Biostage, Inc.
Form 10-Q
May 11, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2017

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 001-37627

Biostage, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**45-5210462**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**

84 October Hill Road, Suite 11, Holliston, MA	**01746**
(Address of Principal Executive Offices)	**(Zip Code)**

(774) 233-7300

(Registrant's telephone number, including area code)

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 x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	o (Do not check if a smaller reporting company)	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. ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of May 11, 2017, there were 37,116,570 shares of common stock, par value $0.01 per share, outstanding

Biostage Inc.,

Form 10-Q

For the Quarter Ended March 31, 2017

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	March 31, 2017	December 31, 2016
Assets		
Current Assets:		
Cash	$ 6,582	$ 2,941
Accounts receivable	37	42
Prepaid expenses	249	291
Other current assets	36	212
Total current assets	6,904	3,486
Property, plant and equipment, net	1,049	1,065
Total assets	$ 7,953	$ 4,551
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 713	$ 962
Accrued and other current liabilities	917	1,210
Warrant liabilities	4,800	605
Total current liabilities	6,430	2,777
Total liabilities	$ 6,430	$ 2,777
Stockholders' equity:		
Undesignated Preferred stock, $0.01 par value; 1,000,000 shares authorized; none issued and outstanding	-	-
Series B convertible preferred stock, $0.01 par value; 1,000,000 shares authorized; 695,857 shares issued and none outstanding	-	-
Common stock, $0.01 par value; 60,000,000 shares authorized and 37,116,570 and 17,108,968 shares issued and outstanding, respectively	371	171
Additional paid-in capital	41,311	37,921

Accumulated deficit	(40,159)	(36,318)
Total stockholders' equity	1,523	1,774
Total liabilities and stockholders' equity	$ 7,953	$ 4,551

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2017	2016
Revenues	$ -	$ -
Operating expenses:		
Research and development	2,069	1,378
Selling, general and administrative	979	1,094
Total operating expenses	3,048	2,472
Operating loss	(3,048)	(2,472)
Other income (expense):		
Change in fair value of warrant liability, including issuance costs	(793)	-
Other expense, net	(793)	-
Loss before income taxes	(3,841)	(2,472)
Income taxes	-	-
Net loss and comprehensive loss	$ (3,841)	$ (2,472)
Basic and diluted net loss per share	$ (0.14)	$ (0.18)
Weighted-average common shares, basic and diluted	27,113	14,108
Comprehensive loss:		
Net loss	$ (3,841)	$ (2,472)
Foreign currency translation adjustments	-	-
Total comprehensive loss	$ (3,841)	$ (2,472)

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended March 31,	
	2017	2016
Cash flows from operating activities		
Net loss	$ (3,841)	$ (2,472)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Share-based compensation expense	191	347
Depreciation	121	111
Change in fair value of warrants including issuance costs	793	-
Changes in operating assets and liabilities:		
Accounts receivable	5	3
Inventories	-	(4)
Prepaid expenses	42	(155)
Other assets	176	-
Accounts payable	(249)	(137)
Accrued and other current liabilities	(293)	(173)
Net cash used in operating activities	(3,055)	(2,480)
Cash flows from investing activities		
Additions to property and equipment	(105)	(128)
Net cash used in investing activities	(105)	(128)
Cash flows from financing activities		
Proceeds from issuance of common stock and warrants to purchase common stock, net	6,801	-
Net cash provided by financing activities	6,801	-
Net increase (decrease) in cash	3,641	(2,608)
Cash at beginning of period	2,941	7,456
Cash at end of period	$ 6,582	$ 4,848
Supplemental non-cash investing activities:		
Issuance of warrant liability in connection with issuance of common stock	$ 3,787	$ -
Equipment purchases included in accounts payable	$ -	$ 44

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

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

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

Basis of Presentation

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

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.

Unaudited Interim Financial Information

The accompanying interim balance sheet as of March 31, 2017 and consolidated interim statements of operations and comprehensive loss and cash flows for the three months ended March 31, 2017 and 2016 are unaudited. The interim unaudited consolidated financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company’s financial position as of March 31, 2017 and its results of operations and cash flows for the three month periods ended March 31, 2017 and 2016. The financial data and other information disclosed in these notes related to the three month periods ended March 31, 2017 and 2016 are unaudited. The results for the three months ended March 31, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, any other interim periods or any future year or period.

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

Summary of Significant Accounting Policies

The accounting policies underlying the accompanying unaudited consolidated financial statements are those set forth in Note 2 to the financial statements for the year ended December 31, 2016 included in the Company's Annual Report on Form 10-K.

3. Capital Stock, Financing and Liquidity

Capital Stock

On February 10, 2017, the Company completed a public offering of 20,000,000 shares of common stock at a purchase price of $0.40 per share and the issuance of warrants to purchase 20,000,000 shares of common stock at an exercise price of $0.40 per warrant for gross proceeds of $8.0 million or approximately $6.8 million net of issuance costs. Additionally, the Company issued to the placement agent warrants to purchase 1,000,000 shares of common stock for the offering at an exercise price of $0.50 per warrant. The warrants are immediately exercisable and remain exercisable for five years from date of grant.

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

Aspire Purchase Agreement

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

7

3. Capital Stock, Financing and Liquidity (continued)

Upon execution of the Purchase Agreement, the Company sold to Aspire Capital 500,000 shares of common stock at $2.00 per share, which resulted in net proceeds of approximately $0.9 million.

On May 12, 2016, the Company issued 150,000 shares of common stock under the common stock purchase agreement with Aspire Capital Fund, LLC in exchange for gross proceeds of $0.37 million, or $0.35 million net of issuance costs. On May 17, 2016, the Company terminated the Aspire purchase agreement without any penalty or cost.

Liquidity

The Company has incurred substantial operating losses since its inception, and as of March 31, 2017 has an accumulated deficit of approximately $40.2 million. The Company is currently investing significant resources in development and commercialization of products for use by clinicians and researchers in the field of regenerative medicine. The Company expects to continue to incur operating losses and negative cash flows from operations for the remainder of 2017 and in future years. The Company believes that its cash at March 31, 2017 will be sufficient to meet the Company's obligations through the third quarter of 2017. 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 in future periods to fund our operations. In the event that we do not raise additional capital from outside sources in the near future, we may be forced to curtail or cease our operations. Cash requirements and cash resource needs will vary significantly depending upon the timing and the financial and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for our products that are currently under development. We will seek to raise necessary funds through a combination of public or private equity offerings, debt financings, other financing mechanisms, or strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all.

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

4. Fair Value Measurements

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

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.

The 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 and comprehensive loss.

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

The Company had no assets or liabilities classified as Level 1 or Level 2. The Company has concluded that its warrants meet the definition of a liability under *ASC 480 Distinguishing Liabilities From Equity* and has classified the liability as Level 3.

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

	Assumptions for warrants issued on	Weighted average assumptions for estimating fair value on reporting dates of	
	February 10, 2017	December 31, 2016	March 31, 2017
Risk-free interest rate	2.01 %	1.93 %	1.93 %
Expected volatility	77.9 %	72.7 %	77.9 %
Expected term (in years)	5.0	4.9	4.6
Expected dividend yield	-	-	-
Exercise price	$ 0.40	$ 1.76	$ 0.50
Warrants to purchase shares of common stock	21,000,000	1,560,284	22,560,284

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 March 31, 2017:

	Fair Value Measurement as of March 31, 2017 (In thousands)			
	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 4,800	$ 4,800
Total	$ -	$ -	$ 4,800	$ 4,800

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, 2016:

	Fair Value Measurement as of December 31, 2016 (In thousands)			
	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 605	$ 605
Total	$ -	$ -	$ 605	$ 605

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2017:

	Warrant Liability (in thousands)
Balance at December 31, 2016	$ 605
Issuance of warrants	3,787
Change in fair value upon re-measurement	408
Balance at March 31, 2017	$ 4,800

Issuance costs allocated to the warranty liability issued in the first quarter of 2017 amounted to $385,000 and have been included in the change in fair value of the warranty liability in the accompanying consolidated statements of operations.

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

5. Relationship with Harvard Bioscience

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 of all the shares of common stock of Biostage to Harvard Bioscience stockholders (the "Distribution").

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

6. Stock-Based Compensation

Biostage 2013 Equity Incentive Plan

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

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

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

The Company has granted options to purchase common stock and restricted stock units (RSUs) under the Plan. Stock option and restricted stock unit activity during the three months ended March 31, 2017 was as follows:

	Stock Options		Restricted Stock Units	
	Amount	**Weighted-average exercise price**	Amount	Weighted –average grant date fair value
Outstanding at December 31, 2016	3,877,681	$ 2.81	268	$ 6.00
Granted	1,664,000	0.39	404,750	0.38
Vested (RSUs)	-		268	6.00
Canceled	(224,380)	3.14	-	
Outstanding at March 31, 2017	5,317,301	$ 2.04	404,750	$ 0.38

6. Stock-Based Compensation (continued)

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

Expected volatility	78.06%
Expected dividends	0.00 %
Expected term	6.21 years
Risk-free rate	2.27 %

The Company recorded total stock-based compensation expense during the three months ended March 31 as follows (in thousands):

	2017	2016
Research and development	$71	$157
Selling, general and administrative	120	190
Total	$191	$347

Included in above table for 2016 is stock-based compensation related to the Harvard Bioscience Plan, which is described below. There is no expense related to the Harvard Bioscience Plan in 2017.

Harvard Bioscience Stock Option and Incentive Plan

Harvard Bioscience maintains the Third Amended and Restated 2000 Stock Option and Incentive Plan (as amended, the “Harvard Bioscience Plan”) for the benefit of certain of its officers, directors and employees. In connection with the Separation, those employees of Harvard Bioscience who became employees of Biostage were allowed to continue vesting in their stock-based awards of stock options and restricted stock units granted under the Harvard Bioscience Plan. Accordingly, the Company recognized compensation expense as services are provided by those employees through the time of their vesting. All stock-based awards granted to Biostage employees were fully vested as of January 1, 2017.

7. Commitments and Contingencies

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. 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.

8. Subsequent Events

On April 26, 2017, the Company's stockholders approved the following proposals at the Company's Annual Meeting of Shareholders:

- An amendment to the Company's charter to increase the number of authorized shares of the Company's common stock from 60,000,000 shares to 120,000,000 shares;

- An amendment of the Company's 2013 Equity Incentive Plan to increase the number of shares of the Company's common stock available for issuance pursuant to the 2013 Plan by 4,000,000 shares; and

- An amendment of the Company's charter to effect a reverse stock split of the shares of the Company's common stock at a ratio of not less than 1-for-2 and not greater than 1-for-20, with the exact ratio of, effective time of and decision whether or not to implement a reverse stock split to be determined by the Company's board of directors.

On April 14, 2017, anticipated representatives for the estate of an individual plaintiff filed a wrongful death complaint with the Suffolk Superior Court, in the County of Suffolk, Massachusetts, against the Company and other defendants, including Harvard Bioscience, the Company's former parent entity that spun the Company off in 2013, as well as another third party. The complaint seeks payment for an unspecified amount of damages and alleges that the plaintiff sustained terminal injuries allegedly caused by products, including synthetic trachea scaffolds and bioreactors, provided by certain of the named defendants and utilized in connection with surgeries performed by third parties in 2012 and 2013. This complaint 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 and its lead development product candidate, the Cellspan™ esophageal implant. The litigation is at an early stage and the Company intends to vigorously defend this case. While the Company believes that such claim is without 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 Separation, 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 contacted its liability insurance carriers to request defense and indemnification of any losses incurred in connection with this lawsuit.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward Looking Statements

This Quarterly Report on Form 10-Q 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"). The forward-looking statements are principally, but not exclusively, contained in "Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations." 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," "expects," "plans," "a "believes," "goals," "sees," "estimates," "projects," "predicts," "intends," "think," "potential," "objectives," "optimistic," 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. Factors that may cause our actual results to differ materially from those in the forward-looking statements include the success of our collaborations, clinical trials and pre-clinical development efforts and programs, which success may not be achieved on a timely basis or at all; our ability to obtain and maintain regulatory approval for our implant products, bioreactors, scaffolds and other devices we pursue, including for the esophagus or airway, which approvals may not be obtained on a timely basis or at all; our ability to access debt and equity markets and raise additional funds when needed; the number of patients who can be treated with our products; the amount and timing of costs associated with our development of implant products, bioreactors, scaffolds and other devices; our failure to comply with regulations and any changes in regulations; unpredictable difficulties or delays in the development of new technology; our collaborators or other third parties we contract with, including with respect to conducting any clinical trial or pre-clinical development efforts, not devoting sufficient time and resources to successfully carry out their duties or meet expected deadlines; our ability to attract and retain qualified personnel and key employees and retain senior management; potential liability exposure with respect to our products; our inability to operate effectively as a stand-alone, publicly traded company; the actual costs of separation may be higher than expected; the availability and price of acceptable raw materials and components from third-party suppliers; difficulties in obtaining or retaining the management and other human resource competencies that we need to achieve our business objectives; increased competition in the field of regenerative medicine and the financial resources of our competitors; our ability to obtain and maintain intellectual property protection for our device and product candidates; our inability to implement our growth strategy; plus factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the Securities and Exchange Commission (the "SEC") on March 17, 2017 or described in our other public filings. Our results may also be affected by factors of which we are not currently aware. 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.

Overview

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

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

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

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

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

Study animals were returned to a solid diet two weeks after implantation surgery. The scaffolds, which are intended to be in place only temporarily, were later retrieved via the animal's mouth in a non-surgical endoscopic procedure. After 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 appear healthy and free of any significant side effects, including two that are now more than one year post implantation, and are receiving no specialized care.

In November 2016, we were granted Orphan Drug Designation for our Cellspan esophageal implant by the FDA to restore the structure and function of the esophagus subsequent to esophageal damage due to cancer, injury or congenital abnormalities. Orphan drug 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 or BLA fee. We also intend to apply for orphan drug designation for our Cellspan

esophageal implant in Europe in the near term. Orphan drug status in Europe provides market exclusivity there for ten years from the date of the product's approval for marketing.

We are conducting Good Laboratory Practice or 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 or IND application with the FDA, which would seek approval to initiate clinical trials for Biostage Cellspan esophageal implants in humans.

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

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

On February 10, 2017, we completed a public offering of 20,000,000 shares of common stock at a purchase price of $0.40 per share and the issuance of warrants to purchase 20,000,000 shares of common stock at an exercise price of $0.50 per warrant for gross proceeds of $8.0 million and net proceeds of $6.8 million. Additionally, we issued warrants to purchase 1,000,000 shares of common stock to the placement agent for the offering at an exercise price of $0.40 per warrant. The current stock price is below the warrants' exercise prices. However, if in the future the stock's market price were to increase and market conditions were such that all of the above-mentioned 21,000,000 warrants were to be exercised, then such exercises could provide approximately $7.8 million of cash proceeds to the Company, net of issuance costs.

We have incurred substantial operating losses since inception, and as of March 31, 2017 have an accumulated deficit of approximately $40.2 million. We expect to continue to incur operating losses and negative cash flows from operations for the remainder of 2017 and in future years. We believe that our cash at March 31, 2017 will be sufficient to meet the Company's obligations through the third quarter of 2017. Therefore, these conditions raise substantial doubt about the Company's ability to continue as a going concern.

We will need to raise additional funds in future periods to fund our operations. In the event that we do not raise additional capital from outside sources in the near future, we may be forced to curtail or cease our operations. Cash requirements and cash resource needs will vary significantly depending upon the timing 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 products that are currently under development. We will seek to raise necessary funds through a combination of public or private equity offerings, debt financings, other financing mechanisms, or strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all.

13

Results of Operations

Components of Operating Loss

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

Selling, general and administrative expense. Selling, general and administrative expense consists primarily of salaries and other related expenses, including stock-based compensation, for personnel in executive, accounting, information technology and human resources roles. Other costs include professional fees for legal and accounting services, insurance, investor relations and facility costs. We expect our sales and marketing expenses to be immaterial given our focus on research and development and moving toward submission of an IND.

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

Comparison of the three months ended March 31, 2017 to the three months ended March 31, 2016:

Research and Development Expense

Research and development expense increased $0.7 million, to $2.1 million or 49.5% for the three months ended March 31, 2017 compared to $1.4 million for the three months ended March 31, 2016. The increase was primarily due to increases of $0.3 million in compensation expense, which reflected a net headcount increase of seven employees in the first quarter of 2017 compared to the same quarter of 2016, $0.3 million of outsourced research and consulting costs, and $0.1 million of costs associated with scientific conferences and related travel.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased $0.1 million, or 10.5%, to $1.0 million for the three months ended March 31, 2017 compared to $1.1 million for the three months ended March 31, 2016. The $0.1 million decrease was due to a decrease in stock-based compensation primarily due to options previously issued becoming fully vested during the first quarter of 2017.

Change in fair value of warrant liability, including issuance costs

The warrant liability increased $0.8 million for the three months ended March 31, 2017 compared to its fair value at December 31, 2016 primarily due to the addition of 21,000,000 warrants issued in the first quarter of 2017 in connection with the issuance of 20,000,000 shares of common stock. The change in the fair value of the warrant liability for the three months ended March 31, 2017 also included an allocation of $0.4 million of costs of the issuance of the common stock and warrants in the first quarter of 2017.

Financial Condition, Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of March 31, 2017, we had an accumulated deficit of approximately $40.2 million. We are currently investing significant resources in the development of our product candidates for use by clinicians and researchers in the field of regenerative medicine. As a result, we expect to incur operating losses and negative operating cash flow for the foreseeable future.

We expect to continue to incur operating losses and negative cash flows from operations for the remainder of 2017 and in future years. We believe that our cash at March 31, 2017 will be sufficient to meet the Company's obligations through the third quarter of 2017.

We will need to raise additional funds in future periods to fund our operations. In the event that we do not raise additional capital from outside sources in the near future, we may be forced to curtail or cease our operations. Cash requirements and cash resource needs will vary significantly depending upon the timing 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 products that are currently under development. We will seek to raise necessary funds through a combination of public or private equity offerings, debt financings, other financing mechanisms, or strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all.

Operating activities. Net cash used in operating activities of $3.1 million for the three months ended March 31, 2017 was primarily a result of our $3.8 million net loss and $0.3 million of cash used for working capital, partially offset by a $1.0 million add-back of non-cash expenses related to the change in the fair value of the Company's warrant liability, including issuance costs, stock-based compensation and depreciation.

Net cash used in operating activities of $2.5 million for the three months ended March 31, 2016 was primarily a result of our $2.5 million net loss and $0.5 million of cash used for working capital, partially offset by a $0.5 million add-back of non-cash expenses of stock-based compensation and depreciation.

Investing activities. Net cash used in investing activities during the three month periods ended March 31, 2017 and 2016 of $0.1 million reflects cash used for additions to property, plant and equipment.

Financing activities Net cash generated from financing activities during the three months ended March 31, 2017 of $6.8 million consisted of the net proceeds from the issuance of 20,000,000 shares of our common stock at a purchase price of $0.40 per share, the issuance of warrants to purchase 20,000,000 shares of common stock at an exercise price of $0.40 per warrant and warrants issued to placement agents for the offering to purchase 1,000,000 shares of common stock at an exercise price of $0.50 per warrant.

There was no cash generated from financing activities during the three months ended March 31, 2016.

Recent Authoritative Accounting Guidance

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

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

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (ASU 2016-15). This amendment addresses eight classification issues related to the statement of cash flows. For public business entities, the amendments in ASU 2016-15 are effective for public business entities for annual and interim periods in fiscal years beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The Company has not yet selected a transition method and is evaluating the effect the updated standard will have on its consolidated financial statements and related disclosures.

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 should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company is in the process of evaluating the impact of ASU 2016-17 on its financial statements.

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

Critical Accounting Policies and Estimates

The critical accounting policies and estimates underlying the accompanying unaudited consolidated financial statements are those set forth in Part II, Item 7 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which was filed with the SEC on March 17, 2017.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We do not have any material foreign currency exchange risks, we do not enter into derivative agreements, we do not have any off balance-sheet arrangements, and we do not have any interest rate risks. Additionally, we have no debt outstanding.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, 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 March 31, 2017. 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 Quarterly Report on Form 10-Q.

Changes in Internal Control over Financial Reporting

During the period covered by this report, we have concluded that there were no changes during the fiscal quarter in our internal control over financial reporting, as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On April 14, 2017, anticipated representatives for the estate of an individual plaintiff filed a wrongful death complaint with the Suffolk Superior Court, in the County of Suffolk, Massachusetts, against the Company and other defendants, including Harvard Bioscience, the Company's former parent entity that spun the Company off in 2013, as well as another third party. The complaint seeks payment for an unspecified amount of damages and alleges that the plaintiff sustained terminal injuries allegedly caused by products, including synthetic trachea scaffolds and bioreactors, provided by certain of the named defendants and utilized in connection with surgeries performed by third parties in 2012 and 2013. This complaint 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 and its lead development product candidate, the Cellspan™ esophageal implant. The litigation is at an early stage and the Company intends to vigorously defend this case. While the Company believes that such claim is without 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 Separation, 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 contacted its liability insurance carriers to request defense and indemnification of any losses incurred in connection with this lawsuit.

Item 1A. Risk Factors

To our knowledge and except to the extent additional factual information disclosed in this Quarterly Report on Form 10-Q relates to such risk factors, there have been no material changes in the risk factors described in "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016, which was filed with the SEC on March 17, 2017.

Item 6. Exhibits

Exhibit

Index

3.1(1)	Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc.
4.1(2)	Form of Warrant.
4.2(2)	Form of Placement Agent Warrant.
10.1(2)	Engagement Letter, dated January 3, 2017, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
10.2(2)	Amendment to Engagement Letter, dated February 7, 2017, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
10.3(2)	Form of Securities Purchase Agreement.
31.1+	Certification of Chief Financial Officer of Biostage, Inc., pursuant to Rules 13a-14(a) and 15d-14(a), 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-14(a) and 15d-14(a), 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.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

(1) 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.

(2) 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.

\+ 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by undersigned thereunto duly authorized.

Date: May 11, 2017

BIOSTAGE, INC.

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

By: /s/ Thomas McNaughton
Thomas McNaughton
Chief Financial Officer

19

INDEX TO EXHIBITS

3.1(1)	Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc.
4.1(2)	Form of Warrant.
4.2(2)	Form of Placement Agent Warrant.
10.1(2)	Engagement Letter, dated January 3, 2017, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
10.2(2)	Amendment to Engagement Letter, dated February 7, 2017, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
10.3(2)	Form of Securities Purchase Agreement.
31.1+	Certification of Chief Financial Officer of Biostage, Inc., pursuant to Rules 13a-14(a) and 15d-14(a), 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-14(a) and 15d-14(a), 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.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

(1) 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.

(2) 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.

+ 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.