Biostage, Inc.
Form 10-Q
May 12, 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 March 31, 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 May 11, 2016, there were 14,110,540 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, 2016

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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, 2016	December 31, 2015
Assets		
Current Assets:		
Cash	$ 4,848	$ 7,456
Accounts receivable	18	21
Inventory	79	75
Prepaid expenses	485	330
Total current assets	5,430	7,882
Property, plant and equipment, net	1,135	1,074
Total assets	$ 6,565	$ 8,956
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 264	$ 357
Accrued and other current liabilities	124	297
Total current liabilities	388	654
Total liabilities	$ 388	$ 654
Stockholders' equity:		
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 14,110,540 and 14,101,395 shares issued and outstanding, respectively	141	141
Additional paid-in capital	33,255	32,908
Accumulated deficit	(27,211)	(24,739)
Accumulated other comprehensive loss	(8)	(8)

Total stockholders' equity	6,177	8,302
Total liabilities and stockholders' equity	$ 6,565	$ 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 March 31,	
	2016	2015
Revenues	$ —	$ —
Cost of revenues	—	—
Gross profit	$ —	$ —
Operating expenses:		
Research and development	1,378	1,242
Selling, general and administrative	1,094	1,378
Total operating expenses	2,472	2,620
Operating loss	(2,472)	(2,620)
Other expense, net	—	(3)
Loss before income taxes	(2,472)	(2,623)
Income taxes	—	—
Net loss	$ (2,472)	$ (2,623)
Basic and diluted net loss per share	$ (0.18)	$ (0.39)
Weighted-average common shares, basic and diluted	14,108	8,873
Comprehensive loss:		
Net loss	$ (2,472)	$ (2,623)
Foreign currency translation adjustment	—	(9)
Comprehensive loss	$ (2,472)	$ (2,632)

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (2,472)	$ (2,623)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Share-based compensation expense	347	738
Depreciation	111	112
Changes in operating assets and liabilities:		
Related party receivables, net	-	21
Accounts receivable	3	-
Non-trade receivables	-	5
Inventories	(4)	(5)
Prepaid expenses	(155)	48
Accounts payable	(137)	(109)
Accrued and other current liabilities	(173)	126
Net cash used in operating activities	(2,480)	(1,687)
Cash flows from investing activities		
Additions to property and equipment	(128)	(6)
Net cash used in investing activities	(128)	(6)
Cash flows from financing activities		
Proceeds from issuance of convertible preferred stock, net	—	5,357
Proceeds from issuance of common stock, net	—	3,237
Net cash provided by financing activities	—	8,594
Effect of foreign exchange rates on cash		(9)
Net (decrease) increase in cash	(2,608)	6,892
Cash at beginning of period	7,456	5,272
Cash at end of period	$ 4,848	$ 12,164
Supplemental non-cash investing activities:		
Equipment purchases included in accounts payable	$ 44	$ —

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

Biostage, Inc., 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 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 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 $107 thousand for the three months ended March 31, 2015 has 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 March 31, 2016 and consolidated interim statements of operations and comprehensive loss and cash flows for the three months ended March 31, 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 March 31, 2016 and its results of operations and cash flows for the three months ended March 31, 2016 and 2015. The financial data and other information disclosed in these notes related to the three month period ended March 31, 2016 and 2015 are unaudited. The results for the three months ended March 31, 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.

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.

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.

3. Capital Stock, Financing and Liquidity

Capital Stock

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 24,536 shares of Series B which were converted into 122,680 shares of common stock during the three months ended March 31, 2015.

Aspire Purchase Agreement

On December 15, 2015, the Company entered into a common stock purchase agreement (the "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 Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued Aspire Capital 150,000 shares of our common stock as a commitment fee (the "Commitment Shares").

3. Capital Stock, Financing and Liquidity (continued)

Upon execution of the Purchase Agreement, the Company sold to Aspire Capital 500,000 shares of common stock at $2.00 per share (the "Initial Purchase Shares"), which resulted in net proceeds of approximately $0.9 million. Pursuant to the 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 Purchase Agreement, on any trading day on which the closing sale price of the Company's common stock exceeds $0.50, the Company has 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 (the "Purchase Price") calculated by reference to the prevailing market price of the Company's common stock. In addition, the Company has the right, from time to time in our 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 are calculated by reference to the prevailing market price of the Company's common stock.

There are no trading volume requirements or restrictions under the Purchase Agreement, and the Company controls the timing and amount of any sales of our common stock to Aspire Capital. There are no monetary penalties for the Company failing to maintain effectiveness of registration. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from us as the Company directs in accordance with the Purchase Agreement. There are 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 cannot hedge its position in the Company's common stock. The Purchase Agreement may be terminated by the Company at any time, at the Company's discretion, without any penalty or cost to the Company.

Liquidity

The Company has incurred substantial operating losses since its inception, and as of March 31, 2016 has an accumulated deficit of approximately $27.2 million. The Company is currently investing significant resources in development and commercialization of products for use by clinicians and researchers in the field of regenerative medicine. The Company expects to continue to incur operating losses and negative cash flows from operations in 2016 and in future years. Management believes that the Company's cash at March 31, 2016 will not be sufficient to meet the Company's obligations through December 31, 2016. 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 2016 and in future years 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 additional sales of common stock to Aspire Capital, other public 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 our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and therefore, the financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amount and classifications of liabilities that may result from the outcome of this uncertainty.

4. 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 is still a member of the Boards of Directors of both the Company and Harvard Bioscience. Related party rent expenses with Harvard Bioscience for the period of January 1, 2015 through March 31, 2015, was $42,000.

5. 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 three months ended March 31, 2016 was as follows:

	Amount	Weighted-average exercise price
Outstanding at December 31, 2015	3,253,118	$ 3.29
Granted	690,000	1.66
Canceled	(208,188)	3.74
Outstanding at March 31, 2016	3,734,930	$ 2.97

5. 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-Sholes model during the three months ended March 31, 2016 was $1.09. The weighted average assumptions for valuing those options granted were as follows:

Expected volatility	74.35	%
Expected dividends	0.00	%
Expected term	6.09 years	
Risk-free rate	1.53	%

There was no material restricted stock unit activity during the three months ended March 31, 2016.

The Company recorded total stock-based compensation during the three months ended March 31 as follows:

	2016	2015
Research and development	$157	$231
Selling, general and administrative	190	507
Total	$347	$738

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.

6. 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 actual costs of separation may be higher than expected; the availability and price of acceptable raw materials and components from third-party suppliers; difficulties in obtaining or retaining the management and other human resource competencies that we need to achieve our business objectives; increased competition in the field of regenerative medicine and the financial resources of our competitors; our ability to obtain and maintain intellectual property protection for our device and product candidates; our inability to implement our growth strategy; plus factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 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 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.

On May 12, 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 90 days post implantation, and are receiving no specialized care.

We plan to apply for orphan drug designation for our Cellspan esophageal implant in the U.S. and Europe. Orphan drug status provides market exclusivity in the U.S. for seven years from the date of the product's approval for marketing. This exclusivity is in addition to any exclusivity we may obtain due to our patents. Additionally, orphan designation provides a waiver of the BLA application fee of $672,000. 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 provide 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 U.S. FDA, which would seek approval to initiate clinical trials for Biostage Cellspan esophageal implants in humans. Our goal is to complete an IND filing by year-end 2016.

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

We have incurred substantial operating losses since our Company's inception, and as of March 31, 2016, we have an accumulated deficit of approximately $27.2 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 March 31, 2016 will

not be sufficient to meet our obligations through December 31, 2016. We will need to raise additional funds in 2016 and in future years to fund our operations and we may seek to raise necessary funds through a combination public or private equity offerings, which may include additional sales of common stock to Aspire Capital Fund, LLC., 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 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. Commencing 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.

Comparison of the three months ended March 31, 2016 to the three months ended March 31, 2015:

Research and Development Expense

Research and development expense increased $0.2 million, to $1.4 million or 16.6% for the three months ended March 31, 2016 compared to $1.2 million for the three months ended March 31, 2015. The increase was primarily due to increased spending on outsourced preclinical studies of $0.3 million and internal laboratory costs of $0.1 million, partially offset by a decrease in compensation-related costs of $0.2 million, including $0.1 million of stock-based compensation costs.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased $0.3 million, or 26.0%, to $1.1 million for the three months ended March 31, 2016 compared with $1.4 million for the three months ended March 31, 2015. The $0.3 million decrease was due to a $0.3 million decrease in compensation-related costs, including stock-based compensation, related primarily to the departure of our former Chairman and CEO in April 2015.

Financial Condition, Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of March 31, 2016, we had an accumulated deficit of approximately $27.2 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 March 31, 2016 will not be sufficient to meet our obligations through December 31, 2016.

We will need to raise additional funds in 2016 and in future years 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 additional sales of common stock to Aspire Capital, other 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 $2.5 million for the three months ended March 31, 2016 was primarily a result of our $2.5 million net loss and $0.5 million of cash used for working capital, partially offset by a $0.5 million add-back of non-cash expenses of stock-based compensation and depreciation.

Net cash used in operating activities of $1.7 million for the three months ended March 31, 2015 reflects our $2.6 million net loss, offset by a $0.7 million add-back of non-cash stock-based compensation expense, a $0.1 million add-back for depreciation and changes in working capital items.

Investing activities. Net cash used in investing activities during the three month periods ended March 31, 2016 and 2015 of $0.1 million and $6 thousand, respectively, reflects cash used for additions to property, plant and equipment.

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

Net cash generated from financing activities during the three months ended March 31, 2015 of $8.6 million consisted of the net proceeds from the issuance of convertible preferred and shares of our common stock.

Recent Authoritative Accounting Guidance

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 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.

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.

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, 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 March 31, 2016, of the net proceeds of the Offering, we used approximately $3.3 million for research and development, including funding preclinical efforts relating to bioengineered organs, approximately $2.5 million to fund Selling, General and Administrative costs of operations and $0.2 million to purchase and install laboratory equipment.

Item 6. Exhibits

Exhibit Index

10.1#(1)	Amendment to Employment Agreement, by and between Biostage, Inc. and Saverio LaFrancesca, M.D., dated as of March 24, 2016
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

\# Management contract or compensatory plan or arrangement

(1) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on March 24, 2016) and incorporated by reference thereto.

\+ Filed herewith.

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

SIGNATURES

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

Date: May 12, 2016

BIOSTAGE, INC.

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

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

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Management contract or compensatory plan or arrangement.

(1) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on July 6, 2015) and incorporated by reference thereto.

+ 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.