Biostage, Inc.
Form 10-Q
May 11, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended March 31, 2018

¨ **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 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. x YES ¨ NO

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). x YES ¨ NO

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.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (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 x NO

As of May 8, 2018, there were 2,859,419 shares of common stock, par value $0.01 per share, outstanding

Biostage Inc.,

(formerly, Harvard Apparatus Regenerative Technology, Inc.)

Form 10-Q

For the Quarter Ended March 31, 2018

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	March 31, 2018	December 31, 2017
Assets		
Current Assets:		
Cash	$ 2,819	$ 4,038
Prepaid expenses	357	289
Unbilled grant receivable	59	-
Other current assets	36	86
Total current assets	3,271	4,413
Property, plant and equipment, net	586	632
Total assets	$ 3,857	$ 5,045
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 239	$ 923
Accrued and other current liabilities	430	383
Due to related party	-	300
Warrant liability	140	16
Total current liabilities	809	1,622
Total liabilities	$ 809	$ 1,622
Stockholders' equity:		
Undesignated preferred stock, $0.01 par value; 984,000 shares authorized and none issued and outstanding	-	-
Series D convertible preferred stock, par value $0.01 per share, 12,000 shares authorized and 3,108 shares issued and outstanding	1,475	1,475
	29	25

Common stock, $0.01 par value; 120,000,000 shares authorized and 2,859,419 and 2,507,304 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively		
Additional paid-in capital	51,323	50,157
Accumulated deficit	(49,779)	(48,234)
Total stockholders' equity	3,048	3,423
Total liabilities and stockholders' equity	$ 3,857	$ 5,045

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,	
	2018	2017
Revenues	$ -	$ -
Operating expenses:		
Research and development	552	2,069
Selling, general and administrative	928	979
Total operating expenses	1,480	3,048
Operating loss	(1,480)	(3,048)
Other income (expense), net:		
Grant income	59	-
Change in fair value of warrant liability, including issuance costs	(124)	(793)
Total other income (expense), net	(65)	(793)
Loss before income taxes	(1,545)	(3,841)
Income taxes	-	-
Net loss and comprehensive loss	$ (1,545)	$ (3,841)
Basic and diluted net loss per share	$ (0.56)	$ (2.83)
Weighted-average common shares, basic and diluted	2,751	1,359

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities		
Net loss	$ (1,545)	$ (3,841)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Share-based compensation expense	75	191
Depreciation	63	121
Change in fair value of warrant liability, net of issuance costs	124	793
Changes in operating assets and liabilities:		
Accounts receivable	-	5
Prepaid expenses	(68)	42
Unbilled grant receivable	(59)	-
Other current assets	1	176
Accounts payable	(698)	(249)
Accrued and other current liabilities	47	(293)
Net cash used in operating activities	(2,060)	(3,055)
Cash flows from investing activities		
Additions to property and equipment	(3)	(105)
Cash received from sale of property, plant and equipment	49	-
Net cash provided by (used in) investing activities	46	(105)
Cash flows from financing activities		
Return of related party advance	(300)	-
Proceeds from issuance of common stock and warrants, net of offering costs	1,095	6,801
Net cash provided by financing activities	795	6,801
Net increase (decrease) in cash	(1,219)	3,641
Cash at beginning of period	4,038	2,941
Cash at end of period	$ 2,819	$ 6,582
Supplemental non-cash investing activities:		
Fair value of liability warrants issued in connection with issuance of common stock	$ -	$ 3,787
Equipment purchases included in accounts payable	$ 14	$ -

See accompanying notes to unaudited consolidated financial statements.

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BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Number of Common Shares Outstanding	Common Stock	Number of Series D Convertible Preferred Shares	Series D Convertible Preferred Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017	2,507	$ 25	3	$ 1,475	$ 50,157	$ (48,234)	$ 3,423
Net loss	-	-	-	-	-	(1,545)	(1,545)
Share-based compensation	-	-	-	-	75	-	75
Issuance of common stock, net of offering costs	352	4	-	-	1,040	-	1,044
Issuance of warrants to purchase common stock in connection with issuance of common stock above	-	-	-	-	51	-	51
Balance at March 31, 2018	2,859	$ 29	3	$ 1,475	$ 51,323	$ (49,779)	$ 3,048

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

Biostage, Inc., formerly Harvard Apparatus Regenerative Technology, Inc. ("Biostage" or the "Company") is a biotechnology company developing bioengineered organ implants based on 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. The Company has one business segment and does not have significant costs or assets outside the United States.

The Company's common stock is currently traded on the OTCQB Venture Market.

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").

Going Concern

The Company has incurred substantial operating losses since its inception, and as of March 31, 2018 has an accumulated deficit of approximately $49.8 million and will require additional financing to fund future operations.

The Company expects that its cash at March 31, 2018 of $2.8 million will enable it to fund its operating expenses and capital expenditure requirements into the third quarter of 2018. 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 its operations. In the event the Company does not raise additional capital from outside sources in the near future, it may be forced to curtail or cease its operations. Cash requirements and cash resource needs will vary significantly depending upon the timing and the financial and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for the Company's products that are currently under development. The Company will seek to raise necessary funds through a combination of public or private equity offerings, debt financings, other financing mechanisms, research grants, or strategic collaborations and licensing arrangements. The Company may not be able to obtain additional financing on terms favorable to us, if at all.

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

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 consolidated balance sheet as of March 31, 2018 and consolidated interim statements of operations and comprehensive loss and cash flows for the three months ended March 31, 2018 and 2017 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, 2018 and its results of operations and cash flows for the three-month periods ended March 31, 2018 and 2017. The financial data and other information disclosed in these notes related to the three-month periods ended March 31, 2018 and 2017 are unaudited. The results for the three months ended March 31, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, 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, 2017 included in the Company's Annual Report on Form 10-K.

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. The award for Phase I, which is

expected to be earned through the third quarter of 2018, provides for the reimbursement of up to $225,000 of qualified research and development costs or expenditures. The SBIR grant has the potential to provide a total award up to $1.7 million. If Phase I is successful, and funding is available, a Phase II award of up to approximately $1.5 million would support pre-clinical testing of pediatric Cellspan™ Esophageal Implants planned to begin later in 2018. The Phase II Funds, if awarded, would be spent over an estimated two years.

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.

Recently Adopted Accounting Pronouncements

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. The Company adopted this standard on January 1, 2018 and its adoption did not have a material impact on the Company's consolidated financial statements.

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. The Company adopted this standard on January 1, 2018 and its adoption did not have any impact on its consolidated financial statements since the Company does not have restricted cash amounts.

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.

Recently Issued Accounting Pronouncements

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.

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. Capital Stock

On December 27, 2017, the Company issued 518,000 shares of its 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. The Company allocated $2.1 million of consideration to the warrants and included such amount in additional paid in capital.

On January 3, 2018, the Company issued 50,000 shares of our common stock to Connecticut Children's Medical Center 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 a private placement transaction of unregistered shares. The warrants were immediately exercisable and expire in January 2023.

On February 20, 2018, the Company issued 302,115 shares of common stock to an investor at a purchase price of $3.31 per share for aggregate gross proceeds of approximately $1.0 million in a private placement transaction of unregistered shares.

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.

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 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, 2018:

	Fair Value Measurement as of March 31, 2018 (In thousands)			
	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 140	$ 140
Total	$ -	$ -	$ 140	$ 140

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, 2017:

	Fair Value Measurement as of December 31, 2017 (In thousands)			
	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 16	$ 16
Total	$ -	$ -	$ 16	$ 16

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, 2018:

	Warrant Liability (in thousands)
Balance at December 31, 2017	$ 16
Change in fair value upon re-measurement	124
Balance at March 31, 2018	$ 140

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

The Company has re-measured the warrant 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:

	March 31, 2018	December 31, 2017
Risk-free interest rate	2.48 %	2.09 %
Expected volatility	94.73 %	85.0 %
Expected term (in years)	3.9	4.1
Expected dividend yield	-	-
Exercise price	$ 8.00	$ 8.00
Market value of common stock	$ 3.10	$ 0.87
Warrants to purchase shares of common stock	92,212	92,212

5.Stock-Based Compensation

The Company recorded equity-based compensation expense in the following expense categories of its consolidated statements of operations:

	Three Months Ended March 31,	
	2018	2017
	(in thousands)	
Research and development	$ 9	$ 71
General and administrative	66	120
Total stock-based compensation	$ 75	$ 191

The Company did have any significant stock option activity during the three months ended March 31, 2018.

6. Commitments and Contingencies

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 9,700,000 shares of its common stock at a purchase price of $0.315 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 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 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 is not entitled to any termination fee thereunder, as the failure to consummate the Pecos Placement resulted from 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.

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, 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 Cellspan esophageal implant. The litigation is at a relatively early 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 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 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.

7. Related Party Transactions

Relationship with Harvard Bioscience

On October 31, 2013, Harvard Bioscience, Inc. 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 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.

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 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.

8. Net Loss Per Share

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

	Three Months Ended March 31,	
	2018	**2017**
Series D convertible preferred stock	1,554,000	-
Unvested restricted common stock units	7,735	20,237
Warrants to purchase common stock	4,178,647	1,128,041
Options to purchase common stock	156,968	265,865
Total	5,897,350	1,414,143

9. Income Taxes

The Company did not provide for any income taxes in its statement of operations for the three months ended March 31, 2018 or 2017. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at March 31, 2018 and December 31, 2017, it was more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized.

The Company has not recorded any amounts for unrecognized tax benefits as of March 31, 2018 or December 31, 2017. As of March 31, 2018 and December 31, 2017, the Company had no accrued interest or tax penalties recorded related to income taxes. 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, 2017; currently, no federal or state income tax returns are under examination by the respective taxing authorities.

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 percent, 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 periods through March 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.

10. Headcount Reduction in 2017

During October and November 2017 and 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. During Q1 2018, the salaries of the officers of the Company were increased to approximately 80% of the contracted rate. The Company has accrued the difference between the officers contracted rate and amount paid for November 2017 through March 2018. In the quarter ended December 31, 2017, the Company recorded charges for termination benefits in connection with the headcount reduction of approximately $99,000 for employee severance and related costs, which was recorded in accrued expenses and other current liabilities at December 31, 2017. The Company paid the entire amount of $99,000 in January and February 2018.

11. Subsequent Event

On May 1, 2018, the Company entered into Securities Purchase Agreements (the “Purchase Agreements”) with Chu Bogang and Zhou Heping (each an “Investor” and together “Investors”) pursuant to which the Investors agreed to purchase in private placements (the “Private Placements”), and the Company agreed to issue, 500,000 shares of the Company’s common stock, par value $0.01 per share (the “Common Stock”) at a purchase price of $3.60 per share to each of the Investors for a total combined Company issuance of 1,000,000 shares of Common Stock. The Private Placements are expected to close later in May.

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," "anticipates," "believes," "goals," "sees," "estimates," "projects," "predicts," "intends," "think," "potential," "objectives," "optimistic," "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. 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; 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; the control our principal stockholders can exert based on holding a majority of voting power; plus factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission (the "SEC") on April 2, 2018 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 congenital abnormalities, cancer, infection or trauma. 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 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 cancer 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 2,500 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 Cellspan esophageal implant 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, 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 believe that, of our two current programs, the Cellspan Esophageal Implant program to treat pediatric esophageal atresia may provide a shorter time to a commercial product and the greater overall potential value. We also believe that the pediatric esophageal atresia program needs to advance in the first position with the FDA to ensure eligibility for the pediatric rare disease accelerated review voucher program. Receipt of such a voucher, if achieved, could potentially provide significant value to the company in the future. As a result, we elevated the pediatric program to our lead program. We will continue to advance the Cellspan Esophageal Implant adult program, but have not filed an IND for that product candidate at this time. Our current plan for that product candidate is to update the FDA on the progress and status of the our preclinical testing, including our GLP studies, for the adult esophagus program in the near future. Based on the FDA's feedback, the we may amend its preclinical testing plan and continue toward the filing of an IND.

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

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 Q1 2018, the salaries of our officers were increased to approximately 80% of their contracted rate. We have accrued the difference between the officers contracted rate and amount paid for November 2017 through March 2018. Following the capital raises in December 2017 and January 2018 described below we re-hired five of our former employees into key positions in January 2018. We believe that our new staffing level after those hires is sufficient to

pursue both of our esophageal programs and we anticipate our 2018 cash burn needs to be significantly less than our 2017 burn.

December 2017 Private Placements and Reverse Stock Split

Between December 27 and December 29, 2017, we entered into Securities Purchase Agreements with new investors for the sale of our capital stock. Theses agreement 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 the accompanying consolidated financial statements in this quarterly report on Form 10-Q 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. The Company 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.

On January 3, 2018, we issued 50,000 shares of our 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 a private placement transaction of unregistered shares with Connecticut Children’s Medical Center. The warrants were immediately exercisable and expire in January 2023.

Additionally, 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 net proceeds of $1.0 million.

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. The award for Phase I, which is expected to be earned through the third quarter of 2018, provides for the reimbursement of up to $225,000 of qualified research and development costs or expenditures. The SBIR grant has the potential to provide a total award of $1.7 million. If Phase I is successful, and funding is available, a Phase II award of up to approximately $1.5 million would support pre-clinical testing of pediatric Cellspan Esophageal Implants planned to begin later in 2018. The Phase II funds, if awarded, would be spent over an estimated two years.

Operating Losses and Cash Requirements

We have incurred substantial operating losses since our inception, and as of March 31, 2018 had an accumulated deficit of approximately $49.8 million, which will require us to seek additional financing to fund future operations. We expect that our cash on hand at March 31, 2018 of $2.8 million will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2018.

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 near future, 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 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.

On May 1, 2018, we entered into Securities Purchase Agreements (the “Purchase Agreements”) with Chu Bogang and Zhou Heping (each an “Investor” and together “Investors”) pursuant to which the Investors agreed to purchase in private placements (the “Private Placements”), and we agreed to issue, 500,000 shares of our common stock, par value $0.01 per share (the “Common Stock”) at a purchase price of $3.60 per share to each of the Investors for a total combined issuance of 1,000,000 shares of our Common Stock. The Private Placements are expected to close later in May.

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, 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 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.

Other Income (Expense)

Grant income. Grant income reflects income earned under a Fast-Track Small Business Innovation Research (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, net of issuance costs. Changes in fair value of warrant liability, net of issuance costs, represent the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period during the three months ended March 31, 2018 and 2017, and in subsequent quarterly periods, the change in the fair value of common stock warrants from the date between each reporting period until the liability is settled. We use the Black-Scholes pricing model to value the related warrant liability. The costs associated with the issuance of the warrants have been recorded as an expense upon issuance.

Comparison of the three months ended March 31, 2018 to the three months ended March 31, 2017

Research and Development Expense

Research and development expense decreased by $1.5 million, or approximately 73%, to $0.6 million for the three months ended March 31, 2018 compared to $2.1 million for the comparable period in 2017. The decrease was primarily attributed to lower employee and payroll-related costs of $0.7 million attributed to the Company's headcount reductions during the fourth quarter of 2017, lower animal study expenses of $0.4 million and $0.4 million primarily due to other reduced operating expenses.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased by $0.1 million, or approximately 5%, to $0.9 million for the three months ended March 31, 2018 compared to $1.0 million for the comparable period in 2017. The decrease was due primarily to lower investor relations consulting costs during the three months ended March 31, 2018. In addition, stock-based compensation expense decreased due to reduced option grant activity during the year ended December 2017 and the three months ended March 31, 2018 as well as the cancelation of certain options during the fourth quarter of 2017.

Grant income

Grant income for qualified expenditures from a Fast-Track SBIR grant was approximately $59,000 for the three months ended March 31, 2018. There was no grant income recorded in the comparable period in 2017.

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

The fair value of the warrant liability, net of issuance costs, decreased $0.7 million for the three months ended March 31, 2018 compared to the same period in 2017. This decrease was due to a reduction in the number of liability classified warrants as of March 31, 2018 based on the modification of the warrant terms in Q2 and Q3 of 2017, which resulted in a decrease of the fair value. This was offset, in part, by increase in the fair value of the warrants due to changes in share price.

Financial Condition, Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of March 31, 2018 we had an accumulated deficit of approximately $49.8 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 $2.0 million for the three months ended March 31, 2018 was primarily a result of our $1.5 million net loss, in addition to approximately $0.8 million of cash used for working capital, partially offset by $0.3 million add-back of non-cash expenses related to the change in the fair value of our warrant liability, stock-based compensation and depreciation. The cash used for working capital primarily represented the payment of accounts payable and accrued expenses.

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 our warrant liability, including issuance costs, stock-based compensation and depreciation.

Investing activities. Net cash provided by investing activities during the three months ended March 31, 2018 was $46,000 reflecting $49,000 of cash received from the sale of property, plant and equipment, offset in part by $3,000 of property and equipment additions.

Cash used for investing activities for the three months ended March 31, 2017 reflected $0.1 million of additions to property and equipment.

Financing activities Net cash generated from financing activities during the three months ended March 31, 2018 of $0.8 million consisted of the net proceeds from the issuance of 302,115 shares of our common stock on February 20, 2018 at a purchase price of $3.31 per share and the issuance of 50,000 shares of our common stock on January 2, 2018 at a purchase price of $2.00 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 three months ended March 31, 2017 of $6.8 million consisted of the net proceeds from the issuance of 1,000,000 shares of our common stock at a purchase price of $8.00 per share,

the issuance of warrants to purchase 1,000,000 shares of common stock at an exercise price of $8.00 per warrant and warrants issued to placement agents for the offering to purchase 50,000 shares of common stock at an exercise price of $10.00 per warrant.

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, 2017, which was filed with the SEC on April 2, 2018.

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, 2018. 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.

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PART II. OTHER INFORMATION

Item 1. 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 Cellspan esophageal implant. The litigation is at a relatively early stage and the Company intends to vigorously defend this case. While the Company believes that such claim lacks merit and has filed a motion seeking dismissal of the lawsuit, 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 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, we 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 we expect to be material in relation to our business, financial condition, and results of operations or cash flows.

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, 2017, which was filed with the SEC on April 2, 2018.

Item 6. Exhibits

Exhibit

Index

10.1(1)	Securities Purchase Agreement between the Company and Jinhui Liu, dated as of February 2, 2018.
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.
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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 February 8, 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.

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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, 2018

BIOSTAGE, INC.

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

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

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