Biostage, Inc.
Form 10-Q
November 10, 2016

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 September 30, 2016

¨ **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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨

Non-accelerated filer ¨ (Do not check if a smaller reporting company) Smaller reporting company x

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 November 9, 2016, there were 17,108,968 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 September 30, 2016

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

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

Additional paid-in capital	37,599	32,908
Accumulated deficit	(32,976)	(24,739)
Accumulated other comprehensive loss	(8)	(8)
Total stockholders' equity	4,786	8,302
Total liabilities and stockholders' equity	$ 7,197	$ 8,956

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

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

See accompanying notes to unaudited consolidated financial statements.

4

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

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

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

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

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

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

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

Basis of Presentation

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

Earnings per Share

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

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

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

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

Reclassification

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

Unaudited Interim Financial Information

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

6

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

Summary of Significant Accounting Policies

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

Warrant Accounting

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

Recently Issued Accounting Pronouncements

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

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

evaluating the impact that the adoption of ASU 2016-02 will have on the Company's consolidated financial statements or related disclosures.

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

3. Capital Stock, Financing and Liquidity

Capital Stock

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

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

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

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

7

3. Capital Stock, Financing and Liquidity (continued)

Aspire Purchase Agreement

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

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

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

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

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

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

Liquidity

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

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

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

4. Fair Value Measurements

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

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

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

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

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

	September 30, 2016

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

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

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

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

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

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

5. Related Party Transactions

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

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

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

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

6. Stock-Based Compensation

Biostage 2013 Equity Incentive Plan

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

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

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

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

	Amount	**Weighted-average exercise price**
Outstanding at December 31, 2015	3,253,118	$ 3.29
Granted	915,000	1.58
Canceled	(288,817)	3.69
Outstanding at September 30, 2016	3,879,301	$ 2.86

6. Stock-Based Compensation (continued)

The Company uses the Black- Scholes model to value its stock options. Weighted average estimated value of stock options granted using the Black-Scholes model during the nine months ended September 30, 2016 was $1.04. The weighted average assumptions for valuing those options granted were as follows:

Expected volatility	74.26%
Expected dividends	0.00 %
Expected term in years	6.13
Risk-free rate	1.50 %

There was no material restricted stock unit activity during the nine months ended September 30, 2016.

The Company recorded total stock-based compensation during the three and nine months ended September 30 as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Research and development	$ 198	$ 182	$ 535	$ 555
General and administrative	164	246	492	3,057
Total stock-based compensation	$ 362	$ 428	$ 1,027	$ 3,612

Included in the above table is stock-based compensation related to the Harvard Bioscience Plan, which is described below.

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 recognizes compensation expense as services are provided by those employees.

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.

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; our inability to operate effectively as a stand-alone, publicly traded company; 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, 2015 filed with the Securities and Exchange Commission (the "SEC") on March 30, 2016 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. It 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, bronchi, 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 preclinical results of large-animal studies for the esophagus, trachea and bronchus in November 2015. Based on our preclinical testing to date, the Cellspan esophageal implant product will be our lead development product.

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

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

In June 2016, we submitted our application with the U.S. Food and Drug Administration, or the FDA, seeking orphan drug designation for our Cellspan Esophageal Implants. Orphan drug status would provide market exclusivity in the U.S. for seven years from the date of the product's approval for marketing. This exclusivity is in addition to any exclusivity we may obtain due to our patents. Additionally, orphan designation provides a waiver of the BLA application fee of $672,000. 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 now advancing the development of our Cellframe technology, specifically a Cellspan esophageal implant, in collaborative large-animal studies with collaborators. We believe that our recent studies provided sufficient data to initiate Good Laboratory Practice (GLP) studies to demonstrate that our technology, personnel, systems and practices are sufficient for advancing into clinical trials. GLP studies are required to advance to an Investigational New Drug (IND) application with the FDA, which would seek approval to initiate clinical trials for Biostage Cellspan esophageal implants in humans.

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

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

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

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

We have incurred substantial operating losses since our Company's inception, and as of September 30, 2016, we have an accumulated deficit of approximately $33.0 million. We expect to continue to incur operating losses and negative cash flows from operations in 2016 and for the foreseeable future. We believe that our cash on hand at September 30, 2016 will be sufficient to meet our obligations through December 31, 2016 and into early 2017. We will need to raise additional funds in future periods to fund our operations and we may seek to raise necessary funds in 2016 and 2017 through a combination of public or private equity offerings, debt financings, other financing mechanisms or strategic collaborations and licensing arrangements.

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 including animal studies and expenses related to potential patents. We expense research and development costs as incurred.

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

Changes in fair value of warrant liability, net of issuance costs. Changes in fair value of warrant liability, net of issuance costs, represent the change in the fair value of common stock warrants from the date of issuance to the end of the reporting period during the three and nine months ended September 30, 2016 and in subsequent quarterly periods, the change in the fair value of common stock warrants from the date of between each reporting period until the liability is settled. We use the Black-Scholes pricing model to value the related warrant liability. The costs associated with the issuance of the warrants have been recorded as an expense upon issuance.

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

Research and Development Expense

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

Selling, General and Administrative Expense

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

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

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

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

Research and Development Expense

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

Selling, General and Administrative Expense

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

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

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

Financial Condition, Liquidity and Capital Resources

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

We believe that our cash at September 30, 2016 will be sufficient to meet our obligations through December 31, 2016 and into early 2017.

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

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

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

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

Financing activities. Net cash generated from financing activities during the nine months ended September 30, 2016 of $5.0 million consisted of the net proceeds in the amount of $4.5 million from the issuance of 2,836,880 shares of the Company’s common stock at a purchase price of $1.7625 per share and the issuance of warrants to purchase 1,418,440 shares of common stock at an exercise price of $1.7625 per warrant, as well as net proceeds in the amount of $0.4 million from the issuance of 150,000 shares of common stock under the Aspire Purchase Agreement.

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

Recent Authoritative Accounting Guidance

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

In February 2016, the FASB issued ASU, 2016-02, *Leases (Topic 842)*. ASU 2016-02 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 us in the first quarter of 2019, with early adoption permitted. We are currently evaluating the impact that the adoption of ASU 2016-02 will have our consolidated financial statements or related disclosures.

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

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, 2015, which was filed with the SEC on March 30, 2016, and additionally the following accounting policy for warrants.

Warrant Accounting

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

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 September 30, 2016. 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 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, 2015, which was filed with the SEC on March 30, 2016.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On February 18, 2015, we closed our public offering of 2,070,000 shares of common stock, including 270,000 shares of common stock issued (the "Offering") pursuant to the full exercise of the overallotment option granted to the underwriters, and 695,857 shares of Series B Convertible Preferred Stock ("Series B"). At the option of the holder, the Series B was convertible into five shares of our common stock subject to certain limitations related to the holder's ownership percentage of the Company's outstanding common stock, and would vote with the common stock on all matters on an as converted basis. The Series B had no preference to our common shares in respect of dividends, voting, liquidation or otherwise. The offer and sale of all of the shares in the Offering were registered under the Securities Act pursuant to a shelf registration statement on Form S-3 (File No. 333-200926), which was declared effective by the SEC on December 29, 2014. National Securities Corporation and Summer Street Research Partners acted as the underwriters. The public offering price of the shares of common stock sold in the Offering was $1.75 per share and the public offering price of the shares of Series B sold in the Offering was $8.75 per share. The total gross proceeds from the Offering to us were approximately $9.7 million. After deducting underwriting discounts and commissions of $776,900 and offering expenses payable by us of $340,000 (which included $35,000 of expenses we reimbursed of certain institutional investors who purchased Series B shares in the Offering), we received net proceeds of approximately $8.6 million.

Following the consummation of the Offering payments were made in the ordinary course of business to officers for salaries. No other payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates. Through September 30, 2016, we had used all $8.6 million of the net proceeds of the Offering, of which we used approximately $4.8 million for research and development, including funding preclinical efforts relating to bioengineered organs, approximately $3.5 million to fund selling, general and administrative costs of operations and $0.3 million to purchase and install laboratory equipment.

Item 6. Exhibits

Exhibit Index

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

+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: November 10, 2016

BIOSTAGE, INC.

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

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

INDEX TO EXHIBITS

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

+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.