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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

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

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

Commission file number 001-35853

BIOSTAGE, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

(774) 233-7300

(Registrant’s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. x YES ¨ NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x YES ¨ NO

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

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

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

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

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

Biostage Inc.,

(formerly, Harvard Apparatus Regenerative Technology, Inc.)

Form 10-Q

For the Quarter Ended March 31, 2018

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

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

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

See accompanying notes to unaudited consolidated financial statements.

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BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2018	2017
Revenues	$ -	$ -
Operating expenses:		
Research and development	552	2,069
Selling, general and administrative	928	979
Total operating expenses	1,480	3,048
Operating loss	(1,480)	(3,048)
Other income (expense), net:		
Grant income	59	-
Change in fair value of warrant liability, including issuance costs	(124)	(793)
Total other income (expense), net	(65)	(793)
Loss before income taxes	(1,545)	(3,841)
Income taxes	-	-
Net loss and comprehensive loss	$ (1,545)	$ (3,841)
Basic and diluted net loss per share	$ (0.56)	$ (2.83)
Weighted-average common shares, basic and diluted	2,751	1,359

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

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

See accompanying notes to unaudited consolidated financial statements.

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BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

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

See accompanying notes to unaudited consolidated financial statements.

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BIOSTAGE, INC.

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

1. Overview and Basis of Presentation

Overview

Biostage, Inc., formerly Harvard Apparatus Regenerative Technology, Inc. ("Biostage" or the "Company") is a biotechnology company developing bioengineered organ implants based on the Company's novel Cellframe™ technology. The Company's Cellframe technology is comprised of a biocompatible scaffold that is seeded with the recipient's own stem cells. The Company believes that this technology may prove to be effective for treating patients across a number of life-threatening medical indications who currently have unmet medical needs. The Company is currently developing its Cellframe technology to treat life-threatening conditions of the esophagus, bronchus or trachea with the objective of dramatically improving the treatment paradigm for those patients. Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and acquiring operating assets. The Company has one business segment and does not have significant costs or assets outside the United States.

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

Basis of Presentation

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

Going Concern

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

The Company expects that its cash at March 31, 2018 of $2.8 million will enable it to fund its operating expenses and capital expenditure requirements into the third quarter of 2018. Therefore, these conditions raise substantial doubt about the Company's ability to continue as a going concern.

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

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

Net loss per Share

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

The Company applies the two-class method to calculate basic and diluted net loss per share attributable to common stockholders as its warrants to purchase common stock are participating securities.

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

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

Unaudited Interim Financial Information

The accompanying interim consolidated balance sheet as of March 31, 2018 and consolidated interim statements of operations and comprehensive loss and cash flows for the three months ended March 31, 2018 and 2017 are unaudited. The interim unaudited consolidated financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company’s financial position as of March 31, 2018 and its results of operations and cash flows for the three-month periods ended March 31, 2018 and 2017. The financial data and other information disclosed in these notes related to the three-month periods ended March 31, 2018 and 2017 are unaudited. The results for the three months ended March 31, 2018 are not necessarily indicative of results to be expected for the year ending December 31, 2018, any other interim periods or any future year or period.

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

Summary of Significant Accounting Policies

The accounting policies underlying the accompanying unaudited consolidated financial statements are those set forth in Note 2 to the financial statements for the year ended December 31, 2017 included in the Company’s Annual Report on Form 10-K.

SBIR Award

On March 28, 2018, the Company was awarded a Fast-Track Small Business Innovation Research (SBIR) grant by the Eunice Kennedy National Institute of Child Health and Human Development. The award for Phase I, which is expected to be earned through the third quarter of 2018, provides for the reimbursement of up to $225,000 of qualified research and development costs or expenditures. The SBIR grant has the potential to provide a total award up to $1.7 million. If Phase I is successful, and funding is available, a Phase II award of up to approximately $1.5 million would support pre-clinical testing of pediatric Cellspan™ Esophageal Implants planned to begin later in 2018. The Phase II Funds, if awarded, would be spent over an estimated two years.

Grant income is recognized based on timing of when qualified research and development costs are incurred and recorded and classified as grant income in other income (expense), net in the consolidated statements of operations.

Recently Adopted Accounting Pronouncements

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"). This amendment addresses eight classification issues related to the statement of cash flows. The Company adopted this standard on January 1, 2018 and its adoption did not have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18 Statement of Cash Flows ("ASU 2016-18") which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted this standard on January 1, 2018 and its adoption did not have any impact on its consolidated financial statements since the Company does not have restricted cash amounts.

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

Recently Issued Accounting Pronouncements

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

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

3. Capital Stock

On December 27, 2017, the Company issued 518,000 shares of its Common stock at $2.00 per share, 3,108 shares of our Series D Convertible Preferred Stock at $1,000 per share, and warrants to purchase 3,108,000 shares of common stock at an exercise price of $2.00 per share, in exchange for aggregate gross proceeds of approximately $4.1 million in a private placement transaction of unregistered shares with a new investor. The warrants were immediately exercisable and expire in December 2022. The Company allocated $2.1 million of consideration to the warrants and included such amount in additional paid in capital.

On January 3, 2018, the Company issued 50,000 shares of our common stock to Connecticut Children’s Medical Center at $2.00 per share and warrants to purchase 75,000 shares of common stock at an exercise price of $2.00 per share, in exchange for aggregate gross proceeds of $100,000 in a private placement transaction of unregistered shares. The warrants were immediately exercisable and expire in January 2023.

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

4. Fair Value Measurements

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

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs