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

At March 25, 2019, there were 6,169,645 shares of the registrant's common stock issued and outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Company's definitive Proxy Statement in connection with the 2019 Annual Meeting of Stockholders (the Proxy Statement), to be filed within 120 days after the end of the Registrant's fiscal year, are incorporated by reference into Part III of this Form 10-K. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.



**BIOSTAGE, INC.**

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*This Annual Report on Form 10-K contains statements that are not statements of historical fact and are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the Exchange Act), each as amended. The forward-looking statements are principally, but not exclusively, contained in “Item 1: Business” and “Item 7: Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about management’s confidence or expectations and our plans, objectives, expectations and intentions that are not historical facts. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “seek,” “expect,” “plans,” “aim,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “intends,” “think,” “continue,” “potential,” “is likely,” “permit,” “objectives,” “optimistic,” “new,” “goal,” “target,” “strategy” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and 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 detail under the heading “Item 1A. Risk Factors” beginning on page 15 of this Annual Report on Form 10-K. You should carefully review all of these factors, as well as other risks described in our public filings, and you should be aware that there may be other factors, including factors of which we are not currently aware, that could cause these differences. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. 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. Biostage, Inc. is referred to herein as “we,” “our,” “us,” and “the Company.”*

## **PART I**

### **Item 1. *Business.***

#### **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 that is 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 materials 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 regenerate tissue and restore the continuity and integrity of the organ. We are pursuing our Cellspan™ Esophageal Implant (CEI) technology as our first two product candidates, to address pediatric esophageal atresia and to address esophageal disease, 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 advancing our technology toward filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for our two CEI product candidates. We are focusing our product development program based on the greatest medical need, analysis of existing surgical options and physician validation.

We believe that, of our two current programs, the CEI program to treat pediatric esophageal atresia may provide a shorter time to a commercial product and the greater overall potential value in the U.S. market. In addition to providing a novel solution for a great medical need, approval of our pediatric esophageal atresia product candidate may result in receipt of a priority review voucher, which if achieved, could potentially provide significant value to Biostage in the future. We have continued to advance the CEI adult program and we will be in a position to file an IND application for that product first, as the data set for that application will be completed first. We plan to file an IND for the adult esophageal disease product candidate mid-year 2019. We are now completing the remaining preclinical studies for the esophageal atresia product candidate and expect to file an IND for that product candidate in early 2020.



**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 proprietary biocompatible, synthetic scaffold, produced to mimic the dimensions of the organ to be regenerated, and incubated in a proprietary organ bioreactor. The scaffold is electrospun from polyurethane (PU) to form a non-woven, hollow tube. The specific microstructures of the Cellspan implants are designed to allow the cultured cells to attach to and cover the scaffold fibers.

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

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

In May 2016, we reported an update of results from additional, confirmatory pre-clinical large-animal studies. We disclosed that the studies had demonstrated in a predictive large-animal model the ability of our Cellspan organ implant to successfully stimulate the regeneration of a section of esophagus that had been surgically removed. CEIs, consisting of a proprietary biocompatible synthetic scaffold seeded with the recipient animal's own stem cells, were surgically implanted in place of the esophagus section that had been removed. After the surgical full circumferential resection of a portion of the thoracic esophagus, the Cellspan implant stimulated the reconstitution of full esophageal structural integrity and continuity.

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

Study animals were returned to a solid diet three weeks after the implantation surgery. The scaffold portions of the Cellspan implants, which are intended to be in place only temporarily, were retrieved approximately three weeks post-surgery via the animal's mouth in a non-surgical endoscopic procedure. Within 2.5 to 3 months, a complete inner epithelium layer and other specialized esophagus tissue layers were regenerated. Two animals in the study were kept in life for almost two years to evaluate the long-term viability of the newly regenerated tubular conduit and were then sacrificed for histological data. Prior to their sacrifice, these animals demonstrated normal weight gain, appeared healthy and free of any significant side effects and received no specialized care.

## **Platform Technology in Life-threatening Orphan Indications**

In November 2016, we were granted Orphan Drug Designation for our CEI 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 (BLA) fee. We also plan to apply for Orphan Drug Designation for our CEI 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 have advanced the development of our Cellframe technology, specifically a CEI, in a series of preclinical studies, including large-animal studies with collaborators. In order to seek approval for the initiation of clinical trials for our CEIs in humans, Good Laboratory Practice (GLP) studies to support the safety of the CEI are required to submit an IND application with the FDA. We have now performed the GLP studies to demonstrate that our technology, personnel, systems and practices are sufficient for advancing into human clinical trials. We have conducted a number of IND-enabling GLP studies demonstrating safety and feasibility of the Cellspan implant. These studies were done primarily in pursuit of our adult esophageal cancer program. During 2018 we also performed additional non-GLP studies for the pediatric esophageal atresia program to optimize that product candidate.

### **First-In-Human Use of Esophageal Implant Product Candidate**

On August 7, 2017, we announced the use of our CEI product candidate in a patient at a major U.S. hospital via an FDA-approved single-use expanded access application. The surgery took place at Mayo Clinic, but we were not allowed to identify the institution publicly at that time. The patient was a 75-year-old male with a life-threatening cancerous mass in his chest that spanned his heart, a lung and his esophagus. The surgery was performed in May 2017 to remove the tumor, repair the heart, part of one lung, and a section of the esophagus. The CEI was interpositioned into the gap in the esophagus created by the removal of the tumor. The patient's surgeon informed us at that time that the surgery was a success and the patient was later discharged from the hospital. In February 2018 the surgeon informed us that the patient had died after living approximately eight months after surgery. The surgeon stated that the cause of death was a stroke, and that the stroke was unrelated to the esophageal implant. The surgeon also informed us that a preliminary autopsy had shown that the esophageal implant resulted in a regenerated esophageal tube in the patient, except for a very small (approximately 5mm) hole outside the implant zone on the lateral wall that was right up against a synthetic graft inserted as part of the patient's heart repair on the vena cava in that same surgery. The synthetic graft on the pericardium was not related to our esophageal implant product and may have acted as an irritant to esophageal tissue where it contacted the esophageal implant. The surgeon also informed us that the esophageal regeneration in this patient was consistent with the regeneration previously observed in our large-animal studies. In January 2019, the surgeon presented the case study publicly at a major U.S. medical conference, including histological data supporting his earlier statements regarding successful regeneration. Mayo Clinic expects to publish an article in a peer-reviewed journal and we expect to be in a position to release additional information on this landmark case at that time.

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 572,000 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 CEIs 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.

## **Focus on Pediatric Esophageal Atresia: a Congenital Abnormality in Need of a Better Solution**

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 CEI solution to address the complications of esophageal atresia, that could potentially be life-changing, organ-sparing, or both.

## **Our Mission and Our Strategy**

Our mission is to revolutionize regenerative medicine by bioengineering patient-specific Cellspan implants that use the patient's own cells to stimulate organ regeneration and restore an organ's structure and continuity. 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 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 based on our Cellframe technology. We are also collaborating with Connecticut Children's Medical Center on a co-development project to translate our Cellframe technology for pediatric esophageal atresia from pre-clinical studies to clinical trials. 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, will stimulate 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 few years, may potentially provide solutions to life-threatening conditions for patients with unmet medical needs.

We believe that our 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 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 CEI is constructed primarily of PU. 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 CEI 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 CEI 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.

## **Unmet Patient Needs and Cellspan Implant Solutions**

### *Esophageal Disease*

There are approximately 572,000 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 20,000 new diagnoses of esophageal cancer in the U.S. each year, and there are more than 16,000 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 approximately one half of the world's esophageal cancer cases occur in China, which would represent the largest potential patient population for our adult esophageal product candidate. We believe that our CEI, 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 CEI 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.

#### *Pediatric 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 in the hospital for several months during the process.

We believe that a pediatric CEI 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 to 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 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. 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, 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* preclinical 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 third phase in our company's progression.

We discontinued development of our earlier initiative in 2014; 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.

## **Clinical Trials**

Our CEI has been designated by the FDA as a combination product biologic. We believe that this is a favorable designation as it allows for orphan designation and a more participatory path to approval. To date, we have conducted numerous pre-clinical studies in our esophageal implant programs and continue to see consistent regeneration. Additionally, our CEI product candidate was used in an FDA-approved first-in-human compassionate use successfully in 2017. We plan to file an IND application at the end of the second quarter of 2019 with the FDA seeking its approval to conduct a Phase I human clinical trial. We are pursuing two indications in the esophagus. The two indications we are pursuing are pediatric esophageal atresia and esophageal disease. 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 or stenosis due to cancer, injury or infection.

We believe that we have excellent pre-clinical and clinical support of the pediatric atresia program through our collaboration with Connecticut Children's Medical Center and our primary investigator Dr. Christine Finck, who is also a member of our Scientific Advisory Board. Essentially, we liken the pediatric atresia market to a rare disease market. Accordingly, the clinical trial population should reflect the ultra-orphan nature of the disease state.

Because esophageal cancer affects only approximately 20,000 patients per year in the U.S. we anticipate that clinical trials for our adult esophageal implant product candidate 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 CEI product. Receipt of expedited review would reduce the overall time through the regulatory approval process. These expedited requests are submitted during the IND process.

We believe that, of our two current programs, the esophageal implant program to treat pediatric esophageal atresia may provide a shorter time to a commercial product and the greater overall potential value in the U.S. market. In addition to providing a novel solution for a great medical need, approval of our pediatric esophageal atresia product candidate may result in receipt of a priority review voucher, which if achieved, could potentially provide significant value to our company in the future. We have continued to advance the esophageal implant adult program for esophageal disease and we will be in a position to file an IND application for that product first, as the data set for that application will be completed first. We plan to file an IND for the adult esophageal disease product candidate mid-year 2019. We are now completing the remaining preclinical studies for the esophageal atresia product candidate and expect to file an IND for that product candidate in early 2020.

We intend to pursue regulatory approval for the CEI product candidates in the U.S., initially. Following clinical trials in other foreign markets, we expect to pursue regulatory approval for the CEI in those foreign markets, as well. We believe that approximately one half of the world's esophageal cancer cases occur in China, which would represent the largest potential patient population for our adult esophageal implant product candidate, and we are consequently preparing to address that market.

## **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 our *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.

Following the failure to receive the funding with respect to a Securities Purchase Agreement in August 2017, and in an effort to conserve cash, we completed a reduction in headcount of 20 persons during October and November 2017, of whom 18 were directly involved in research and development activities. As a result, we had one research and development employee as of December 31, 2017. Following our raising of additional capital in December 2017 and January 2018, we re-hired four of our former research and development employees into key scientific and engineering positions, and retained two others as consultants, in January 2018. Since then several other former employees have rejoined our Company and we have made additional hires such that we ended 2018 with 16 employees. We believe that our new staffing level after those hires, combined with our consultant and co-development collaborator resources, is sufficient to pursue both of our esophageal programs.

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. 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, and then working together to translate our technology from pre-clinical studies to clinical trials. In certain instances, we have entered into agreements that govern the ownership of the technologies developed in connection with these collaborations.

We incurred approximately \$3.9 million and \$7.6 million of research and development expenses in 2018 and 2017, respectively. As we have not yet applied for or received regulatory approval to market any clinical products, no significant amount of these research and development costs have been passed on to our customers.

On March 28, 2018, we were awarded a Fast-Track Small Business Innovation Research (SBIR) grant by the Eunice Kennedy National Institute of Child Health and Human Development to support testing of pediatric CEI. The award for Phase I, which was earned over the nine months ended September 30, 2018, provided for the reimbursement of approximately \$0.2 million of qualified research and development costs.

On October 26, 2018, we were awarded Phase II of the SBIR grant for \$1.1 million to support development, testing, and translation to the clinic through September 2019. The Phase II grant includes an additional \$0.5 million for future period support through September 2020, subject to availability of funding and satisfactory progress on the project.

Based on the above, we have the opportunity to receive up to \$1.8 million under the SBIR grant.

## **Manufacturing**

Biostage has developed a comprehensive manufacturing process for our product candidates, including: cell biology, scaffold production, cell isolation and expansion, seeding of cells on the scaffold, incubation and expansion processes in the bioreactor and product transportation. We currently perform certain manufacturing steps in-house and subcontract certain processes and activities, primarily those related to cell expansion, seeding and incubation, to experienced partners.

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 process and end product have been developed over many years and involve many trade secrets and proprietary know-how. Our Cellspan scaffolds are made from PU, 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 Practices (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 CEI product will be performed at a relatively small number of major hospitals in the U.S., Canada, China 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 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 Cellspan programs are for the esophagus, the bronchi and the trachea, three organs all treated by thoracic surgeons. Therefore, all of those product candidates, 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 anticipate that we will sell products in various markets in the U.S. and various jurisdictions under brand name, logo and product design trademarks and service marks and that these marks will attain material importance in the future.

We also own select U.S. Patents as well as certain patents in Germany. These patents cover aspects of device and processes currently under development by our company. Patents for various processes and devices extend for varying periods according to the date of patent filing or grant and the legal term of patents in the country or countries in which the patent was obtained. The actual protection afforded by a patent can vary from country to country and depends on factors such as the type of patent, scope of protection and available legal remedies.

In addition to issued patents, we have several pending patent applications in the U.S. and key target jurisdictions. We believe that one or more of these pending patent applications may be of importance to material position depending upon factors such as the relevant patent jurisdiction, type of patent granted, and scope of patent claims ultimately allowed in a given jurisdiction. Depending upon factors such as the type of grant and the date on which the patent application was filed, we anticipate that the term of certain pending patents may extend to 2036.

We also rely on unpatented proprietary technologies in the development and commercialization of our products, and we depend upon the skills, knowledge and experience of our scientific and technical personnel, and 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 entered into a sponsored research agreement with Sara Mantero, Maria Adelaide Asnaghi, and the Department of Bioengineering of the Politecnico Di Milano (PDM). Under the terms of this agreement, PDM was 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 were 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. We terminated the sponsored research agreement in 2017.

#### **Sublicense Agreement with Harvard Bioscience**

We have entered into a sublicense agreement with Harvard Bioscience pursuant to which Harvard Bioscience has 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. 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 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 (ATMP), pathway in the European Union (E.U.). On October 18, 2016, we also received written confirmation from FDA's Center for Biologics Evaluation and Research (CBER), that the FDA intends to regulate our CEI as a combination product under the primary jurisdiction of CBER. We further understand that CBER may choose to consult or collaborate with the FDA's Center for Devices and Radiological Health (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.

## Regulatory Strategy

### *Domestic Regulation of Our Products and Business*

The testing, manufacturing, and potential labeling, advertising, promotion, distribution, importing 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 (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. Further, we are required to meet regulatory requirements in countries outside the U.S., which can change rapidly with relatively short notice.

We have been informed by the FDA that our CEI product candidates are combination biologic/device products. 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 (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 (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.

Based on preliminary discussions with the FDA, we expect the clinical trials for our esophageal implant product candidates to be conducted in two sequential phases:

• A Phase 1, or Pilot Trial, where our product would be tested on a small number, perhaps five or six, of patients to demonstrate the product's safety. If successful, that study would be followed by,

A Phase II Registration, or Pivotal Trial, to test the product's efficacy. We believe that the nature of our esophageal products and the sizes of their targeted patient populations would lead to a small number of patients in this trial, relative to most biotechnology clinical trials.

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 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.

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 ensure 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.

*Priority Review Voucher*

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.

Separately, but somewhat related, is a product's ability to qualify its sponsor to receive a Priority Review Voucher (PRV). For a product aimed at prevention or treatment of a "rare pediatric disease" as defined by Food, Drug and Cosmetics Act at 21 USC 360ff, and that also meets certain other qualifying attributes, the product's sponsor may qualify, apply for and receive a PRV, from the FDA. A PRV entitles its holder to Priority Review for a drug application, and the PRV is transferable. Some companies who have received PRV's have sold their PRV's to other companies who have then used the PRV to receive Priority Review for a drug application with the FDA. Recent transfers of PRV's from one company to another have occurred at prices in the \$80 – 125 million range. We intend to apply for rare pediatric disease designation for our pediatric esophageal implant product candidate as a first step in pursuit of a PRV. A PRV is earned only upon marketing approval of the product. There is no certainty that our pediatric esophageal product will achieve marketing approval from the FDA, or that if it does, that FDA would award us a PRV. Further, if received, there is no certainty that the value of a PRV at that future date will compare favorably with the values reflected in recent transfers of PRVs.

### *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. 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 CEI by the FDA to restore the structure and function of the esophagus subsequent to esophageal damage due to cancer, injury or congenital abnormalities. 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. The marketing exclusivity prevents FDA approval of another application for the same product for the same indication for a period of seven years. Orphan status also entitles the product's sponsor to certain other benefits, such as a waiver of the BLA user fee, which is currently a \$2 million value. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

### *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 Asian and European markets, 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.

Legislation similar to the Orphan Drug Act has been enacted in other jurisdictions, including the E.U. The orphan legislation in the E.U. 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, 2018, we had 16 employees working in our business, of whom 15 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 companies, 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, Orgagen, 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 of ours.

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 our 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.

**Executive Officers of the Registrant**

The following table shows information about our executive officers as of December 31, 2018:

<b>Name</b>	<b>Age</b>	<b>Position(s)</b>
James McGorry	62	Chief Executive Officer and Member of the Board of Directors
Hong Yu	46	President
Thomas McNaughton	58	Chief Financial Officer
Dr. William Fodor	60	Chief Scientific Officer

**James McGorry - Chief Executive Officer and Director**

Mr. McGorry has served as our 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 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 was also 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.

**Hong Yu – President**

Mr. Yu has served as our President since May 31, 2018. Mr. Yu is a seasoned executive with extensive knowledge in strategic analytics, wealth management, and investment research. Prior to Biostage, Mr. Yu was most recently a Senior Vice President responsible for strategic analytics at Bank of America, where he was employed for nearly 20 years. During his career, Mr. Yu has built strong business connections in various industries, including biotech/healthcare, financial services, and robotics/artificial intelligence. He developed an expertise in matching emerging companies with cross-border investors, often providing U.S. companies with market access to the vast capital supply in China. Mr. Yu graduated from Huanggang High School (Hubei, China) in 1990 and obtained a B.S.

in biophysics from Peking University (Beijing, China), and M.S. in biostatistics from School of Public Health, University of Illinois (Chicago, IL). Mr. Yu is a charterholder of Chartered Financial Analyst (CFA).

### **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 September 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.

### **Dr. William Fodor - Chief Scientific Officer**

Dr. William Fodor has served as our Chief Scientific Officer since July 2017. On July 2, 2018, Dr. Fodor became an employee of Biostage after serving via a consulting arrangement. Dr. Fodor was a founding scientist at Alexion Pharmaceuticals, where he served as an executive management team member and Senior Director of the Cell/Tissue Engineering, Transgenic Animal and Transplant Programs. He has also served as an Associate Professor at the University of Connecticut Department of Molecular Cell Biology and the Center for Regenerative Biology, extending research areas into stem cells and stem cell engineering. Dr. Fodor was Senior Director of Product Development at ViaCell Inc., leading programs in hematopoietic stem cell process development and manufacturing, mesenchymal stem cell basic research and manufacturing for cardiac repair and pancreatic stem cell research. He was a consultant for the biotechnology industry, serving clients in stem cell research, gene therapy, stem cell manufacturing and stem cell genome engineering. Dr. Fodor has expertise in programs targeting transplant immunology, hematopoiesis, cardiac repair, stem cell potency, gene therapy for liver diseases, tissue engineering, design and oversight of pre-clinical non-GLP and GLP animal models and IND Applications (Pre-clinical and CMC Modules). Dr. Fodor earned a PhD. in genetics from Ohio State University. He completed post-doctoral work at Yale University School of Medicine in the department of immunobiology, investigating the regulation of MHC class I and MHC class II genes in the histocompatibility complex.

### **Available Information and Website**

## Edgar Filing: Biostage, Inc. - Form 10-K

Our website address is *www.biostage.com*. Our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and exhibits and amendments to those reports filed or furnished with the Securities and Exchange Commission (SEC) pursuant to Section 13(a) of the Exchange Act are available for review on our website and the SEC website at *www.sec.gov*. Any such materials that we file with, or furnish to, the SEC in the future will be available on our website as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information on our website is not incorporated by reference into this Annual Report on Form 10-K.

**Item 1A. Risk Factors.**

*The following factors should be reviewed carefully, in conjunction with the other information contained in this Annual Report on Form 10-K. As previously discussed, our actual results could differ materially from our forward-looking statements. Our business faces a variety of risks. We describe below what we believe are currently the material risks and uncertainties we face, but they are not the only risks and uncertainties we face. Additional risks and uncertainties of which we are unaware, or that we currently believe are not material, may also become important factors that adversely affect our business. In addition, past financial performance may not be a reliable indicator of future performance and historical trends should not be used to anticipate results or trends in future periods. If any of the following risks and uncertainties develops into actual events, these events could have a material adverse effect on our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment in our securities. The risk factors generally have been separated into three groups: (i) risks relating to our business, (ii) risks relating to the Separation and (iii) risks relating to our common stock. These risk factors should be read in conjunction with the other information in this Annual Report on Form 10-K.*

**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 U.S. Food and Drug Administration (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 esophageal and trachea implants 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. In 2017, our Cellspan Esophageal Implant (CEI) product candidate was used in a human surgery at Mayo Clinic via an FDA-approved single-use expanded access application. In 2013 and 2014 we had provided a previous generation trachea scaffold device that was used in implants in human patients under compassionate use. To date, we believe that at least four of the six patients who received those tracheal implants have died. While we believe that none of those patients died because of a failure of the applicable device, 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 (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 European Union (E.U.), 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 (IND), pathway for biologics or combination products.

*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., China or the E.U. 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 Premarket Approval (PMA), New Drug Application (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 China, the E.U. 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 first bioengineered trachea implant approved in the U.S. using our first-generation trachea scaffold in an implant was approved under the IND pathway through the FDA's Center for Biologics Evaluation and Research (CBER) for a single compassionate use. Such initial U.S. surgery was led by Professor Paolo Macchiarini, M.D., a surgeon pioneering tracheal replacement techniques. Dr. Macchiarini was not employed or affiliated with our company, and we did not pay him any compensation 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. Since the time we withdrew from involvement with Dr. Macchiarini, 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 product candidates or company and make it difficult to recruit patients for any clinical trials.

*The FDA has informed us that our CEI 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 CEI 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 (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, the FDA's Center for Devices and Radiological Health (CDRH) takes the lead. Alternatively, if the primary mode of action is cellular, then the CBER takes the lead. On October 18, 2016, we also received written confirmation from the CBER that the FDA intends to regulate our CEI 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 E.U., 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 E.U.

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 (U.K.) decided by referendum to leave the the E.U., commonly referred to as "Brexit". On March 29, 2017, the U.K. formally notified the E.U. of its intention to withdraw pursuant to the Treaty on the E.U. The withdrawal of the U.K. from the E.U. will take effect either when agreed upon or, in the absence of such an agreement, two years after the U.K. provided its notice of withdrawal. It appears likely that this withdrawal will continue to involve a process of lengthy negotiations between the U.K. and the E.U. member states to determine the terms of the withdrawal as well as the U.K.'s relationship with the E.U. going forward. The effects of Brexit will depend on any agreements the U.K. makes to retain access to the E.U. markets either during a transitional period or more permanently. Since a significant proportion of the regulatory framework in the U.K. is derived from the E.U. directives and regulations, the referendum could materially change the regulatory regime applicable to the approval of any product candidates in the U.K. In addition, since the EMA is located in the U.K., the implications for the regulatory review process in the E.U. 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.

## **Financial and Operating Risks**

*Our audited financial statements for the year ended December 31, 2018 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.*

We ended December 31, 2018 with approximately \$1.4 million of cash on-hand and will need to raise additional capital in the second quarter to fund operations. We believe that our existing cash resources will be sufficient to fund our planned operations into the second quarter of 2019, and 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. Based on these circumstances, our ability to continue as a going concern is at risk and our independent registered public accounting firm included a "going concern" qualification as to our ability to continue as a going concern in their audit report dated March 29, 2019, included in this Form 10-K. Our cash requirements and cash resources will vary significantly depending upon the timing, financial and other resources that will be required to complete ongoing development and pre-clinical and clinical testing of our products as well as regulatory efforts and collaborative arrangements necessary for our products that are currently under development. In addition to development and other costs, we expect to incur capital expenditures from time to time. These capital expenditures will be influenced by our regulatory compliance efforts, our success, if any, at developing collaborative arrangements with strategic partners, our needs for additional facilities

and capital equipment and the growth, if any, of our business in general. We will require additional funding by the end of the second quarter of 2019 to continue our anticipated operations and support our capital needs. We are currently seeking and will continue to seek financings from other existing and/or new investors to raise necessary funds through a combination of public or private equity offerings. We may also pursue 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, as well as the effects of laws and regulations on foreign investment in the United States under the jurisdiction of the Committee on Foreign Investment in the United States (CFIUS), and other agencies and related regulations, including the Foreign Investment Risk Review Modernization Act (FIRRMA), adopted in August 2018, 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, respond to competitive pressures or unanticipated requirements, or at worst may be forced to curtail or cease our operations.

*We are subject to new U.S. foreign investment regulations, which may impose additional burdens on or may limit certain investors' ability to purchase our common stock, potentially making our common stock less attractive to investors, and may also impact our ability to generate revenues outside of the U.S.*

In October 2018, the U.S. Department of Treasury announced a pilot program to implement part of the FIRRMA, effective November 10, 2018. The pilot program expands the jurisdiction of CFIUS to include certain direct or indirect foreign investments in a defined category of U.S. companies, which may include companies such as Biostage in the biotechnology industry. Among other things, FIRRMA empowers CFIUS to require certain foreign investors to make mandatory filings and permits CFIUS to charge filing fees related to such filings. Such filings are subject to review by CFIUS. Any such restrictions on the ability to purchase shares of our common stock may have the effect of delaying or deterring any particular investment and could also affect the price that some investors are willing to pay for our common stock. In addition, such restrictions could also limit the opportunity for our stockholders to receive a premium for their shares of our common stock in relation to any potential change in control.

We intend to generate significant revenues outside the U.S., including in China. Restrictions, such as those related to CFIUS, not only affect foreign ownership and investments, but also the transfer or licensing of technology from the U.S. into certain foreign markets, including China. Such restrictions, including to the extent they block strategic transactions that might otherwise be in shareholders' interests, may materially and adversely affect our ability to generate revenues in those foreign markets and the results of our operations.

*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 December 31, 2018, we had an accumulated deficit of approximately \$55.8 million. We expect to continue to experience losses in the foreseeable future due to our limited anticipated revenues and significant anticipated expenses. We do not anticipate that we will achieve meaningful revenues for the foreseeable future. In addition, we expect that we will continue to incur significant operating expenses as we continue to focus on additional research and development, preclinical testing, clinical testing and regulatory review and/or approvals of our products and technologies. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

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

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

*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, James McGorry, our President, Hong Yu, our Chief Financial Officer, Thomas McNaughton, our Chief Scientific Officer, Dr. William Fodor, 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 co-development collaboration arrangements 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 implantations involving our products, including the patients who had surgeries utilizing our first-generation scaffold device or our bioreactor technology or our esophageal implant, or patients that may have surgeries utilizing any of our products in the future. Our current product liability coverage is \$10 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 or judgments 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.

*If we incur higher costs as a result of trade policies, treaties, government regulations or tariffs, it could have a materially adverse effect on our business, financial condition or results of operations.*

There is currently significant uncertainty about the future relationship between the United States and China, including with respect to trade policies, treaties, government regulations and tariffs. The current U.S. administration has called for substantial changes to U.S. foreign trade policy including greater restrictions on international trade and significant increases in tariffs on goods imported into the U.S. Under the current status, we do not expect that this tariff will significantly impact any Biostage products and thus the tariff should not have a materially adverse effect on our business, financial condition or results of operations. We are unable to predict whether or when additional tariffs will be imposed or the impact of any such future tariff increases.

*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, manufacturing, 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. 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 materially 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, Orgagen, 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 materially 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 Chinese Renminbi, 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.

*Comprehensive tax reform legislation could adversely affect our business and financial condition.*

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act of 2017 (TCJA), which significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, effective January 1, 2018; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”. The tax rate change resulted in (i) a reduction in the gross amount of our deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of our deferred tax assets, which are recorded with a full valuation allowance. We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the TCJA on us and our affiliates, whether adverse or favorable, is uncertain and may not become evident for some period of time. We urge investors to consult with their legal and tax advisers regarding the implications of the TCJA on an investment in our common stock.

*Changes in the European regulatory environment regarding privacy and data protection regulations could have a materially adverse impact on our results of operations.*

The E.U. has adopted a comprehensive overhaul of its data protection regime in the form of the General Data Protection Regulation (GDPR), which came into effect in May 2018. GDPR extends the scope of the existing E.U. data protection law to foreign companies processing personal data of E.U. residents. The regulation imposes a strict data protection compliance regime with severe penalties of 4% of worldwide turnover or €20 million, whichever is greater, and includes new rights such as the right of erasure of personal data. Although the GDPR will apply across the E.U., as has been the case under the current data protection regime, E.U. Member States have some national derogations and local data protection authorities that will still have the ability to interpret the GDPR, which has the potential to create inconsistencies on a country-by-country basis. Implementation of, and compliance with the GDPR could increase our cost of doing business and/or force us to change our business practices in a manner adverse to our business. In addition, violations of the GDPR may result in significant fines, penalties and damage to our brand and business which could, individually or in the aggregate, materially harm our business and reputation.

### **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., China or the E.U., 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 (QSR), and current Good Manufacturing Practices (cGMP) for our medical products, and International Standards Organization (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, China's National Medical Products Administration, the competent authorities of the E.U. Member States, the EMA and notified bodies, enforce the QSR, cGMP 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, or 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.

*Healthcare legislative reform measures may have a materially adverse effect on our business and results of operations.*

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (ACA) was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to Judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA.

Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The TCJA includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax, an annual fee on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the Medical Device Excise Tax (MDET) on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." The effect that the ACA and its possible repeal and replacement may have on our business remains unclear.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Middle Class Tax Relief and Job Creation Act of 2012 required that the Centers for Medicare & Medicaid Services (CMS), the agency responsible for administering the Medicare program, reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for any product candidate we develop or complementary diagnostics or companion diagnostics or additional pricing pressures.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

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 MDET, 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 the ACA, 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 MDET 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 the MDET has been suspended since 2016, there is no guarantee that the moratorium will be approved for subsequent years. The MDET 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 MDET, 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 the MDET 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 MDET. 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 MDET. To the extent we do not comply with the requirements of the MDET we may be subject to penalties.

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

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

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

*We may 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.

*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

*Our principal stockholders hold a majority of voting power and will be able to exert significant control over us.*

The stockholders who purchased shares of our common stock and related warrants pursuant to a Securities Purchase Agreement dated December 27, 2017 collectively hold shares of common stock that represent approximately 41% of all outstanding voting power, and as such may significantly influence the results of matters voted on by our shareholders. The interests of these stockholders may conflict with your interests. These stockholders have the right to nominate a majority of our Board of Directors and, therefore, effectively could control many other major decisions regarding our operations. This significant concentration of share ownership may adversely affect the trading price for our common stock because investors may perceive disadvantages in owning stock in companies with controlling stockholders.

*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 or exercisable into common stock. On February 10, 2017, we completed a public offering of 1,000,000 shares of common stock and the issuance of warrants to purchase 1,000,000 shares of common stock. Additionally, we issued to the placement agent warrants to purchase 50,000 shares of common stock to the placement agent for the offering. The purchasers of the shares of common stock and warrants to purchase shares of common stock from that offering, as well as our December 2017 private placement and other offerings consummated thereafter, may sell significant quantities of our common stock in the market, which may cause 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, 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 preclinical 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 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 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. We 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 we may at any time in the future issue, additional shares of authorized preferred stock. For example, in our December 2017 private placement transaction, we authorized 12,000 shares of Series D convertible preferred stock, of which we issued 3,108 shares, all of which have been converted into shares of 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.

*Our common stock has been delisted on the NASDAQ Capital Market, which may negatively impact the trading price of our common stock and the levels of liquidity available to our stockholders.*

Our common stock was suspended from trading on the NASDAQ Capital Market, prior to the opening of the market on October 6, 2017 and began quotation on the OTCQB Venture Market on that date, retaining the symbol “BSTG”. On December 7, 2017, the NASDAQ Capital Market filed a Form 25-NSE with the SEC to complete the delisting process. The trading of our common stock on the OTCQB Venture Market rather than the NASDAQ Capital Market may negatively impact the trading price of our common stock and the levels of liquidity available to our stockholders.

Upon such delisting, our common stock became subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than \$5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of shareholders to sell securities in the secondary market. Accordingly, investors in our common stock may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will continue to be eligible for trading or quotation on the OTCQB Venture Market or any other alternative exchanges or markets.

The delisting of our common stock from the NASDAQ Capital Market may adversely affect our ability to raise additional financing through public or private sales of equity securities, may significantly affect the ability of investors to trade our securities, and may negatively affect the value and liquidity of our common stock. Such delisting may also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. Furthermore, because of the limited market and low volume of trading in our common stock that could occur, the share price of our common stock could more likely be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market’s perception of our business, and announcements made by us, our competitors, parties with whom we have business relationships or third parties.

**Item 1B. *Unresolved Staff Comments.***

None.

**Item 2. *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, which is our corporate headquarters, from Harvard Bioscience. 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.

**Item 3. *Legal Proceedings.***

On April 14, 2017, representatives for the estate of a deceased individual filed a civil lawsuit in the Suffolk Superior Court, in Boston, Massachusetts, against the Company, Harvard Bioscience and other defendants. The complaint alleges that the decedent's injury and death were caused by two tracheal implants that incorporated synthetic trachea scaffolds and a biologic component combined by the implanting surgeon with a bioreactor, and surgically implanted in the decedent in two surgeries performed in 2012 and 2013. The civil complaint seeks a non-specific sum of money to compensate the plaintiffs. This civil lawsuit relates to the Company's first-generation trachea scaffold technology for which the Company discontinued development in 2014, and not to the Company's current Cellframe technology nor to its lead development product candidate, the CEI. The litigation is in the discovery stage and the Company intends to vigorously defend this case. While the Company believes that such claim lacks merit, the Company is unable to predict the ultimate outcome of such litigation. In accordance with a separation and distribution agreement between Harvard Bioscience and the Company relating to the spin-off, the Company would be required to indemnify Harvard Bioscience against losses that Harvard Bioscience may suffer as a result of this litigation. The Company has been informed by its insurance provider that the case has been accepted as an insurable claim under the Company's product liability insurance policy.

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. Other than the above matter, there are no such matters pending that the Company expects to be material in relation to its business, financial condition, and results of operations or cash flows.

**Item 4. *Mine Safety Disclosures.***

Not Applicable.



## PART II

### Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.*

#### **Market Information**

Our common stock was initially quoted on the OTCQB Venture Marketplace at the opening of business on October 6, 2017 under the symbol "BSTG." Prior to that time, our common stock traded on the NASDAQ Capital Market also under the symbol "BSTG." From our initial public offering on October 21, 2013 until April 1, 2016, in connection with our name change, our common stock traded on the NASDAQ Capital Market under the symbol "HART."

There were 122 holders of record of our common stock as of March 25, 2019. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

#### **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.

#### **Recent Sales of Unregistered Securities**

In 2018, we completed the following transactions under the Securities Act of 1933 (the Securities Act) in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

·On or about January 3, 2018, we sold to Connecticut Children's Medical Center, 50,000 shares of our common stock at a purchase price of \$2.00 per share and warrants to purchase 75,000 shares of our common stock, with an exercise

price of \$2.00 per warrant. The warrants were immediately exercisable and expire in January 2023.

On or about February 2, 2018, we sold to Jinhui Liu, 302,115 shares of our common stock at a purchase price of \$3.31 per share.

On or about May 29, 2018, we sold to two investors, Du Xiaoyu and Zhou Heping, each 500,000 shares of our common stock at a purchase price of \$3.60 per share for a total combined issuance of 1,000,000 shares of our common stock.

On or about June 29, 2018, we sold to Du Xiaoyu, 250,000 shares of common stock at a purchase price of \$3.60 per share.

**Item 6. *Selected Financial Data.***

Not Applicable.



**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

**NOTE REGARDING FORWARD-LOOKING STATEMENTS**

**Forward-Looking Statements**

*The following section of this Annual Report on Form 10-K entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains statements that are not statements of historical fact and are forward-looking statements within the meaning of federal securities laws. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties.*

*In some cases, you can identify forward-looking statements by terms such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "could," "would," "target," "seek," "aim," "believe," "predicts," "think," "objectives," "optimistic," "new," "goal," "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 in Item 1A. "Risk Factors" of this Annual Report on Form 10-K. You should carefully review all of these factors, as well as the comprehensive discussion of forward-looking statements on page 1 of this Annual Report on Form 10-K.*

**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 and 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 congenital abnormalities, diseases, infections and traumas. Products being developed based on our Cellframe technology for those indications are called Cellspan™ products.

We announced favorable preliminary pre-clinical results of large-animal studies for the esophagus, trachea and bronchus in November 2015. Since then, the Cellspan Esophageal Implant (CEI) product candidates have been our lead development product candidates. We are pursuing two development programs that address conditions of the esophagus: esophageal atresia in pediatric patients and esophageal disease in adult patients. Our Cellspan esophageal product candidates are each intended to provide a surgical solution to stimulate regeneration of a segment of the esophagus missing due to a congenital abnormality or following surgical removal, to establish or reestablish the organ's continuity and integrity.

Approximately one in 4,000 babies in the U.S. is born with esophageal atresia, a congenital condition where the child's esophagus is underdeveloped and 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 together so they can be connected at a later date. This process can take weeks and the procedure can result in 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 that would be pulled up, or a piece of the patient's intestine that would be moved to the gap, to allow a connection to the mouth. We are working to develop a CEI product candidate to address newborns' esophageal atresia, to provide a simpler, more effective and potentially organ-sparing solution.

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, can lead to a severely diminished quality of life and require costly ongoing care. Our CEIs 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.

In May 2016, we reported an update of 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 the esophagus that had been surgically removed for the study. This study and its results were published in an article in Nature Scientific Reports in March 2018. CEIs, 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 two and a half months post-surgery, a complete epithelium and other specialized esophagus tissue layers were regenerated. Animals in the study demonstrated weight gain and appeared healthy and free of any significant side effects, including two that were studied for almost two years and received no specialized care.

In November 2016, we were granted Orphan Drug Designation for our CEI by the U.S. Food and Drug Administration (FDA) to restore the structure and function of the esophagus subsequent to esophageal damage due to cancer, injury or congenital abnormalities. Orphan drug status provides market exclusivity in the U.S. for seven years from the date of the product's approval for marketing. This exclusivity is in addition to any exclusivity we may obtain due to our patents. Additionally, orphan designation provides certain incentives, including tax credits and a waiver of the Biologics License Application (BLA) fee. We also intend to apply for Orphan Drug Designation for our CEI in Europe in the future. Orphan drug status in Europe provides market exclusivity there for ten years from the date of the product's approval for marketing.

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 CEIs in humans.

In October 2016, we announced a regulatory update following our planned pre-Investigational New Drug (pre-IND) meeting with the FDA, for the advancement of our lead product candidate, a CEI to be used to stimulate esophageal regeneration following surgery to address esophageal cancer in adults, into human clinical studies. We subsequently announced our expectation at that time that we would 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. In October 2018, we submitted a follow-up package to the FDA summarizing three additional GLP preclinical studies and an FDA approved first-in-human use of our CEI.

On August 7, 2017, we announced the use of our CEI product candidate in a patient at a major U.S. hospital via an FDA-approved single-use expanded access application. The patient was a 75-year-old male with a life-threatening cancerous mass in his chest that spanned his heart, a lung and his esophagus. The surgery was performed in May 2017

to remove the tumor, repair the heart, part of one lung, and a section of the esophagus. The CEI was inserted into the gap in the esophagus created by the removal of the tumor. In February 2018 the patient's surgeon informed us that the patient had died after living approximately eight months after surgery. The surgeon stated that the cause of death was stroke, and that the stroke was unrelated to the esophageal implant. The surgeon also informed us that a preliminary autopsy had shown that the esophageal implant resulted in a regenerated esophageal tube in the patient, except for a very small (approximately 5mm) hole on the lateral wall that was right up against a synthetic graft inserted as part of the patient's heart repair on the pericardium in that same surgery. The synthetic graft on the pericardium was not related to our esophageal implant product and may have acted as an irritant to esophageal regeneration where it contacted the esophageal implant. The surgeon also informed us that the esophageal regeneration in this patient was consistent with the regeneration previously observed in our large-animal studies. On January 28, 2019 we announced that the surgeon revealed for the first time the details of a single-patient case report that describes the use of new technology to repair the patient's esophagus following esophageal reconstruction associated with the removal of a tumor mass in the chest and noted the segment of the patient's esophagus was successfully reconstructed. This demonstrated that segmental esophageal reconstruction using a stem cell-coated implant can facilitate reconstruction, regrowth and regeneration of a gastrointestinal tissue in a human patient.

In August 2017, we announced that we were reprioritizing our product development program based on greatest unmet medical need, analysis of existing surgical options, and physician validation. We believe that, of our two current programs, the CEI program to treat pediatric esophageal atresia may provide a shorter time to a commercial product and the greater overall potential value. Additionally, approval of our pediatric esophageal atresia product candidate may result in receipt of a priority review voucher, which if achieved, could potentially provide significant value to us in the future. We have continued to advance the CEI adult program and we will be in a position to file an IND application for that product first, as the data set for that application will be completed first. We plan to file an IND for the adult esophageal disease product candidate by the end of the second quarter of 2019. We are completing the GLP studies for the esophageal atresia product candidate and expect to file an IND for that product candidate in early 2020.

We were incorporated and commenced operations on November 1, 2013 as a result of a spin-off from Harvard Bioscience, Inc. (Harvard Bioscience). On that date, we became an independent company that operates the regenerative medicine business previously owned by Harvard Bioscience. The spin-off was completed through the distribution of all the shares of common stock of Biostage to Harvard Bioscience stockholders.

Since our incorporation, we have devoted substantially all of our resources to developing our programs, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. To date, we have financed our operations with proceeds from the sales of common stock and preferred stock. We did not recognize any revenues from research bioreactors during the years ended December 31, 2018 and December 31, 2017. In December 2017, we sold the inventory and rights to manufacture and sell research-only versions of our bioreactors to Harvard Bioscience. We expect to continue to incur operating losses and negative cash flows from operations for the remainder of 2019 and in future years.

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

#### ***December 2017 Private Placements and Reverse Stock Split***

Between December 27, 2017 and December 29, 2017, we entered into Securities Purchase Agreements with new investors for the sale of our capital stock. These agreements and related transactions resulted in the following:

On December 22, 2017, we effected a reverse stock split of our shares of common stock at a ratio of 1-for-20. All share and per share amounts of common stock in this Annual Report on Form 10-K have been retroactively adjusted to reflect the reverse stock split.

Our common stock commenced trading on the OTCQB Venture Market on a reverse stock split basis on December 22, 2017. We had delisted from the NASDAQ Capital Market in October 2017 and commenced trading on the OTCQB Venture Market at that time.

On December 27, 2017, we issued 518,000 shares of our common stock at \$2.00 per share, 3,108 shares of our Series D convertible preferred stock at \$1,000 per share, and warrants to purchase 3,108,000 shares of common stock at an exercise price of \$2.00 per share, in exchange for aggregate gross proceeds of approximately \$4.1 million in a private placement transaction of unregistered shares with a new investor. The warrants were immediately exercisable and expire in December 2022.

***2018 Private Placements***

During 2018 we completed the following private placements:

On January 3, 2018, we issued 50,000 shares of common stock at \$2.00 per share and warrants to purchase 75,000 shares of common stock at an exercise price of \$2.00 per share, in exchange for aggregate gross proceeds of \$100,000 in an unregistered private placement with Connecticut Children's Medical Center (Connecticut Children's). The warrants were immediately exercisable and expire in January 2023. Connecticut Children's Chief Executive Officer, James Shmerling, is a member of our Board of Directors as well as the Board of Directors of Connecticut Children's.

On February 20, 2018, we completed a private placement of 302,115 shares of common stock at a purchase price of \$3.31 per share for gross and net proceeds of \$1.0 million.

On May 29, 2018, we issued 1,000,000 shares of common stock to two new investors at a purchase price of \$3.60 per share for aggregate gross and net proceeds of approximately \$3.6 million and \$3.4 million, respectively, in an unregistered private placement transaction. Following the issuance of these shares, the holders of Series D preferred stock exercised their right to convert all of the 3,108 shares outstanding of Series D preferred stock into 1.554 million shares of common stock as provided for under terms of the Series D preferred stock.

On June 29, 2018, we issued 250,000 shares of common stock to an investor at a purchase price of \$3.60 per share for aggregate gross and net proceeds of approximately \$0.9 million and \$0.8 million, respectively, in an unregistered private placement transaction.

***Small Business Innovation Research Grant***

On March 28, 2018, we were awarded a Fast-Track Small Business Innovation Research (SBIR) grant by the Eunice Kennedy National Institute of Child Health and Human Development to support testing of pediatric CEIs. The award for Phase I, which was earned over the nine months ended September 30, 2018, provided for the reimbursement of up to approximately \$0.2 million of qualified research and development costs.

On October 26, 2018, we were awarded Phase II of the SBIR grant for \$1.1 million to support development, testing, and translation to the clinic through September 2019. The Phase II grant includes an additional \$0.5 million for future period support through September 2020, subject to availability of funding and satisfactory progress on the project.

Based on the above, we have the opportunity to receive up to approximately \$1.8 million total under the SBIR grant.

### ***Headcount***

Following the failure to receive the funding with respect to a Securities Purchase Agreement in August 2017, and in an effort to conserve cash, we completed a reduction in headcount of 20 persons during October and November 2017. In addition, our officers agreed to a temporary reduction in their cash salaries by 50% effective November 2017. During the first quarter of 2018, the salaries paid to our officers were increased to approximately 80% of their contracted rate. We accrued the \$104,000 difference between the officers' contracted rates and amounts paid. In July 2018, we paid these amounts and reinstated the officers' salaries to their contracted rates. Following the capital raises in December 2017 and January 2018 described above, we re-hired several of our former employees into key positions in January 2018, and have since made additional hires. At December 31, 2018, we had 16 employees, of whom fifteen were full-time and one was part-time.

### ***Operating Losses and Cash Requirements***

We have incurred substantial operating losses since our inception, and as of December 31, 2018 have an accumulated deficit of approximately \$55.8 million and will require additional financing to fund future operations. We expect that our cash on hand at December 31, 2018 of \$1.4 million, along with net proceeds of approximately \$1 million from the issuance of 500,000 shares of common stock in January 2019 in connection with the exercise of warrants that were issued in December 2017, will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2019. As discussed in Note 1 to the consolidated financial statements, these conditions raise substantial doubt about our ability to continue as a going concern.

We are currently investing significant resources in development of products for use by clinicians in the field of regenerative medicine. 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 second quarter, we may be forced to further curtail or cease our operations. Cash requirements and cash resource needs will vary significantly depending upon the timing of clinical and animal studies 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 product candidates that are currently under development. We are currently seeking and continue to seek financings from existing and/or new investors to raise necessary funds through a combination of public or private equity

offerings. We may also pursue 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.

### ***Components of Operating Loss***

***Research and Development Expense.*** Research and development expense consists of salaries and related expenses, including share-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, as well as studies of cells and cell behavior. 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 preclinical 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 share-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.

### ***Other Income (Expense)***

***Grant Income.*** Grant income reflects income earned under the SBIR grant. Grant income is recognized based on timing of when qualified research and development costs are incurred.



*Changes in Fair Value of Warrant Liability.* Changes in fair value of warrant liability represent the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period during the years ended December 31, 2018 and 2017. 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.

*Other Expense.* Other expense represents a loss on disposal of equipment.

### *Critical Accounting 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.

Total share-based compensation expense for the years ended December 31, 2018 and 2017 was \$0.8 million and \$0.7 million, respectively. Share-based compensation is further described in Note 13 to our consolidated financial statements.

*Warrant Liability*

Most of the warrants to purchase shares of our common stock have been classified on our consolidated balance sheets as equity. We classify warrants as a liability in our consolidated balance sheets if the warrant is a free-standing financial instrument that may require us to transfer cash consideration upon exercise and that cash transfer event would be out of our control. Such a “liability warrant” is initially recorded at fair value on the date of grant using the Black-Scholes model, 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) in the consolidated statement of operations. We will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

**Results of Operations**

*Year Ended December 31, 2018 Compared to Year Ended December 31, 2017*

*Research and Development Expense*

Research and development expense decreased \$3.7 million, or 48.4% to \$3.9 million for the year ended December 31, 2018 compared to \$7.6 million for the year ended December 31, 2017. This decrease was primarily attributed to a \$1.8 million decline in personnel-related costs due to our headcount reductions implemented during the fourth quarter of 2017, lower outsourced study costs of \$1.3 million, a \$0.3 million decrease in operating supplies, and lower other expenses of \$0.3 million.

*Selling, General and Administrative Expense*

Selling, general and administrative expense was virtually unchanged at \$3.9 million for the year ended December 31, 2018 compared to the year ended December 31, 2017. We had a \$0.3 million increase in personnel-related costs due primarily to reinstating officers' salaries to contracted rates (see Headcount section above for additional information) and the hiring of a new President in 2018, and \$0.2 million of business exit taxes mainly related to the dissolution of European operations, offset by decreases of \$0.4 million in investor relations consulting costs and \$0.1 million in public reporting costs.

*Change in Fair Value of Warrant Liability*

During the year ended December 31, 2018, the change in fair value of our warrant liability was expense of \$0.1 million compared to expense of \$0.3 million for the year ended December 31, 2017. The higher expense in 2017 was due to the liability and related fair value treatment of a substantial number of warrants for a portion of 2017 prior to their modification to allow for fixed accounting - which classified these awards to permanent stockholders' equity. In addition, there were a significant amount of warrants exercised in 2017.

*Other Expense*

During the year ended December 31, 2018, other expense represented a loss on the disposal of equipment of approximately \$7,000 compared to a loss on the disposal of equipment of approximately \$0.1 million for the year ended December 31, 2017.

*Liquidity and Capital Resources*

*Sources of Liquidity.* We have incurred operating losses since inception, and as of December 31, 2018 we had an accumulated deficit of approximately \$55.8 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.

*Operating Activities.* Net cash used in operating activities of \$7.6 million for the year ended December 31, 2018 was primarily a result of our \$7.5 million net loss and \$1.2 million of cash used for working capital representing the

payment of accounts payable and the timing of prepaid expenses, offset in part by \$1.1 million add-back of non-cash expenses related to the change in the fair value of our warrant liability, share-based compensation and depreciation.

Net cash used in operating activities of \$11.0 million for the year ended December 31, 2017 was primarily a result of our \$11.9 million net loss and \$0.7 million of unfavorable changes in working capital due primarily to timing of payment of accrued and other current liabilities, which were partially offset by a \$1.4 million add-back of non-cash expenses of stock-based compensation, depreciation, and change in fair value of warrant liability.

*Investing Activities.* Net cash used in investing activities for the years ended December 31, 2018 and 2017 totaled \$67,000 and \$136,000, respectively, and represented additions to property, plant and equipment, which in the case for 2018 were partially offset by proceeds from the sale of certain property, plant and equipment assets.

*Financing Activities.* Net cash generated from financing activities decreased to \$5.0 million during the year ended December 31, 2018 from \$12.2 million during the year ended December 31, 2017. The \$5.0 million of cash generated from financing activities during the year ended December 31, 2018 consisted primarily of the net proceeds in the amount of \$5.3 million received from private placement transactions that resulted in the issuance of 1.6 million shares of our common stock at an average purchase gross price of \$3.495 per share, partially offset by the repayment of a \$0.3 million deposit to an investor related to the private placement transaction from December 2017.

Net cash generated from financing activities during the year ended December 31, 2017 of \$12.2 million consisted primarily of net proceeds in the amount of \$6.8 million from the issuance of 1,000,000 shares of common stock and warrants to purchase 1,000,000 shares of common stock in February 2017, net proceeds of \$1.1 million from the exercise of warrants during 2017, and net proceeds of \$4.1 million from the issuance of Series D preferred stock, common stock and warrants in a private placement transaction in December 2017. Net cash generated from cash flows from financing activities also included the proceeds of a deposit of \$0.3 million from an investor related to the private placement transaction that was subsequently repaid in January 2018.

We continue to pursue both of our esophageal programs, which we anticipate will contribute to a 10-20% increase in our 2019 cash burn compared to our 2018 cash burn.

### **Recently Issued Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

### **Off-Balance Sheet Arrangements**

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable Securities and Exchange Commission rules.

### **Item 7A. *Quantitative and Qualitative Disclosures about Market Risk.***

Not Applicable.

### **Item 8. *Financial Statements and Supplementary Data.***

The information required by this item is contained in the consolidated financial statements filed as part of this Annual Report on Form 10-K listed under Item 15 of Part IV below.

### **Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

None.

### **Item 9A. *Controls and Procedures.***

This Report includes the certifications of our Chief Executive Officer and Chief Financial Officer required by Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the Exchange Act). See Exhibits 31.1 and 31.2. This Item 9A includes information concerning the controls and control evaluations referred to in those certifications.

**(a) Evaluation of Disclosure Controls and Procedures**

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

In connection with the preparation of this Annual Report on Form 10-K, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2018. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and our management necessarily was required to apply its judgment in evaluating and implementing our disclosure controls and procedures. Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer have concluded that they believe that our disclosure controls and procedures were effective, as of the end of the period covered by this report, in providing reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

**(b) Management's Annual Report on Internal Control Over Financial Reporting**

Our management, under the supervision of the Chief Executive Officer and the Chief Financial Officer, is responsible for establishing and maintaining an adequate system of internal control over financial reporting. Internal control over financial reporting (as defined in Rules 13a-15(f) and 15d(f) under the Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

A company's internal control over financial reporting includes those policies and procedures that: (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. GAAP; (c) provide reasonable assurance that receipts and expenditures are being made only in accordance with appropriate authorization of management and the Board of Directors; and (d) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of this report, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). As a result of that evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2018.

As an "emerging growth company" under the Jumpstart Our Business Startups Act, and as a smaller reporting company, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result, RSM US LLP, our independent registered public accounting firm, has not audited or issued an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2018.

### **(c) Changes in Internal Controls Over Financial Reporting**

Our management, with the participation of the Chief Executive Officer and the Chief Financial Officer, has evaluated whether any change in our internal control over financial reporting occurred during the fourth quarter ended December 31, 2018. Based on that evaluation, management concluded that there were no changes in our internal controls over financial reporting during the quarter ended December 31, 2018 that materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

### **Item 9B. Other Information.**

None.





## **PART III**

### **Item 10. *Directors, Executive Officers and Corporate Governance.***

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act, in connection with our 2019 Annual Meeting of Stockholders. Information concerning executive officers of our company is included in Part I of this Annual Report on Form 10-K as Item 1. Business-Executive Officers of the Registrant and incorporated herein by reference.

### **Item 11. *Executive Compensation.***

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2019 Annual Meeting of Stockholders.

### **Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2019 Annual Meeting of Stockholders.

### **Item 13. *Certain Relationships and Related Transactions, and Director Independence.***

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2019 Annual Meeting of Stockholders.

### **Item 14. *Principal Accounting Fees and Services.***

Incorporated by reference to our definitive Proxy Statement to be filed pursuant to Regulation 14A under the Exchange Act in connection with our 2019 Annual Meeting of Stockholders.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

(a) Documents Filed. The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements. The consolidated financial statements of Biostage, Inc. and its subsidiaries filed under this Item 15:

	<b>Page</b>
<u>Index to Consolidated Financial Statements</u>	<u>F-1</u>
<u>Reports of Independent Registered Public Accounting Firms</u>	<u>F-2</u>
<u>Consolidated Balance Sheets as of December 31, 2018 and 2017</u>	<u>F-4</u>
<u>Consolidated Statements of Operations for the years ended December 31, 2018 and 2017</u>	<u>F-5</u>
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017</u>	<u>F-6</u>
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017</u>	<u>F-7</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-8</u>

Financial Statement Schedules: None. Financial statement schedules have been omitted since the required (2) information is included in our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K.

(3) Exhibits. The exhibits listed in the accompanying Exhibit Index are filed as a part of this Annual Report on Form 10-K.

(b) Exhibits: The exhibits listed in the accompanying Exhibit Index are filed as a part of this Annual Report on Form 10-K.

(c) Separate Financial Statements and Schedules: None. Financial statement schedules have been omitted since the required information is included in our consolidated financial statements contained elsewhere in this Annual Report on Form 10-K.

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**BIOSTAGE, INC.**

	<b>Page</b>
<u>Reports of Independent Registered Public Accounting Firms</u>	<u>F-2</u>
<u>Consolidated Balance Sheets as of December 31, 2018 and 2017</u>	<u>F-4</u>
<u>Consolidated Statements of Operations for the years ended December 31, 2018 and 2017</u>	<u>F-5</u>
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## Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of

Biostage, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Biostage, Inc. and subsidiaries (the Company) as of December 31, 2018, the related consolidated statements of operations, stockholders' equity and cash flows for the year then ended, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

### Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has an accumulated deficit, uses cash flows in operations, and will require additional financing to continue to fund operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 2018.

Boston, Massachusetts

March 29, 2019

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Biostage, Inc.:

*Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheet of Biostage, Inc. and subsidiaries (the Company) as of December 31, 2017, the related consolidated statement of operations and comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2017, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Biostage, Inc. and subsidiaries as of December 31, 2017, and the results of their operations and their cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

*Going Concern*

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, 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. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ KPMG LLP

We served as the Company's auditor from 2012 to 2018.

Cambridge, Massachusetts  
April 2, 2018

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**BIOSTAGE, INC.****CONSOLIDATED BALANCE SHEETS****(in thousands, except par value and share data)**

	December 31, 2018	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash	\$ 1,305	\$ 4,038
Restricted cash	50	-
Grant receivable	176	-
Prepaid expenses and other current assets	623	375
Total current assets	2,154	4,413
Property, plant and equipment, net	479	632
Total assets	\$ 2,633	\$ 5,045
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 160	\$ 923
Due to related party	-	300
Accrued and other current liabilities	404	383
Warrant liability	98	16
Total current liabilities	662	1,622
Total liabilities	\$ 662	\$ 1,622
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Undesignated preferred stock, \$0.01 par value; 984,000 shares authorized at December 31, 2018 and 2017, none issued and outstanding	-	-
Series D convertible preferred stock, par value \$0.01 per share, 12,000 shares authorized at December 31, 2018 and 2017, 3,108 shares issued at December 31, 2018 and 2017; 0 and 3,108 shares outstanding at December 31, 2018 and 2017, respectively	-	1,475
Common stock, par value \$0.01 per share, 120,000,000 shares authorized at December 31, 2018 and 2017; 5,669,645 and 2,507,304 issued and outstanding at December 31, 2018 and 2017, respectively	57	25
Additional paid-in capital	57,677	50,157
Accumulated deficit	(55,763)	(48,234)
Total stockholders' equity	1,971	3,423
Total liabilities and stockholders' equity	\$ 2,633	\$ 5,045



*See accompanying notes to consolidated financial statements.*

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**BIOSTAGE, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(in thousands, except per share data)**

	Years ended December 31,	
	2018	2017
Revenues	\$ -	\$ -
Operating expenses:		
Research and development	3,916	7,588
Selling, general and administrative	3,925	3,880
Total operating expenses	7,841	11,468
Operating loss	(7,841 )	(11,468 )
Other income (expense):		
Grant income	401	-
Change in fair value of warrant liability	(82 )	(337 )
Other expense	(7 )	(111 )
Total other income (expense), net	312	(448 )
Net loss	\$ (7,529 )	\$ (11,916 )
Basic and diluted net loss per share	\$ (1.69 )	\$ (6.63 )
Weighted average common shares, basic and diluted	4,463	1,797

*See accompanying notes to consolidated financial statements.*

**BIOSTAGE, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY****(in thousands)**

	<b>Number of Common Shares Outstanding</b>	<b>Common Stock</b>	<b>Number of Series D Convertible Preferred Shares</b>	<b>Series D Convertible Preferred Stock</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Equity</b>
Balance at December 31, 2016	855	\$ 9	-	\$ -	\$ 38,083	\$ (36,318 )	\$ 1,774
Net loss	-	-	-	-	-	(11,916 )	(11,916 )
Share-based compensation	-	-	-	-	693	-	693
Issuance of common stock under employee stock purchase plan	1	-	-	-	13	-	13
Issuance of common stock, net of offering costs	1,518	15	-	-	3,876	-	3,891
Reclassification of warrant liability upon modification	-	-	-	-	3,746	-	3,746
Reclassification of warrant liability upon warrant exercise	-	-	-	-	581	-	581
Issuance of common stock upon warrant exercises	133	1	-	-	1,059	-	1,060
Issuance of series D convertible preferred, net of offering costs	-	-	3	1,475	-	-	1,475
Issuance of warrants to purchase common stock in connection with issuance of Series D preferred and common stock above	-	-	-	-	2,106	-	2,106
Balance at December 31, 2017	2,507	\$ 25	3	\$ 1,475	\$ 50,157	\$ (48,234 )	\$ 3,423
Net loss	-	-	-	-	-	(7,529 )	(7,529 )
Share-based compensation	-	-	-	-	755	-	755
Vesting of restricted stock units	6	-	-	-	-	-	-
Issuance of common stock, net of offering costs	1,603	16	-	-	5,255	-	5,271
Conversion of Series D preferred to common stock	1,554	16	(3 )	(1,475 )	1,459	-	-
Issuance of warrants to purchase common stock in connection with	-	-	-	-	51	-	51

issuance of Series D preferred and  
common stock above

Balance at December 31, 2018	5,670	\$ 57	-	\$ -	\$ 57,677	\$ (55,763 )	\$ 1,971
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*See accompanying notes to unaudited consolidated financial statements.*

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**BIOSTAGE, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS****(in thousands)**

	<b>Years ended December</b>	
	<b>31,</b>	<b>2017</b>
	<b>2018</b>	<b>2017</b>
<b>CASH FLOWS USED IN OPERATING ACTIVITIES</b>		
Net loss	\$ (7,529 )	\$ (11,916 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	755	693
Depreciation	261	413
Loss on sale of equipment	7	160
Change in fair value of warrant liability	82	337
Changes in operating assets and liabilities:		
Accounts receivable	-	42
Grant receivable	(176 )	-
Prepaid expenses	(317 )	2
Other current assets	20	126
Accounts payable	(763 )	(43 )
Accrued and other current liabilities	22	(828 )
Net cash used in operating activities	(7,638 )	(11,014 )
<b>CASH FLOWS USED IN INVESTING ACTIVITIES</b>		
Additions to property, plant and equipment	(131 )	(136 )
Cash received from sale of property, plant and equipment	64	-
Net cash used in investing activities	(67 )	(136 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Advance from (return of advance to) related party	(300 )	300
Proceeds from issuance of Series D convertible preferred stock, common stock and warrants, net	-	4,086
Proceeds from issuance of common stock and warrants, net of offering costs	5,322	6,801
Proceeds from exercise of warrants	-	1,060
Net cash provided by financing activities	5,022	12,247
Net (decrease) increase in cash and restricted cash	(2,683 )	1,097
Cash and restricted cash at the beginning of the year	4,038	2,941
Cash and restricted cash at the end of the year	\$ 1,355	\$ 4,038
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Reclassification of warrant liability upon modification	\$ -	\$ 3,746

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Reclassification of warrant liability upon exercise of options	\$ -	\$ 581
Receivable for sale of equipment included in loss on sale of equipment	\$ -	\$ 49
Equipment purchases included in accounts payable	\$ -	\$ 4
Fair value of liability warrants issued in connection with issuance of common stock	\$ -	\$ 3,787
Conversion of Series D preferred stock into common stock	\$ 1,475	\$ -

*See accompanying notes to consolidated financial statements.*

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**BIOSTAGE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Years Ended December 31, 2018 and 2017**

**1. Organization**

*Overview*

Biostage, Inc. (Biostage or the Company) is a biotechnology company developing bioengineered organ implants based on the Company's novel Cellframe™ technology. The Company's Cellframe technology is comprised of a biocompatible scaffold that is seeded with the recipient's own stem cells. The Company believes 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. The Company is currently developing its 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.

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).

*Basis of Presentation*

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

*Going Concern*

The Company has incurred substantial operating losses since its inception, and as of December 31, 2018 had an accumulated deficit of approximately \$55.8 million and will require additional financing to fund future operations. The Company expects that its cash at December 31, 2018 of \$1.4 million, along with net proceeds of approximately \$1.0 million from the issuance of 500,000 shares of common stock in January 2019 in connection with the exercise of warrants that were issued in December 2017, will enable it to fund its operating expenses and capital expenditure requirements into the second quarter of 2019. Therefore, these conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company will need to raise additional funds to fund its operations. In the event the Company does not raise additional capital from outside sources in the second quarter, it may be forced to curtail or cease its operations. Cash requirements and cash resource needs will vary significantly depending upon the timing of the financial and other resource needs that will be required to complete ongoing development, 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 is currently seeking and will continue to seek financings from other existing and/or new investors to raise necessary funds through a combination of public or private equity offerings. The Company may also pursue debt financings, other financing mechanisms, research grants, or strategic collaborations and licensing arrangements. The Company may not be able to obtain additional financing on favorable terms, 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 consolidated 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.



## 2. Summary of Significant Accounting Policies

### *Principles of Consolidation*

The consolidated financial statements include the accounts of Biostage and its three wholly-owned subsidiaries, Harvard Apparatus Regenerative Technology GmbH (Germany), Harvard Apparatus Regenerative Technology AB (Sweden) and Biostage Limited (UK), which are currently dormant and do not have any net assets at December 31, 2018. The functional currency for these subsidiaries is the U.S dollar based on the immateriality of transactions and related amounts for these dormant subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

### *Reclassification*

Certain amounts in the prior period consolidated financial statements have been reclassified to conform to the presentation of the current period consolidated financial statements. These reclassifications had no effect on the previously reported consolidated financial statements.

### *Use of Estimates*

The process of preparing consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such estimates include, but are not limited to, share-based compensation, valuation of warrant liability, accruals, depreciation and income taxes. Actual results could differ from those estimates.

### *Segment*

The Company has one business segment and does not have significant costs or assets outside the U.S.

### *Restricted Cash*

Restricted cash consists of \$50,000 held as collateral for the Company's credit card program as of December 31, 2018.

### *Property, Plant and Equipment*

Property, plant and equipment are carried at cost and depreciated using the straight-line method over the estimated useful lives of the assets as follows:

Leasehold improvements	Shorter of expected useful life or lease term
Furniture, machinery and equipment, computer equipment and software	3—7 years

Maintenance and repairs are charged to expense as incurred, while any additions or improvements are capitalized.

### *Impairment of Long-Lived Assets*

Assessments of long-lived assets and the remaining useful lives of such long-lived assets are reviewed for impairment whenever a triggering event occurs or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An asset, or group of assets, are considered to be impaired when the undiscounted estimated net cash flows expected to be generated by the asset, or group of assets, are less than its carrying amount. The impairment recognized is the amount by which the carrying amount exceeds the fair market value of the impaired asset, or group of assets. Through December 31, 2018, no such impairment charge has been recorded.

### *Revenue Recognition*

The Company did not recognize any revenue during the years ended December 31, 2018 or December 31, 2017.

### *Research and Development*

Research and development costs are expensed as incurred.



### *Share-based Compensation*

The Company measures all stock options and restricted stock awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards, net of forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options and restricted stock awards with only service-based vesting conditions on a straight-line basis over the requisite service period for the entire award (that is, over the requisite service period of the last separately vesting portion of the award). Expense on share-based awards for which vesting is performance or milestone based is recognized on a straight-line basis from the date when it is determined that the achievement of the milestone is probable to the vesting/milestone achievement date.

The Company measures share-based awards granted to consultants and non-employees based on the fair value of the award on the date at which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is re-measured using the then-current fair value of the Company's ordinary shares and updated assumption inputs in the Black-Scholes option-pricing model.

The Company elected to use the Black-Scholes option-pricing model for valuation of stock-based payment awards. The determination of fair value of stock-based payment awards on the date of grant using the Black-Scholes option-pricing model is affected by its stock price as well as assumptions regarding a number of subjective variables. These variables include, but are not limited to, its expected stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors. When performance-based grants are issued, the Company recognizes no expense until achievement of the performance requirement is deemed probable.

Share-based compensation expense is based on awards ultimately expected to vest and has been reduced for annualized estimated forfeiture where the minimum amount of expense recorded is at least equal to the percent of an award vested. Forfeitures were estimated based on historical experience and weighting of various employee classes under the respective plan at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The fair values of Restricted Stock Units (RSU) are based on the number of shares granted and market price of the stock on the date of grant and are recorded as compensation expense ratably over the applicable service period, which is generally four years. Unvested restricted stock units and vested and unvested stock options are forfeited in the event of termination of employment.

*Income Taxes*

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to be applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Deferred tax assets and liabilities are recorded net as long-term on the consolidated balance sheets.

A valuation allowance is recorded when it is more likely than not that some or all of the deferred tax assets will not be realized. Accordingly, the Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are expected to be realizable.

Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet a "more-likely-than-not" threshold would be recorded as a tax expense in the current year.

When necessary, the Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

*Net Loss 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, warrants, and the impact of unvested restricted stock.

The Company applies the two-class method to calculate basic and diluted net loss per share attributable to common stockholders 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 has been in a net loss position and the 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.

#### *Warrant Liability*

The Company classifies warrants to purchase shares of its common stock as a liability on its consolidated balance sheets when the warrant is a free-standing financial instrument that may require the Company to transfer cash consideration upon exercise and that cash transfer event would be out of the Company's control. Such a "liability 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. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

For warrants that do not meet the criteria of a liability warrant and are classified on the Company's consolidated balance sheets as equity instruments, the Company measures the value assigned to the warrant using the relative value method to allocate value to the common stock, preferred stock and warrants at issuance date. The Company uses the Black-Scholes model to measure the value of the warrants at issuance and then applies the relative fair-value of the equity transaction between common stock, preferred stock and warrants. Common stock, preferred stock, and warrants each are considered permanent equity and any potential difference in fair value of each instrument would be reallocated within permanent equity with no periodic remeasurement.

#### *Concentration of Credit Risk*

Financial investments that potentially subject the Company to credit risk consists of cash. Deposits at banks may exceed the insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

#### *SBIR Award*

On March 28, 2018, the Company was awarded a Fast-Track Small Business Innovation Research (SBIR) grant by the Eunice Kennedy National Institute of Child Health and Human Development to support testing of pediatric Cellspan™ Esophageal Implants (CEIs). The award for Phase I, which was earned over the nine months ended September 30, 2018, provided for the reimbursement for up to \$225,000 of qualified research and development costs.

On October 26, 2018, the Company was awarded Phase II of the SBIR grant for \$1.1 million to support development, testing, and translation to the clinic through September 2019. The Phase II grant includes an additional \$0.5 million for future period support through September 2020, subject to availability of funding and satisfactory progress on the project. Accordingly, the SBIR grant has the potential to provide a total award of approximately \$1.8 million.

Grant income is recognized based on timing of when qualified research and development costs are incurred and recorded and classified as grant income in other income (expense), net in the consolidated statements of operations. The Company recognized \$225,000 from Phase I and \$176,000 from Phase II in 2018. There was no grant income in 2017.

#### *Recently Adopted Accounting Pronouncements*

In June 2018, the Financial Accounting Standards Board (FASB), issued Accounting Standards Update 2018-07 (ASU 2018-07) *Compensation—Stock Compensation: Improvements to Non-Employee Share-Based Compensation Accounting*. ASU 2018-07 generally allows the Company to treat awards to non-employees similar to employees for purposes of measuring and recognition stock-based compensation. The ASU is effective for public business entities for fiscal years beginning after December 15, 2018. The Company adopted this pronouncement in 2018 and its adoption did not have a material impact on its consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting (ASU 2017-09)*, which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. The new standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. The new standard is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted. A reporting entity must apply the amendments in the ASU prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 as of the required effective date of January 1, 2018 and its adoption did not have a material impact on the Company's financial statements. The adoption of ASU 2017-09 will have an impact on the accounting for the modification of stock-based awards, if any, to the extent stock-based awards are modified.

In November 2016, the FASB issued ASU 2016-18 *Statement of Cash Flows* (ASU 2016-18) which requires that amounts generally described as restricted cash and restricted cash equivalents to 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. The Company had approximately \$50,000 of restricted cash balances at December 31, 2018 and the adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

#### *Recently Issued Accounting Pronouncements*

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share, Distinguishing Liabilities from Equity, Derivatives and Hedging (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (ASU 2017-11)*. This guidance is intended to reduce the complexity associated with accounting for certain financial instruments with characteristics of liabilities and equity. Specifically, a down round feature would no longer cause a freestanding equity-linked financial instrument (or an embedded conversion option) to be considered "not indexed to an entity's own stock" and therefore accounted for as a derivative liability at fair value with changes in fair value recognized in current earnings. Down round features are most often found in warrants and conversion options embedded in debt or preferred equity instruments. In addition, the guidance re-characterized the indefinite deferral of certain provisions on distinguishing liabilities from equity to a scope exception with no accounting effect. This guidance becomes effective January 1, 2019. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2017-11 will have on its consolidated financial statements.

In February 2016, the FASB, issued ASU 2016-02 *Leases* (Topic 842) (ASU 2016-02). ASU 2016-02 requires lessees to recognize most leases on the balance sheet. This is expected to increase both reported assets and liabilities. The new lease standard does not substantially change lessor accounting. The Company adopted the new leasing standard on January 1, 2019, using a modified retrospective transition approach to be applied to leases existing as of, or entered into after, January 1, 2019. The Company elected to apply the package of practical expedients which allows entities not to reassess whether contracts are or contain leases, lease classification, and whether initial direct costs qualify for capitalization. Additionally, the Company elected not to separate lease and non-lease components. Upon adoption of the new leasing standard, the Company expects to recognize a related right to use asset and a lease liability of approximately \$0.2 million on its consolidated balance sheet. The impact of adoption of the new leasing standards will have an immaterial impact to the Company's consolidated statements of operations and cash flows.

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.

### **3. 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.

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 2. The Company's restricted cash that serves as collateral for the Company's credit card program is held in a demand money market account and is measured at fair value based on quoted prices, which are Level 1 inputs. The Company has concluded that warrants to purchase common stock, which are accounted for as liabilities as discussed in Note 7 are classified as Level 3.

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 December 31, 2018 and 2017:

Fair Value Measurement as of December 31, 2018				
<b>(in thousands)</b>				
	Level 1	Level 2	Level 3	Total
Assets:				
Restricted cash	\$ 50	\$ -	\$ -	\$ 50
Total	\$ 50	\$ -	\$ -	\$ 50
Liabilities:				
Warrant liability	\$ -	\$ -	\$ 98	\$ 98
Total	\$ -	\$ -	\$ 98	\$ 98

Fair Value Measurement as of December 31, 2017				
<b>(in thousands)</b>				
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant liability	\$ -	\$ -	\$ 16	\$ 16
Total	\$ -	\$ -	\$ 16	\$ 16

There were no transfers between Level 1, Level 2 and Level 3 in either of the years ended December 31, 2018 and December 31, 2017.

#### 4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	December 31,	
	2018	2017
	<b>(in thousands)</b>	
Insurance	\$ 347	\$ 253
Sponsored research	149	-
Annual contracts	37	16
Other current assets	90	106
Total prepaid expenses and other current assets	\$ 623	\$ 375

**5. Property, Plant and Equipment, Net**

Property, plant and equipment, net consist of the following:

	December 31,	
	2018	2017
	<b>(in thousands)</b>	
Leasehold improvements	\$584	\$584
Furniture, machinery and equipment	1,417	1,350
Computer equipment and software	477	464
Total property, plant and equipment	2,478	2,398
Less: accumulated depreciation	(1,999)	(1,766)
Property, plant and equipment, net	\$479	\$632

Depreciation expense amounted to \$261,000 and \$413,000 for the years ended December 31, 2018 and 2017, respectively.

**6. Accrued and Other Current Liabilities**

Accrued and other current liabilities consist of the following:

	December 31,	
	2018	2017
	(in thousands)	
Payroll	\$ 113	\$ 145
Audit expenses	110	133
Advisory costs	79	25
Legal fees	40	-
Research costs	26	64
Other current liabilities	36	16
Total accrued and other current liabilities	\$ 404	\$ 383

**7. Warrant Liability**

On May 19, 2016 and February 10, 2017, the Company closed on the sale of shares of the Company's common stock, the issuance of warrants to purchase shares of common stock, and the issuance of warrants to the placement agent for each transaction. See Note 12.

Due to a cash put provision within the warrant agreement, which could be enacted in certain change in control events, a liability associated with those warrants was initially recorded at fair value in the Company's consolidated balance sheets upon issuance, and subsequently re-measured each fiscal quarter. The changes in the fair value between issuance and the end of each reporting period is recorded as a component of other income (expense), net in the consolidated statement of operations.

During the three months ended June 30, 2017 and September 30, 2017, warrant holders of 952,184 warrants agreed to a modification of the terms of their warrants which resulted in placing all situations that would allow the warrant holder to put the warrant for cash fully in control of the Company. As a result of the modification, the modified warrants are no longer liability classified and do not need to be re-measured. These modifications resulted in a \$3.7 million value of those warrants being reclassified from Warrant Liabilities to Additional Paid in Capital. There were 132,367 warrants exercised during 2017. The remaining un-modified 92,213 warrants continue to be re-measured at each reporting period as long as they are outstanding and un-modified.

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The Company has re-measured the liability to estimated fair value at inception, prior to modification and at each reporting date using the Black-Scholes option pricing model with the following weighted average assumptions:

	Assumptions for estimating fair value of warrants modified during the three months ended			Assumptions for estimating fair value on reporting dates of				
	September 30, 2017		<b>June 30, 2017</b>	December 31, 2018		December 31, 2017		
Risk-free interest rate	1.89	%	1.77	%	2.46	%	2.09	%
Expected volatility	82.3	%	82.4	%	121.9	%	85.0	%
Expected term (in years)	4.6		4.6		3.1		4.1	
Expected dividend yield	-		-		-		-	
Exercise price	\$ 8.00		\$ 10.00		\$ 8.00		\$ 8.00	
Market value of common stock	\$ 8.20		\$ 6.60		\$ 2.06		\$ 0.87	
Warrants to purchase shares of common stock	100,101		824,442		92,212		92,212	

The following table presents a reconciliation of the Company’s warrant liabilities for the years ended December 31, 2018 and 2017:

	Warrant Liability (in thousands)
Balance at December 31, 2016	\$ 605
Issuance of warrants	3,787
Reclassification of warrant liability to additional paid in capital upon modification	(3,746 )
Reclassification of warrant liability to additional paid in capital upon exercise	(581 )
Change in fair value upon re-measurement (1)	(49 )
Balance at December 31, 2017	16
Change in fair value upon re-measurement	82
Balance at December 31, 2018	\$ 98

(1) Issuance costs allocated to the warrant liability issued in 2017 amounted to \$385 and have been included in the change in fair value of the warrant liability in the accompanying consolidated statements of operations.

## 8. Commitments and Contingent Liabilities

### *First Pecos Breach Notice*

In June, 2017, the Company entered into a binding Memorandum of Understanding with First Pecos, LLC (First Pecos), pursuant to which the Company agreed to issue to First Pecos in a private placement 485,000 shares of its common stock on a post-reverse split basis at a purchase price of \$6.30 per share or, to the extent First Pecos, following the transaction, would own more than 19.9% of the Company’s common stock, shares of a new class of preferred stock of the Company with a per-share purchase price of \$1,000.

In October 2017, as a result of the First Pecos failure to deliver the Purchase Price to the Company following satisfaction of all closing conditions in the Purchase Agreement, the Company delivered a notice to First Pecos and its manager, Leon “Chip” Greenblatt III, stating that First Pecos was in breach of the Purchase Agreement. None of the shares of common stock, shares of preferred stock or warrants were issued to First Pecos. Also in October 2017, First Pecos delivered a notice to the Company stating that, as a result of alleged breaches by the Company of its obligations pursuant to the Purchase Agreement, First Pecos terminated the Purchase Agreement and demanded that the Company pay a \$500,000 termination fee pursuant to the terms of the Purchase Agreement.

The Company believes that it was not in breach of the Purchase Agreement at any time, and that the First Pecos notice was unjustified and without any legal merit or factual basis. Accordingly, the Company believes that First Pecos was not entitled to terminate the Purchase Agreement, and was not entitled to any termination fee thereunder, as the failure to consummate the Pecos Placement resulted from the First Pecos breach of the Purchase Agreement. The Company has not accrued for this liability as the Company believes the claim to be without merit.

#### *Lease Arrangement*

In October 2013, the Company entered into a sublease with Harvard Bioscience effective November 1, 2013 for its headquarters, offices, manufacturing, and research and development facilities located in Holliston, Massachusetts. The operating lease was non-cancelable for an initial eighteen-month period. The sublease was automatically extended in 2018 through May 31, 2019 and will renew annually unless the Company or Harvard Bioscience provides a notice of termination within one hundred and eighty days prior to May 31 of each year. Total rent expense was \$102,000 and \$59,000 for the years ended December 31, 2018 and 2017, respectively. Future minimum lease payments for operating leases with initial or remaining terms in excess of one year at December 31, 2018 amounts to \$102,000 in 2019 and \$42,000 in 2020. See Note 17.

#### *Other*

On April 14, 2017, representatives for the estate of a deceased individual filed a civil lawsuit in the Suffolk Superior Court, in Boston, Massachusetts, against the Company and Harvard Bioscience. The complaint alleges that the decedent's injury and death were caused by two tracheal implants that incorporated synthetic trachea scaffolds and a biologic component combined by the implanting surgeon with a bioreactor, and surgically implanted in the decedent in two surgeries performed in 2012 and 2013. The civil complaint seeks a non-specific sum of money to compensate the plaintiffs. This civil lawsuit relates to the Company's first-generation trachea scaffold technology for which the Company discontinued development in 2014, and not to the Company's current Cellframe technology nor to its lead development product candidate, the CEI. The Company intends to vigorously defend this case. While the Company believes that such claim lacks merit, the Company is unable to predict the ultimate outcome of such litigation. In accordance with the Separation and Distribution agreement between Harvard Bioscience and the Company relating to the spin-off, the Company would be required to indemnify Harvard Bioscience against losses that Harvard Bioscience may suffer as a result of this litigation. The Company has been informed by its insurance provider that the case has been accepted as an insurable claim under the Company's product liability insurance policy. The Company has not accrued for a potential liability as it is not considered probable at this time.

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. Other than the above matter, there are no such matters pending that the Company expects to be material in relation to its business, financial condition, and results of operations or cash flows.

## 9. Income Taxes

The Company's net loss was generated entirely in the U.S. in 2018 and 2017. Income taxes for the years ended December 31, 2018 and 2017 differed from the amount computed by applying the U.S. federal income tax rate of 21% for 2018 and 34% for 2017 to pre-tax loss as a result of the following:

	Years ended December 31,	
	2018	2017
	<b>(in thousands)</b>	
Computed "expected" income tax benefit	\$ (1,581 )	\$ (4,051 )
Change in deferred income tax rate	-	5,652
State income tax benefit, net of federal income tax benefit	(476 )	(716 )
Permanent items, primarily change in fair value of warrants and non-deductible share-based compensation	24	143
Tax credits	(224 )	(452 )
Share-based compensation	1,531	-
Adjustment of prior year income tax	55	729
Change in valuation allowance	671	(1,305 )
Total income taxes	\$ -	\$ -

The components of the Company's deferred tax asset are as follows:

	Years ended December 31,	
	2018	2017
	<b>(in thousands)</b>	
Deferred tax assets:		
Operating loss and credit carryforwards	\$ 11,184	\$ 6,819
Capitalized research and development	2,680	4,939
Stock-based compensation	696	2,021
Other	-	56
Total deferred tax assets	14,560	13,835
Less: valuation allowance	(14,506 )	(13,835 )
Deferred tax assets	54	-

Deferred tax liability:



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Excess tax over book depreciation	(54	)	-
Total deferred tax liability	(54	)	-
	\$ -		\$ -

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (TCJA) that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, effective as of January 1, 2018; limitation of the tax deduction for interest expense; limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”.

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The staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. The Company has reevaluated its assets and liabilities associated with such future tax benefits in the current year and recognized a decrease in its deferred tax asset of \$5.8 million. This reduction in the deferred tax asset from the change in the deferred tax rate has been offset by a coinciding reduction in the associated valuation allowance, creating a \$0, net impact. The Company completed its accounting for the income tax effects of the TCJA during 2018 and there were no resulting differences.

The Company has recorded a valuation allowance against its deferred tax assets for the years ended December 31, 2018 and 2017, because the Company's management believes that it is more likely than not that these assets will not be realized. The valuation allowance increased by \$0.7 million for the year ended December 31, 2018 primarily as a result of operating losses generated with no corresponding financial statement benefit. The valuation allowance decreased by approximately \$1.1 million for the year ended December 31, 2017 due to the decrease in the corporate tax rate from 34% to 21%, which was enacted on December 22, 2017, partially offset by an increase in net operating losses.

As of December 31, 2018, the Company had federal net operating loss carryforwards (NOLs) of approximately \$34.4 million to offset future federal taxable income and state NOLs of approximately \$34.0 million to offset future state taxable income. The federal and state NOLs generated for annual periods prior to January 1, 2017 begin to expire in 2033. The Company's federal NOL generated for the year ended December 31, 2018, which amounted to \$8.1 million, can be carried forward indefinitely. As of December 31, 2018, the Company also has federal and state tax research and development credit carryforwards of approximately \$1.2 million and \$0.6 million, respectively, to offset future income taxes. The federal and state research and development tax credit carryforwards begin to expire in 2033 and 2029, respectively.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has recently completed several equity financings transactions which have either individually or cumulatively resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future. The Company does not believe the impact of any limitation on the use of its net operating loss or credit carryforwards will have a material impact on the Company's consolidated financial statements since the Company has a full valuation allowance against its deferred tax assets due to the uncertainty regarding future taxable income for the foreseeable future.

For all years through December 31, 2018, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carryforwards and the valuation allowance.

Harvard Bioscience 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 Distribution by Harvard Bioscience 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 legal counsel to Harvard Bioscience rely on certain representations, assumptions and undertakings, including those relating to the past and future conduct of the Biostage 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.

To preserve the tax-free treatment to Harvard Bioscience of the Separation and Distribution, for the two-year period following the Distribution, which such period ended November 1, 2015, the Company was limited, except in specified circumstances, from entering into certain transactions pursuant to which all or a portion of the Company's stock would be acquired, whether by merger or otherwise; issuing equity securities beyond certain thresholds; repurchasing the Company's common stock; and ceasing to actively conduct the Company's regenerative medicine business. In addition, at all times, including during and following such two-year period, the Company may not take or fail to take any other action that prevents the Separation and Distribution and related transactions from being tax-free.

If the Distribution fails to qualify for tax-free treatment, in general, Harvard Bioscience would be subject to tax as if it had sold the Company's common stock in a taxable sale for its fair market value, and Harvard Bioscience stockholders who receive shares of Biostage 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 the Company, the Company 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 the Company's stock or assets, whether by merger or otherwise, (ii) other actions or failures to act by the Company, or (iii) any of the Company's representations or undertakings being incorrect or violated. The Company's indemnification obligations to Harvard Bioscience and its subsidiaries, officers and directors are not limited by any maximum amount. If the Company is required to indemnify Harvard Bioscience or such other persons under the circumstances set forth in the tax sharing agreement, the Company may be subject to substantial liabilities.

All deferred tax assets prior to the Separation remained with Harvard Bioscience.

The Company has determined that any uncertain tax positions would have no material impact on the consolidated financial statements of the Company and there are no unrecognized tax benefits or related interest and penalties accrued for the period for the years ended December 31, 2018 and 2017.

The Company is subject to U.S. federal income tax and Massachusetts state income tax. The statute of limitations for assessment by the IRS and state tax authorities is open for all periods from inception through December 31, 2018; currently, no federal or state income tax returns are under examination by the respective taxing authorities.

## **10. Employee Benefit Plan**

The Company sponsors a retirement plan for its U.S. employees, which includes an employee savings plan established under Section 401(k) of the U.S. Internal Revenue Code (the 401(k) Plan). The 401(k) Plan covers substantially all full-time employees who meet certain eligibility requirements. Contributions to the retirement plan are at the discretion of management. The Company's matching contributions to the plan were approximately \$95,000 and \$100,000 for the years ended December 31, 2018 and 2017, respectively.

## **11. Preferred Stock**

The Company had the following categories of Preferred Stock, \$0.01 par value, at December 31, 2018:

	Authorized	Issued	Outstanding
Undesignated Preferred Stock	984,000	-	-
Series B Convertible Preferred Stock (1)	1,000,000	695,857	-
Series C Convertible Preferred Stock (2)	4,000	-	-
Series D Convertible Preferred Stock (3)	12,000	3,108	-

The Company had the following categories of Preferred Stock, \$0.01 par value, at December 31, 2017:

	Authorized	Issued	Outstanding
Undesignated Preferred Stock	984,000	-	-
Series B Convertible Preferred Stock (1)	1,000,000	695,857	-
Series C Convertible Preferred Stock (2)	4,000	-	-
Series D Convertible Preferred Stock	12,000	3,108	3,108

(1) The Company issued 695,857 shares of its Series B convertible preferred stock in February 2015, which were subsequently converted into common stock during the year ended December 31, 2015.

(2) The Company designated the Series C convertible preferred stock in August 2017, but did not issue any Series C convertible preferred shares.

On May 29, 2018, the holders of Series D preferred stock exercised their right to convert all of the 3,108

(3) outstanding shares of Series D preferred stock into 1.554 million shares of common stock as provided for under the Series D preferred stock agreement.

#### *Undesignated Preferred Stock*

The Board of Directors may exercise its authority to issue undesignated preferred shares and determine the price, privileges and other terms of the shares without any further approval of stockholders.

#### *Series D Convertible Preferred Stock*

On December 27, 2017, the Company issued 518,000 shares of its common stock at \$2.00 per share, 3,108 shares of its Series D convertible preferred stock (the Series D preferred stock) at \$1,000 per share, and warrants to purchase 3,108,000 shares of common stock at an exercise price of \$2.00 per share, in exchange for aggregate gross proceeds of approximately \$4.1 million in a private placement transaction of unregistered shares. The warrants were immediately exercisable and expire in December 2022. The Company allocated \$2.1 million of consideration to the warrants using the relative fair-value method and included such amount in additional paid in capital.

On May 29, 2018, the Company issued a total of 1,000,000 shares of common stock to two new investors at a purchase price of \$3.60 per share for aggregate gross and net proceeds of approximately \$3.6 million and \$3.4 million, respectively, in an unregistered private placement transaction. Following the issuance of these shares, the holders of Series D preferred stock exercised their right to convert all of the 3,108 shares outstanding of Series D preferred stock into 1.554 million shares of common stock as provided for under the Series D preferred stock agreement.

The holders of Series D preferred stock were entitled to vote on all matters on which shares of common stock are entitled to vote (on an as-if-converted to common stock basis).

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the affairs of the Company (a Deemed Liquidation Event), each holder of a share of the Series D preferred stock was entitled to receive on a pari-passu basis with common stockholders any distribution of any of the assets or surplus funds of the Company as if all of the shares of Series D preferred stock had been converted to common stock prior to the Deemed Liquidation Event.

Holders of Series D preferred stock were entitled to receive, and the Company would pay, dividends on shares of Series D 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 would be paid on shares of Series D preferred stock.

The holders of Series D preferred stock were not entitled to any redemption rights, other than those under their liquidation rights.

Holders of Series D preferred stock were entitled to certain protective rights whereby the Company cannot make certain decisions without the consent of a majority of the outstanding holders of the Series D preferred stock.

The Company had classified the Series D preferred stock as permanent equity at December 31, 2017 since the ability to control redemption was not outside of the Company's control.

## **12. Common Stock**

During 2017, the Company increased the number of common shares authorized from 60 million to 120 million.

The following represent the Company's common stock transactions during December 31, 2018 and 2017:

### *June 2018 Private Placement*

On June 29, 2018, the Company issued 250,000 shares of common stock to an investor at a purchase price of \$3.60 per share for aggregate gross and net proceeds of approximately \$0.9 million and \$0.8 million, respectively, in an unregistered private placement transaction.

*May 2018 Private Placement*

On May 23, 2018, the Company issued a total of 1,000,000 shares of common stock to two new investors at a purchase price of \$3.60 per share for aggregate gross and net proceeds of approximately \$3.6 million and \$3.4 million, respectively, in an unregistered private placement transaction. Following the issuance of these shares, the holders of Series D preferred stock exercised their right to convert all of the 3,108 shares outstanding of Series D preferred stock into 1.554 million shares of common stock as provided for under the Series D preferred stock agreement.

*February 2018 Private Placement*

On February 20, 2018, the Company completed a private placement of 302,115 shares of common stock at a purchase price of \$3.31 per share for gross and net proceeds of \$1.0 million.

*January 2018 Private Placement*

On January 3, 2018, the Company issued 50,000 shares of its common stock at \$2.00 per share and warrants to purchase 75,000 shares of common stock at an exercise price of \$2.00 per share, in exchange for aggregate gross proceeds of \$100,000 in an unregistered private placement with Connecticut Children's Medical Center (Connecticut Children's). The warrants were immediately exercisable and expire in January 2023. Connecticut Children's Chief Executive Officer, James Shmerling, is a member of the Company's Board of Directors as well as the Board of Directors of Connecticut Children's.

*December 2017 Private Placement*

On December 27, 2017, the Company issued 518,000 shares of its common stock at \$2.00 per share in connection with its Series D preferred stock issuance in a private placement transaction. See Note 11.

*February 2017 Shares Offering*



On February 10, 2017, the Company completed a public offering of 1,000,000 shares of common stock at a purchase price of \$8.00 per share and the issuance of warrants to purchase 1,000,000 million shares of common stock at an exercise price of \$8.00 per warrant for gross proceeds of \$8.0 million or approximately \$6.8 million net of issuance costs. Additionally, the Company issued to the placement agent warrants to purchase 50,000 shares of common stock for the offering at an exercise price of \$10.00 per warrant.

#### *Employee Stock Purchase Plan*

In 2013, the Company approved the 2013 Employee Stock Purchase Plan (the ESPP Plan). Under the ESPP Plan, participating employees can authorize the Company to withhold a portion of their base pay during consecutive six-month payment periods for the purchase of shares of the Company's common stock. At the conclusion of the period, participating employees can purchase shares of the Company's common stock at 85% of the lower of the fair market value of the Company's 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, 7,500 shares of common stock are authorized for issuance of which 4,534 shares were issued as of December 31, 2017. There are 2,966 shares available for issuance as of December 31, 2018 and December 31, 2017. There was no ESPP Plan activity in 2018.

#### *Shareholder Rights Plan*

The Company had adopted a Shareholder Rights Plan and declared a dividend distribution of one preferred stock purchase right for each outstanding share of the Company's common stock. Initially, these rights would not be exercisable and traded with the shares of the Company's common stock. The Company's Board of Directors canceled the Shareholder Right Plan in August 2017.

### **13. Share-based Compensation**

#### *Biostage 2013 Equity Incentive Plan*

The Company maintains the 2013 Equity Incentive Plan (the Plan) for the benefit of certain 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's policy is to issue stock available from its registered but unissued stock pool through its transfer agent to satisfy stock option exercises and vesting of the restricted stock units. The vesting period for awards is generally four years and the contractual life is ten years. In May 2018, the Company's Board of Directors approved an increase of 1,600,000 shares from 498,000 shares of its common stock authorized to be issued under the Plan to 2,098,000 shares.



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. During 2018 and 2017, no options or restricted stock units were granted to Harvard Bioscience employees or directors, and the Company does not anticipate issuing any to Harvard Bioscience employees in the future.

Stock option activity under the Plan for the year ended December 31, 2018 was as follows:

	Amount	Weighted-average exercise price	Weighted-average contractual life
Outstanding at December 31, 2017	167,474	\$ 45.84	6.99
Granted	1,481,475	2.82	
Canceled	(70,966 )	20.83	
Outstanding at December 31, 2018	1,577,983	\$ 6.58	9.16
Options exercisable	287,745	\$ 21.59	7.95
Options vested and expected to vest	1,564,804	\$ 6.44	

Aggregate intrinsic value for outstanding options and exercisable options for the year ended December 31, 2018 was \$0 based on the Company's closing stock price of \$2.06 per share as of December 31, 2018. As of December 31, 2018, unrecognized compensation cost related to unvested awards amounted to \$1.4 million, which will be recognized over a weighted average period of 2.32 years.

The Company uses the Black- Scholes model to value its stock options. The weighted average assumptions for valuing those options granted were as follows:

	Year Ended December 31,			
	2018		2017	
Volatility	95.50	%	79.21	%
Risk-free interest rate	2.70	%	2.27	%
Expected holding period	5.88	years	6.31	years
Dividend yield	n/a		n/a	

The Company has used a mix of comparable companies volatility and its historical volatility to estimate expected volatility. Commencing July 1, 2018, the Company used its trading history to measure volatility. The risk-free interest rate assumption is based upon observed Treasury bill interest rates (risk-free) appropriate for the expected term of the Company's employee stock options. The simplified method of estimating expected term was used.

The Company's outstanding stock options include 583,921 performance-based awards as of December 31, 2018 that have vesting provisions subject to the achievement of certain business milestones. Compensation expense has not yet been recognized for these performance-based awards given that the milestone achievements have not yet been deemed probable for accounting purposes.

The Company also estimated the fair value of non-employee share options using the Black-Scholes option pricing model reflecting the same assumptions as applied to employee and director options in each of the reporting periods, other than the expected life, which is assumed to be the remaining contractual life of the options.

The weighted average estimated fair value of stock options granted using the Black-Scholes model was \$2.38 per share during 2018 and \$5.56 per share during 2017.

The Company also has issued restricted stock units under the Plan. Unvested shares of restricted common stock may not be sold or transferred by the holder. The following table summarizes the Company's unvested restricted stock unit activity under the Plan for the year ended December 31, 2018:

	Amount	<b>Grant date fair value</b>
Unvested at December 31, 2017	14,875	\$ 7.68
Granted	-	-
Canceled	(912 )	7.68
Vested	(6,228 )	7.68
Unvested at December 31, 2018	7,735	\$ 7.68

As of December 31, 2018, there was no unrecognized compensation costs as all awards were fully vested.

Share-based compensation expense related to both the Plan and the Harvard Bioscience Plan for the years ended December 31, 2018 and 2017 was allocated as follows:

	Years Ended December 31,	
	2018	2017
	<b>(in thousands)</b>	
Research and development	\$ 245	\$ 276
Selling, general and administrative	510	417
Total stock-based compensation	\$ 755	\$ 693

#### **14. Net Loss per Share**

Basic and diluted net loss per share was calculated as follows:

	Years Ended December 31,	
	2018	2017
	<b>(in thousands, except per share data)</b>	

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Net loss	\$ (7,529	)	\$ (11,916	)
Weighted average shares outstanding	4,463		1,797	
Net loss per share – basic and diluted	\$ (1.69	)	\$ (6.63	)

The Company's potentially dilutive securities, which include stock options, unvested restricted common stock units, Series D convertible preferred stock and warrants, have been excluded from the computation of diluted net loss per share whenever the effect of including them would be to reduce the net loss per share. In periods where there is a net loss, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following potential common shares were excluded from the calculation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2018 and 2017 because including them would have had an anti-dilutive effect:

	Years Ended December 31,	
	2018	2017
Series D convertible preferred stock	-	1,554,000
Unvested restricted common stock units	7,735	14,875
Warrants to purchase common stock	4,178,647	4,103,647
Options to purchase common stock	1,577,983	167,474
Total	5,764,365	5,839,996

## 15. Headcount Reduction

During October and November 2017, in an effort to conserve cash, the Company completed a reduction in headcount of 20 of its employees. In addition, officers of the Company agreed to a temporary reduction in their salaries, by 50%, effective November 2017. The Company incurred charges for termination benefits in connection with the headcount reduction of approximately \$99,000 for employee severance and related costs. The Company did not make any payments during the year ended December 31, 2017. All termination benefits were paid in January and February 2018.

During the first quarter of 2018, the salaries paid to the officers were increased to approximately 80% of their contracted rate. The Company accrued a \$104,000 difference between the officers' contracted rates and amounts paid. In July 2018, the Company paid these amounts and reinstated the officers' salaries to their contracted rates. Following the capital raises in December 2017 and January 2018 described above, the Company re-hired several of its former employees into key positions in January 2018, and has since made additional hires.

## 16. Other Expense

Other expense consisted of the following for the years ended December 31, 2018 and 2017:

	Years Ended December 31,	
	2018	2017
	(in thousands)	
Other expense:		
Loss on disposal of equipment	\$ (7 )	\$ (111 )
Total other expense	\$ (7 )	\$ (111 )

## 17. Related Party Transactions

### *Relationship with Harvard Bioscience*

On October 31, 2013, Harvard Bioscience contributed its regenerative medicine business assets plus \$15 million of cash into Biostage pursuant to 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 of all the shares of common stock of Biostage to Harvard Bioscience stockholders pursuant to the Distribution.

At the time of the spin-off, the Company entered into a 10-year product distribution agreement with Harvard Bioscience under which each company would 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 agreed that, except for certain existing activities of its German subsidiary, to the extent that any Harvard Bioscience business were to desire to resell or distribute any bioreactor that is then manufactured by the Company, the Company would be the exclusive manufacturer of such bioreactors and Harvard Bioscience would purchase such bioreactors from the Company. Since inception of the Company, sales to Harvard Bioscience accounted for 100% of the Company's trade revenues and trade receivables.

On November 3, 2017, in exchange for settlement of approximately \$0.1 million of outstanding rent and operating expenses due to Harvard Bioscience, Biostage sold all of its current stock of research bioreactor parts, a royalty-free perpetual sublicensable and transferable right and license to use the intellectual property, including but not limited to certain patents covering research bioreactors, and relinquished exclusive manufacturing or distribution rights with respect to research bioreactors to Harvard Bioscience. The Company had ceased the manufacture of research bioreactors in late 2016, to concentrate its efforts solely on development of its clinical product candidates. This settlement only covers research bioreactors, not to be used for clinical purposes. The Company retains full exclusive rights to all assets and rights associated with the clinical bioreactor used in the development of the Company's current Cellframe technology.

#### *Due to Related Party*

In connection with the Company's private placement transaction in December 2017, an investor placed a deposit in the amount of \$0.3 million with the Company, which was subsequently repaid in January 2018.

### **18. Subsequent Events**

On January 31, 2019, the Company issued 500,000 shares of its common stock to an investor in connection with the exercise of a portion of the warrants issued on December 27, 2017. Such warrants were exercised in exchange for the payment to the Company of the aggregate cash exercise price of \$1,000,000.



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Biostage, Inc.

Date: March 29, 2019

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ James McGorry <b>James McGorry</b>	Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2019
/s/ Thomas McNaughton <b>Thomas McNaughton</b>	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2019
/s/ Jason Jing Chen <b>Jason Jing Chen</b>	Chairman	March 29, 2019
/s/ Matthew Dallas <b>Matthew Dallas</b>	Director	March 29, 2019
/s/ Ting Li <b>Ting Li</b>	Director	March 29, 2019
/s/ James Shmerling <b>James Shmerling</b>	Director	March 29, 2019
/s/ Jeffrey Young <b>Jeffrey Young</b>	Director	March 29, 2019
/s/ Wei Zhang <b>Wei Zhang</b>	Director	March 29, 2019



## EXHIBIT INDEX

The following exhibits are filed as part of this Annual Report on Form 10-K. Where such filing is made by incorporation by reference to a previously filed document, such document is identified.

Exhibit Number	Description of Exhibit
<u>2.1</u> <sup>(3)</sup>	<u>Separation and Distribution Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u>
<u>3.1</u> <sup>(1)</sup>	<u>Amended and Restated Certificate of Incorporation of Biostage, Inc.</u>
<u>3.2</u> <sup>(11)</sup>	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc. dated March 30, 2016.</u>
<u>3.3</u> <sup>(13)</sup>	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc. dated May 26, 2016.</u>
<u>3.4</u> <sup>(11)</sup>	<u>Amended and Restated By-laws of the Biostage, Inc.</u>
<u>3.5</u> <sup>(2)</sup>	<u>Certificate of Designations, Preferences and Rights of Series A Preferred Stock of Biostage, Inc. classifying and designating the Series A Junior Participating Cumulative Preferred Stock.</u>
<u>3.6</u> <sup>(6)</sup>	<u>Certificate of Designation of Series B Convertible Preferred Stock of Biostage, Inc. classifying and designating the Series B Convertible Preferred Stock.</u>
<u>3.8</u> <sup>(14)</sup>	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc. dated April 26, 2017.</u>
<u>3.9</u> <sup>(16)</sup>	<u>Certificate of Designations, Preferences, Rights and Limitations of Series C Convertible Preferred Stock of Biostage, Inc. classifying and designating the Series C Convertible Preferred Stock.</u>
<u>3.10</u> <sup>(16)</sup>	<u>Certificate of Elimination of Series A Junior Participating Cumulative Preferred Stock.</u>
<u>3.11</u> <sup>(17)</sup>	<u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc. dated December 22, 2017.</u>
<u>3.12</u> <sup>(19)</sup>	<u>Certificate of Designations, Preferences, Rights and Limitations of Series D Convertible Preferred Stock of Biostage, Inc. classifying and designating the Series D Convertible Preferred Stock.</u>
<u>4.1</u> <sup>(1)</sup>	<u>Specimen Stock Certificate evidencing shares of common stock</u>
<u>4.2</u> <sup>(7)</sup>	<u>Specimen Series B Convertible Preferred Stock Certificate</u>
<u>4.3</u> <sup>(9)</sup>	<u>Registration Rights Agreement, dated December 15, 2015, between Biostage, Inc. and Aspire Capital Fund, LLC.</u>
<u>4.4</u> <sup>(16)</sup>	<u>Amendment No. 2 to Shareholder Rights Agreement, dated as of August 14, 2017 between Biostage, Inc. and Computershare Trust Company, N.A., as successor to Registrar and Transfer Company.</u>
<u>4.5</u> <sup>(19)</sup>	<u>Form of Common Stock Purchase Warrant.</u>
<u>10.1</u> <sup>(3)</sup>	<u>Intellectual Property Matters Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u>
<u>10.2</u> <sup>(3)</sup>	<u>Product Distribution Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u>
<u>10.3</u> <sup>(3)</sup>	<u>Tax Sharing Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u>
<u>10.4</u> <sup>(3)</sup>	<u>Transition Services Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u>
<u>10.5</u> <sup>(3)</sup>	<u>Sublease by and between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u>

- 10.6#<sup>(3)</sup> Employment Agreement between Biostage, Inc. and Thomas McNaughton dated as of October 31, 2013.
- 10.7<sup>(1)</sup> Form of Indemnification Agreement for Officers and Directors.
- 10.8# \* 2013 Equity Incentive Plan, as amended.
- 10.9<sup>(1)</sup> Employee Stock Purchase Plan.
- 10.10#  
(1) Form of Incentive Stock Option Agreement.
- 10.11#  
(1) Form of Non-Qualified Stock Option Agreement for executive officers.
- 10.12#  
(1) Form of Non-Qualified Stock Option Agreement for directors.
- 10.13#  
(1) Form of Deferred Stock Award Agreement.
- 10.14#\* Director Compensation Arrangements.  
Sublicense Agreement dated as of December 7, 2012 between Biostage, Inc. and Harvard Bioscience, Inc.,
- 10.15<sup>(4)</sup> and related Trademark License Agreement, dated December 19, 2002, by and between Harvard Bioscience, Inc. and President and Fellows of Harvard College.
- 10.16<sup>(1)</sup> Patent Rights Assignment dated December 21, 2012 between Biostage, Inc. and Dr. Paolo Macchiarini.

- 10.17<sup>(1)</sup> Novel Surgery Agreement dated as of May 21, 2012 between Biostage, Inc. and State Budget Institution of Public Health Department Regional Clinical Hospital #1 and Vladimir Alekseevich Porhanov.
- 10.18<sup>(1)</sup> Novel Surgery Agreement dated as of May 24, 2012 between Biostage, Inc. and OSF Healthcare System, owner and operator of Saint Francis Medical Center and Children’s Hospital of Illinois, and Mark Holterman, M.D.
- 10.19<sup>(1)</sup> Amendment to Novel Surgery Agreement dated as of April 5, 2013 between Biostage, Inc. and OSF Healthcare System, owner and operator of Saint Francis Medical Center and Children’s Hospital of Illinois, and Mark Holterman, M.D.
- 10.20<sup>(1)</sup> Amendment to Novel Surgery Agreement dated as of June 26, 2013 between Biostage, Inc. and State Budget Institution of Public Health Department Regional Clinical Hospital #1 and Igor S. Polyakov.
- 10.21#<sup>(8)</sup> Employment Agreement between Biostage, Inc. and James McGorry dated as of June 23, 2015.
- 10.22<sup>(10)</sup> Form of Common Stock Purchase Warrant
- 10.23#<sup>(13)</sup> Letter Agreement, dated as of December 17, 2016, between Biostage, Inc. and Saverio LaFrancesca, M.D.
- 10.24<sup>(12)</sup> Form of Securities Purchase Agreement.
- 10.25<sup>(12)</sup> Form of Common Stock Purchase Warrant.
- 10.26<sup>(12)</sup> Form of Placement Agent Common Stock Purchase Warrant.
- 10.27<sup>(15)</sup> Memorandum of Understanding, dated as of June 26, 2017, between Biostage, Inc. and First Pecos, LLC.
- 10.28<sup>(16)</sup> Securities Purchase Agreement, dated August 11, 2017, between Biostage, Inc. and the purchasers named therein.
- 10.29<sup>(18)</sup> Memorandum of Understanding, dated as of December 11, 2017, between Biostage, Inc. and Bin Zhao.
- 10.30<sup>(19)</sup> Securities Purchase Agreement, dated December 27, 2017, between Biostage, Inc. and the purchasers named therein.
- 10.31<sup>(19)</sup> Securities Purchase Agreement, dated December 29, 2017, between Biostage, Inc. and Connecticut Children’s Medical Center.
- 10.32<sup>(20)</sup> Securities Purchase Agreement, dated February 2, 2018, between Biostage, Inc. and Jinhui Liu.
- 10.33<sup>(21)</sup> Securities Purchase Agreement, dated May 1, 2018, between Biostage, Inc. and Chu Bogang.
- 10.34<sup>(21)</sup> Securities Purchase Agreement, dated May 1, 2018, between Biostage, Inc. and Zhou Heping.
- 10.35<sup>(22)</sup> Securities Purchase Agreement, dated May 29, 2018, between Biostage, Inc. and Du Xiaoyu.
- 10.36#<sup>(23)</sup> Offer Letter, dated June 4, 2018, between Biostage, Inc. and William Fodor, PhD.
- 21.1<sup>(13)</sup> Subsidiaries of Biostage, Inc.
- 23.1\* Consent of RSM US LLP.
- 23.2\* Consent of KPMG LLP.
- 31.1\* Certification of Chief Financial Officer of Biostage., pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of Chief Executive Officer of Biostage, Inc., pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\*\* Certification of Chief Financial Officer of Biostage, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\*\* Certification of Chief Executive Officer of Biostage, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS\* XBRL Instance Document.
- 101.SCH\* XBRL Taxonomy Extension Schema Document.
- 101.CAL\* XBRL Taxonomy Extension Calculation Linkbase Document.
- 101.DEF\* XBRL Taxonomy Extension Definition Linkbase Document.
- 101.LAB\* XBRL Taxonomy Extension Label Linkbase Document.
- 101.PRE\* XBRL Taxonomy Extension Presentation Linkbase Document.

- (1) Previously filed as an exhibit to the Company's Registration Statement on Form 10-12B (filed July 31, 2013) and incorporated by reference thereto.
- (2) Previously filed as an exhibit to the Company's Registration Statement on Form 8-A (filed October 31, 2013) and incorporated by reference thereto.
- (3) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on November 6, 2013) and incorporated by reference thereto.

- (4) Previously filed as an exhibit to the Company's Amendment No. 2 to Form S-1 Registration Statement (filed on February 15, 2013) and incorporated by reference thereto.
- (5) Previously filed as Exhibit 10.19 to the Registrant's Amendment No. 2 to Form S-1 Registration Statement (filed on February 15, 2013) and incorporated by reference thereto.
- (6) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on February 12, 2015) and incorporated by reference thereto.
- (7) Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed on March 27, 2015) and incorporated by reference thereto.
- (8) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on July 6, 2015) and incorporated by reference thereto.
- (9) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on December 15, 2015) and incorporated by reference thereto.
- (10) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on May 16, 2016) and incorporated by reference thereto.
- (11) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on March 31, 2016) and incorporated by reference thereto.
- (12) Previously filed as an exhibit to the Company's Amendment No. 2 to Form S-1 Registration Statement (filed on February 7, 2017) and incorporated by reference thereto.
- (13) Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed on March 17, 2017) and incorporated by reference thereto.
- (14) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on April 27, 2017) and incorporated by reference thereto.
- (15) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on June 27, 2017) and incorporated by reference thereto.

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- (16) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on August 17, 2017) and incorporated by reference thereto.
- (17) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on December 22, 2017) and incorporated by reference thereto.
- (18) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on December 14, 2017) and incorporated by reference thereto.
- (19) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on January 3, 2018) and incorporated by reference thereto.
- (20) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on February 8, 2018) and incorporated by reference thereto.
- (21) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on May 1, 2018) and incorporated by reference thereto.
- (22) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on May 29, 2018) and incorporated by reference thereto.



(23) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on June 10, 2018) and incorporated by reference thereto.

\* Filed herewith.

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or \*\* otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

# Management contract or compensatory plan or arrangement.

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

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