Biostage, Inc.
Form 10-Q
December 15, 2017

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, 2017

¨ **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 December 13, 2017, there were 39,787,615 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, 2017

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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)

	September 30, 2017	**December 31, 2016**
Assets		
Current Assets:		
Cash	$ 1,310	$ 2,941
Accounts receivable	-	42
Prepaid expenses	94	291
Other current assets	274	212
Total current assets	1,678	3,486
Property, plant and equipment, net	875	1,065
Total assets	$ 2,553	$ 4,551
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,208	$ 962
Accrued and other current liabilities	529	1,210
Warrant liabilities	339	605
Total current liabilities	2,076	2,777
Total liabilities	$ 2,076	$ 2,777
Stockholders' equity:		
Undesignated Preferred stock, $0.01 par value; 1,000,000 shares authorized; none issued and outstanding	-	-
Series B convertible preferred stock, $0.01 par value; 1,000,000 shares authorized; 695,857 shares issued and none outstanding	-	-
	398	171

Common stock, $0.01 par value; 120,000,000 shares and 60,000,000 shares authorized as of September 30, 2017 and December 31, 2016, respectively, and 39,787,615 and 17,108,968 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively		
Additional paid-in capital	47,084	37,921
Accumulated deficit	(47,005)	(36,318)
Total stockholders' equity	477	1,774
Total liabilities and stockholders' equity	$ 2,553	$ 4,551

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)

	Three Months ended September 30,		Nine Months ended September 30,	
	2017	2016	2017	2016
Revenues	$ -	$ 26	$ -	$ 54
Cost of revenues	-	13	-	57
Gross profit (deficit)	-	13	-	(3)
Operating expenses:				
Research and development	2,364	2,225	7,121	5,279
Selling, general and administrative	888	937	2,906	3,261
Total operating expenses	3,252	3,162	10,027	8,540
Operating loss	(3,252)	(3,149)	(10,027)	(8,543)
Other income (expense):				
Change in fair value of liability warrants	9	96	(660)	306
Other expense	-	-	-	-
	9	96	(660)	306
Loss before income taxes	(3,243)	(3,053)	(10,687)	(8,237)
Income taxes	-	-	-	-
Net loss	$ (3,243)	$ (3,053)	$ (10,687)	$ (8,237)
Basic and diluted net loss per share	$ (0.08)	$ (0.18)	$ (0.31)	$ (0.53)
Weighted average common shares, basic and diluted	38,969	17,107	34,443	15,585
Comprehensive loss:				
Net loss	$ (3,243)	$ (3,053)	$ (10,687)	$ (8,237)
Foreign currency translation adjustments	-	-	-	-
Total comprehensive loss	$ (3,243)	$ (3,053)	$ (10,687)	$ (8237)

See accompanying notes to unaudited consolidated financial statements.

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BIOSTAGE, INC.

UNAUDITED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities		
Net loss	$ (10,687)	$ (8,237)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	591	1,027
Depreciation	334	340
Change in fair value of warrant liability	660	(306)
Changes in operating assets and liabilities:		
Accounts receivable	42	(45)
Inventories	-	34
Prepaid expenses and other current assets	135	234
Accounts payable	246	418
Accrued and other current liabilities	(681)	465
Net cash used in operating activities	(9,360)	(6,070)
Cash flows from investing activities		
Additions to property and equipment	(140)	(225)
Net cash used in investing activities	(140)	(225)
Cash flows from financing activities		
Proceeds from issuance of common stock and warrants, net of issuance costs	6,801	4,496
Proceeds from exercise of warrants	1,059	-
Proceeds from issuance of common stock, net of issuance costs	9	349
Net cash provided by financing activities	7,869	4,845
Net decrease in cash	(1,631)	(1,450)
Cash at beginning of period	2,941	7,456
Cash at end of period	$ 1,310	$ 6,006
Supplemental disclosure of cash flow information and non-cash investing and financing activities:		
Fair value of warrant liability reclassified to additional paid-in capital	$ 4,327	$ -
Fair value of warrants issued in connection with issuance of common stock	$ 3,787	$ -

Equipment purchases included in accounts payable	$ -	$ 28
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. ("Biostage" or the "Company") is a biotechnology company developing bioengineered organ implants based on our novel Cellframe ™ technology. Our Cellframe technology is comprised of a biocompatible scaffold that is seeded with the recipient's own stem cells. We believe that this technology may prove to be effective for treating patients across a number of life-threatening medical indications who currently have unmet medical needs. We are currently developing our Cellframe technology to treat life-threatening conditions of the esophagus, bronchus or trachea with the objective of dramatically improving the treatment paradigm for those patients.

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

Basis of Presentation

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

Net loss per Share

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

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

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

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

Unaudited Interim Financial Information

The accompanying interim consolidated balance sheet as of September 30, 2017 and consolidated interim statements of operations and comprehensive loss and cash flows for the three and nine months ended September 30, 2017 and 2016 are unaudited. The interim unaudited consolidated financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company's financial position as of September 30, 2017 and its results of operations and cash flows for the three and nine month periods ended September 30, 2017 and 2016. The financial data and other information disclosed in these notes related to the three and nine month periods ended September 30, 2017 and 2016 are unaudited. The results for the three and nine months ended September 30, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, any other interim periods or any future year or period.

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

Summary of Significant Accounting Policies

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

3. Capital Stock, Financing and Liquidity

Capital Stock

On February 10, 2017, the Company completed a public offering of 20,000,000 shares of common stock at a purchase price of $0.40 per share and the issuance of warrants to purchase 20,000,000 shares of common stock at an exercise price of $0.40 per warrant for gross proceeds of $8.0 million or approximately $6.8 million net of issuance costs. Additionally, the Company issued to the placement agent warrants to purchase 1,000,000 shares of common stock for the offering at an exercise price of $0.50 per warrant. The warrants are immediately exercisable and remain exercisable for five years from date of grant. During the three and nine months ended September 31, 2017 holders exercised warrants for 2,647,338 shares of common stock for proceeds of $1.1 million.

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

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

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

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

Capital Commitment

On June 26, 2017, the Company entered into a binding Memorandum of Understanding (the "Pecos MOU") with First Pecos, LLC ("First Pecos"), pursuant to which the Company agreed to issue to First Pecos in a private placement (the "Pecos Placement") 9,700,000 shares of its common stock at a purchase price of $0.315 per share or, to the extent First Pecos, following the transaction, would own more than 19.9% of the Company's common stock, shares of a new class of preferred stock of the Company (the "Preferred Stock") with a per-share purchase price of $1,000.

Additionally, First Pecos was to receive warrants (the "Warrants") to purchase 9,700,000 shares of the Company's common stock or, to the extent First Pecos would own more than 19.9% of the Company's common stock, shares of Preferred Stock. The Warrants would have had an exercise price of $0.315 per share and would not have been exercisable until six months after the closing of the Pecos Placement.

Under the Pecos Placement, the Preferred Stock would bear a cumulative annual dividend of 15%, compounding annually, and would be senior to all of the Company's other common stock, but would generally not have any voting rights. Following approval by the Company's stockholders, the Preferred Stock would automatically convert into shares of the Company's common stock. The Company agreed to include a proposal for such stockholder approval in the definitive proxy statement for its 2018 annual meeting of stockholders and, if not approved at such meeting, would seek approval from its stockholders every six months thereafter.

In connection with the Pecos Placement, First Pecos agreed to serve as a backstopping party with respect to two pro rata rights offerings with aggregate gross proceeds of up to $14.0 million that the Company could elect to conduct within 24 months following the closing of the Pecos Placement. Additionally, the Company had agreed to grant board representation and nomination rights to First Pecos that would be proportional to the percentage of the Company's common stock owned by First Pecos and its affiliates.

3. Capital Stock, Financing and Liquidity (continued)

The Pecos Placement was conditioned on satisfaction of customary closing conditions, including the Company terminating its Shareholder Rights Plan, and was expected to be consummated on or prior to August 15, 2017. The definitive agreements relating to the Pecos Placement were to include customary representations, warranties and covenants. The Company agreed to file a resale registration statement promptly after the closing of the Pecos Placement to register the resale of the shares of common stock issued in the Pecos Placement.

The Pecos MOU was intended to be binding upon both the Company and First Pecos. In the event that the Company failed to perform any of its obligations under the Pecos MOU or otherwise breached the Pecos MOU, subject to certain exceptions, First Pecos could terminate the Pecos MOU, and the Company would have been obligated to pay a termination fee of $0.5 million (the “Termination Fee”).

The Company entered into the Securities Purchase Agreement (the “Purchase Agreement) with First Pecos on August 11, 2017, pursuant to which the Company agreed to sell to First Pecos, and First Pecos agreed to purchase from the Company, 9,700,000 shares of the Company’s common stock at a purchase price of $0.315 per share or, to the extent First Pecos, following the transaction, would own more than 19.99% of the Company’s common stock, shares of a new class of preferred stock of the Company with a per-share purchase price of $1,000. Additionally, First Pecos was to receive a warrant to purchase 9,700,000 shares of the Company’s common stock (or, to the extent First Pecos would own more than 19.99% of the Company’s common stock, shares of Preferred Stock). The aggregate gross proceeds from the private placement of common stock, Preferred Stock and the Warrant would have been $3,055,500 (the “Purchase Price”). The Company did not receive the Purchase Price from First Pecos.

On October 5, 2017, the Company delivered a notice (the “Notice”) to First Pecos and its manager, Leon “Chip” Greenblatt III, stating that First Pecos was in breach of the Purchase Agreement as a result of its failure to deliver the Purchase Price to the Company following satisfaction of all closing conditions in the Purchase Agreement. None of the shares of common stock, shares of Preferred Stock or Warrants were issued to First Pecos.

On October 10, 2017, First Pecos delivered a notice to the Company stating that, as a result of alleged breaches by the Company of its obligations pursuant to the Purchase Agreement, First Pecos terminated the Purchase Agreement and demanded that the Company pay the Termination Fee pursuant to the terms of the Purchase Agreement.

The Company believes that it was not in breach of the Purchase Agreement at any time, and that First Pecos’s notice was unjustified and without any legal merit or factual basis. Accordingly, the Company believes that First Pecos was not entitled to terminate the Purchase Agreement, and is not entitled to the Termination Fee, as the failure to

consummate the Pecos Placement resulted from First Pecos's breach of the Purchase Agreement. The Company is reviewing all of its rights and remedies against First Pecos that may be available to the Company.

NASDAQ Compliance and OTCQB Exchange Quotation

The Company had been operating under a grace period from November 18, 2016 through May 17, 2017 with respect to non-compliance of the listing requirements on NASDAQ. The Company then requested a hearing with the NASDAQ Hearings Panel (the "Panel"), and on June 29, 2017, presented its plan to regain compliance with the NASDAQ listing requirements, including Listing Rule 5550(a)(2), which requires an issuer to maintain a closing bid price of at least $1.00 per share, and Listing Rule 5550(b)(1), which requires minimum stockholders' equity of $2.5 million. The Panel accepted the Company's plan and continued listing was subject to a number of conditions, with the Panel's decision ultimately requiring that the Company evidence full compliance with all requirements for continued listing on The NASDAQ Capital Market, including the minimum bid price and stockholders' equity requirements, by no later than November 13, 2017.

The Company determined that as a result of the termination of the Purchase Agreement it could not regain compliance with The NASDAQ Capital Market listing standards by the deadline imposed by NASDAQ, and on October 4, 2017 the Company withdrew its appeal from the Panel.

On October 4, 2017, following the withdrawal by the Company of its appeal to the Panel, the Company received written notification from NASDAQ indicating that the Panel had determined to delist the Company's common stock from The NASDAQ Capital Market, and suspended it from trading on that marketplace effective with the open of business on October 6, 2017. NASDAQ also informed the Company that it would file a Form 25-NSE with the Securities and Exchange Commission (the "SEC") to remove the Company's common stock from listing on NASDAQ, which was filed with the SEC on December 7, 2017..

The Company's common stock began trading on the OTCQB marketplace at the open of business on October 6, 2017. The Company's common stock continues to trade under the symbol "BSTG".

3. Capital Stock, Financing and Liquidity (continued)

The delisting of the Company's common stock from The NASDAQ Capital Market may adversely affect the Company's ability to raise the significant additional capital that it will require, through public or private sales of equity securities, which may in turn adversely affect the ability of investors to trade the Company's securities and may negatively impact the value and liquidity of the Company's common stock. The delisting could also cause the Company to face significant adverse consequences affecting trading in its common stock, including, among others:

because the Company's common stock falls within the definition of a "penny stock," brokers trading in its common stock are required to adhere to more stringent rules, which could result in reduced trading activity in the secondary trading market for its securities;

reduced trading levels could result in limited or no analyst coverage for the Company;

potential limited availability of market quotations for the Company's common stock could adversely affect liquidity; and

restrictions on the Company's ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

Warrants

The Company has issued warrants to purchase common stock, and the warrant activity during the nine months ended September 30, 2017 was as follows:

	Warrants Amount	**Weighted-average exercise price**
Outstanding at December 31, 2016	1,560,284	$ 1.76
Granted	21,000,000	0.40
Exercised	(2,647,338)	0.40
Outstanding at September 30, 2017	19,912,946	$ 0.49

Other

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

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

- An amendment of the Company's charter to effect a reverse stock split of the shares of the Company's common stock at a ratio of not less than 1-for-2 and not greater than 1-for-20, with the exact ratio of, effective time of and decision whether or not to implement a reverse stock split to be determined by the Company's board of directors. There has been no decision by the Company's board of directors as to whether to implement a reverse stock split as of September 30, 2017.

Liquidity

The Company has incurred substantial operating losses since its inception, and as of September 30, 2017 had an accumulated deficit of approximately $47.0 million. The Company is currently investing significant resources in development and commercialization of products for use by clinicians in the field of regenerative medicine. The Company expects to continue to incur operating losses and negative cash flows from operations for the remainder of 2017 and in future years. As a result of First Pecos's refusal to deliver the Purchase Price, the Company is facing significant capital issues, as its current financial obligations exceed its cash on hand, and is exploring financing and other strategic alternatives. The Company cannot provide any assurance that it will be able to obtain sufficient financing. 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 that the Company does not raise additional capital from outside sources in the near future, it may be forced to further 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, or strategic collaborations and licensing arrangements. The Company may not be able to obtain additional financing on terms favorable to it, if at all.

3. Capital Stock, Financing and Liquidity (continued)

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

4. Fair Value Measurements

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

On May 19, 2016 and February 10, 2017, the Company closed on the sale of shares of the Company's common stock, the issuance of warrants to purchase shares of common stock, and the issuance of warrants to the placement agent for each transaction.

Due to a cash put provision within the warrant agreement, which could be enacted in certain change in control events, a liability associated with those warrants was initially recorded at fair value in the Company's consolidated balance sheets upon issuance, and subsequently re-measured each fiscal quarter. The changes in the fair value between issuance and the end of each reporting period is recorded as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss.

During the three and nine months ended September 30, 2017, warrant holders of 19,043,696 warrants agreed to the modification of the terms of their warrants, which resulted in placing all situations that would allow the warrant holder to put the warrant for cash fully in control of the Company. As a result of the modification, the warrants are no longer liability classified and do not need to be re-measured. These modifications resulted in the $4.3 million fair value of those warrants being reclassified from Warrant Liabilities to Additional Paid in Capital. The remaining un-modified 1,844,250 warrants will continue to be re-measured at each reporting period as long as they are outstanding and un-modified.

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

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

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

	Assumptions for estimating fair value of warrants modified during the three months ended		Assumptions for estimating fair value on reporting dates of	
	September 30, 2017	June 30, 2017	September 30, 2017	December 31, 2016
Risk-free interest rate	1.89 %	1.77 %	1.93 %	1.93 %
Expected volatility	82.3 %	82.4 %	85.0 %	72.7 %
Expected term (in years)	4.6	4.6	4.4	4.9
Expected dividend yield	-	-	-	-
Exercise price	$ 0.40	$ 0.50	$ 0.40	$ 1.76
Market value of common stock	$ 0.41	$ 0.33	$ 0.31	$ 0.89
Warrants to purchase shares of common stock	2,002,037	16,568,846	1,844,250	1,560,284

4. Fair Value Measurements (continued)

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, 2017:

	Fair Value Measurement as of September 30, 2017 (In thousands)			
	Level 1	Level 2	Level 3	Total
Warrant liability	$ -	$ -	$ 339	$ 339
Total	$ -	$ -	$ 339	$ 339

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2016:

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

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the nine months ended September 30, 2017:

	Warrant Liability (in thousands)
Balance at December 31, 2016	$ 605
Issuance of warrants	3,787
Change in fair value upon re-measurement	274
Reclassification of warrant liability to additional paid in capital upon modification	(3,746)
Reclassification of warrant liability to additional paid in capital upon exercise	(581)
Balance at September 30, 2017	$ 339

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

operations.

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

5. Relationship with Harvard Bioscience

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

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

From the time of the Company's spin-off from Harvard Bioscience through 2016, the Company manufactured research bioreactors. That business represented a small portion of the Company's operations. In late 2016, the Company ceased the manufacture of research bioreactors to concentrate its efforts solely on development of its clinical product candidates. On November 3, 2017, in exchange for settlement of outstanding rent due to Harvard Bioscience, the Company sold its supply of research bioreactor parts, a royalty free perpetual sublicensable and transferable right and license to use the intellectual property, including certain patents covering research bioreactors, and relinquished exclusive manufacturing or distribution rights with respect to research bioreactors to Harvard Bioscience. This settlement only covers research bioreactors, not to be used for clinical purposes. The Company retains full exclusive rights to all assets and rights associated with the clinical bioreactor used in the development of the Company's current Cellframe technology.

6. Stock-Based Compensation

Biostage 2013 Equity Incentive Plan

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

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

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

The Company has granted options to purchase common stock and restricted stock units (RSUs) under the Plan. Stock option and restricted stock unit activity during the nine months ended September 30, 2017 was as follows:

	Stock Options		Restricted Stock Units	
	Amount	**Weighted-average exercise price**	Amount	**Weighted -average grant date fair value**
Outstanding at December 31, 2016	3,877,681	$ 2.81	268	$ 6.00
Granted	1,896,500	0.40	404,750	0.38
Vested (RSUs)	-	-	(268)	6.00
Canceled	(569,865)	1.67	-	-
Outstanding at September 30, 2017	5,204,316	$ 2.05	404,750	$ 0.38

6. Stock-Based Compensation (continued)

The Company uses the Black-Scholes option pricing model to value its stock options. The weighted average assumptions for valuing the options granted during the nine months ended September 30, 2017 were as follows:

Expected volatility	78.71%
Expected dividends	0.00 %
Expected term	6.26 years
Risk-free rate	2.25 %

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(in thousands)		(in thousands)	
Research and development	$ 98	$ 198	$ 281	$ 535
General and administrative	96	164	310	492
Total stock-based compensation	$ 194	$ 362	$ 591	$ 1,027

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

Harvard Bioscience Stock Option and Incentive Plan

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

7. Commitments and Contingencies

On April 14, 2017, representatives for the estate of a deceased individual filed a civil lawsuit in the Suffolk Superior Court, in Boston, Massachusetts, against the Company, Harvard Bioscience and other defendants. The complaint alleges that the decedent was harmed by two tracheal implants that incorporated synthetic trachea scaffolds and a biologic component combined by the implanting surgeon with a bioreactor, and surgically implanted in the decedent in two surgeries performed in 2012 and 2013, which harm caused her injury and death. The civil complaint seeks a non-specific sum of money to compensate the plaintiffs. This civil lawsuit relates to the Company's first generation trachea scaffold technology for which the Company discontinued development in 2014, and not to the Company's current Cellframe technology nor to its lead development product candidate, the Cellspan esophageal implant. The litigation is at an early stage and the Company intends to vigorously defend this case. While the Company believes that such claim lacks merit, and has filed a motion seeking dismissal of the lawsuit, the Company is unable to predict the ultimate outcome of such litigation. In accordance with a separation and distribution agreement between Harvard Bioscience and the Company relating to the Separation, the Company would be required to indemnify Harvard Bioscience against losses that Harvard Bioscience may suffer as a result of this litigation. The Company has been informed by its insurance provider that the case has been accepted as an insurable claim under the Company's product liability insurance policy.

From time to time, the Company may be involved in various claims and legal proceedings arising in the ordinary course of business. Other than the above matter, there are no such matters pending that the Company expects to be material in relation to its business, financial condition, and results of operations or cash flows.

8. Subsequent Events

NASDAQ Delisting and OTCQB Quotation

On October 4, 2017, following the withdrawal by the Company of its appeal to the NASDAQ Hearings Panel, the Company received written notification from NASDAQ indicating that the Panel had determined to delist the Company's common stock from The NASDAQ Capital Market, and suspended the stock's trading on that marketplace effective with the open of business on October 6, 2017. NASDAQ also informed the Company that it would file a Form 25-NSE with the SEC to formally remove the Company's common stock from listing on NASDAQ, which was filed with the SEC on December 7, 2017.

The Company's common stock began trading on the OTCQB marketplace at the open of business on October 6, 2017. The Company's common stock continues to trade under the symbol "BSTG".

First Pecos Breach Notice

On October 5, 2017, the Company delivered a notice to First Pecos and its manager, Leon "Chip" Greenblatt III, stating that First Pecos was in breach of the Purchase Agreement, as described in note 3, as a result of its failure to deliver the Purchase Price to the Company following satisfaction of all closing conditions in the Purchase Agreement. None of the shares of common stock, shares of Preferred Stock or Warrants were issued to First Pecos.

On October 10, 2017, First Pecos delivered a notice to the Company stating that, as a result of alleged breaches by the Company of its obligations pursuant to the Purchase Agreement, First Pecos terminated the Purchase Agreement and demanded that the Company pay a $500,000 termination fee pursuant to the terms of the Purchase Agreement.

The Company believes that it was not in breach of the Purchase Agreement at any time, and that First Pecos' notice was unjustified and without any legal merit or factual basis. Accordingly, the Company believes that Pecos was not entitled to terminate the Purchase Agreement, and is not entitled to any termination fee thereunder, as the failure to consummate the Pecos Placement resulted from First Pecos' breach of the Purchase Agreement. The Company is reviewing all of its rights and remedies against First Pecos that may be available to the Company.

Headcount Reduction

During October and November, 2017, the Company completed a reduction in headcount of 21 of its employees, which represents 78% of its employees prior to such reduction. The reductions were made with the objective of conserving the Company's remaining cash on hand while the Company explores strategic alternatives with its advisors. The Company estimates that it will incur charges for one-time termination benefits in connection with the headcount reduction of approximately $165,000 for employee severance and related costs, payment of which has been deferred until cash resources become available. At the time of the first reduction the remaining officers reduced their salaries by 50%.

Bioreactor Sale to Harvard Bioscience

On November 3, 2017, in exchange for settlement of outstanding rent due to Harvard Bioscience, Biostage sold all of its current stock of research bioreactor parts, a royalty free perpetual sublicensable and transferable right and license to use the intellectual property, including but not limited to certain patents covering research bioreactors, and relinquished exclusive manufacturing or distribution rights with respect to research bioreactors to Harvard Bioscience. The Company had ceased the manufacture of research bioreactors in late 2016, to concentrate its efforts solely development of its clinical product candidates. This settlement only covers research bioreactors, not to be used for clinical purposes. The Company retains full exclusive rights to all assets and rights associated with the clinical bioreactor used in the development of the Company's current Cellframe technology.

December 2017 Private Placement MOU

On December 11, 2017, the Company entered into a binding Memorandum of Understanding (the "MOU") with Bin Zhao, pursuant to which the Company will issue to Ms. Zhao and her designees in a private placement (the "Private Placement") 40,000,000 shares of its common stock at a purchase price of $0.10 per share or, to the extent Ms. Zhao and her designees, following the transaction, would own more than 49.99% of the Company's common stock, shares of a new class of preferred stock of the Company (the "Preferred Stock") with a per-share purchase price of $1,000.

Additionally, Ms. Zhao and her designees will receive warrants (the "Warrants") to purchase 60,000,000 shares of the Company's common stock (or, to the extent Ms. Zhao and her designees would more than 49.99% of the Company's common stock, shares of Preferred Stock). The Warrants will have an exercise price of $0.10 per share.

The investor advanced a $300,000 deposit on the private placement proceeds concurrently with the MOU's execution.

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The Preferred Stock will be entitled to vote on any matters to which shares of the Company's common stock are entitled to vote, on an as-if-converted basis. The Preferred Stock will include an ownership limitation that will limit Ms. Zhao and her affiliates to owning no more than 49.99% of the Company's common stock. Additionally, the Company has agreed to grant board representation and nomination rights to Ms. Zhao and her affiliates, with two director nominees initially and, to the extent that Ms. Zhao and her affiliates beneficially own more than 50% of the Company's common stock (assuming conversion of all shares of Preferred Stock held by such persons), enough director nominees such that the director nominees of Ms. Zhao and her affiliates shall constitute a majority of the Company's board of directors (but no more than is necessary to constitute such a majority).

Pursuant to the MOU, the Company may identify other investors who may participate in the Private Placement on the same financial terms as Ms. Zhao and her designees, for gross proceeds of up to $2.0 million. In the event such other investors participate in the Private Placement, then Ms. Zhao and her designees may elect to purchase additional securities in the Private Placement, on the same terms, to the extent necessary to maintain the same post-transaction percentage of voting power that Ms. Zhao and her designees would have received if no such additional parties participated in the Private Placement.

The Private Placement is conditioned on satisfaction of customary closing conditions and on the Company completing a reverse stock split, as previously approved by its stockholders, such that the Company will have sufficient authorized but unissued shares of common stock to accommodate the issuance of shares of common stock in the Private Placement, along with all shares of common stock issuable upon exercise of the Warrants or conversion of the Preferred Stock. The numbers of securities, purchase price per share of common stock and exercise price of the Warrants will be adjusted to reflect such reverse stock split. The definitive agreements relating to the Private Placement will include customary representations, warranties and covenants.

The MOU is intended to be binding upon both the Company and Ms. Zhao. The shares of common stock, the Warrants (including shares of common stock issuable upon exercise of the Warrants) and the shares of Preferred Stock (including shares of common stock issuable upon conversion of the Preferred Stock) will be sold and issued without registration under the Securities Act of 1933 (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

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, 2016 filed with the Securities and Exchange Commission (the "SEC") on March 17, 2017 or described in our other public filings. Our results may also be affected by factors of which we are not currently aware. We may not update these forward-looking statements, even though our situation may change in the future, unless we have obligations under the federal securities laws to update and disclose material developments related to previously disclosed information.

Overview

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

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

We announced favorable preliminary pre-clinical results of large-animal studies for the esophagus, trachea and bronchus in November 2015. Since then, the Cellspan esophageal implant product candidates have been our lead development product candidates. We are pursuing two development programs that address conditions of the esophagus: esophageal atresia in pediatric patients and esophageal cancer in adult patients. Our Cellspan esophageal product candidates are each intended to provide a surgical solution to stimulate regeneration of a segment of the esophagus missing due to a congenital abnormality or following surgical removal to establish or reestablish the organ's continuity and integrity.

Approximately one in 2,500 babies in the U.S. is born with esophageal atresia, a congenital condition where the child's esophagus is underdeveloped and does not extend completely from the mouth to the stomach. When a long segment of the esophagus is lacking, the current standard of care is a series of surgical procedures where surgical sutures are applied to both ends of the esophagus in an attempt to stretch them together so they can be connected at a later date. This process can take weeks and the procedure can result in serious complications and may carry high rates of failure. Such approach also requires, in time, at least two separate surgical interventions. Other options include the use of the child's stomach that would be pulled up, or a piece of the patient's intestine that would be moved to the gap, to allow a connection to the mouth. We are working to develop a Cellspan esophageal implant product candidate to address newborns' esophageal atresia, to provide a simpler, more effective and potentially organ-sparing solution.

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

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

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

In November 2016, we were granted Orphan Drug Designation for our Cellspan esophageal implant by the FDA to restore the structure and function of the esophagus subsequent to esophageal damage due to cancer, injury or congenital abnormalities. Orphan drug status provides market exclusivity in the U.S. for seven years from the date of the product's approval for marketing. This exclusivity is in addition to any exclusivity we may obtain due to our patents. Additionally, orphan designation provides certain incentives, including tax credits and a waiver of the Biologics License Application or BLA fee. We also intend to apply for orphan drug designation for our Cellspan esophageal implant in Europe in the future. Orphan drug status in Europe provides market exclusivity there for ten years from the date of the product's approval for marketing.

We are conducting Good Laboratory Practice or GLP studies to demonstrate that our technology, personnel, systems and practices are sufficient for advancing into clinical trials. GLP safety studies are required to advance to an Investigational New Drug or IND application with the FDA, which would seek approval to initiate clinical trials for Biostage Cellspan esophageal implants in humans.

In October 2016, we announced a regulatory update following our planned pre-Investigational New Drug, or pre-IND, meeting with the FDA, for the advancement of our lead product candidate, a Cellspan Esophageal Implant to be used to stimulate esophageal regeneration following surgery to address esophageal cancer in adults, into human clinical studies. We subsequently announced our expectation 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.

On August 7, 2017, we announced the use of our Cellspan Esophageal Implant product candidate in a patient at a major U.S. hospital via an FDA-approved single-use expanded access application. The implant was surgically implanted in May 2017 into a 75-year old male patient with a life-threatening cancerous mass in his chest. The portion of the esophagus affected by the cancer was removed and the Cellspan Esophageal Implant was utilized to reconstruct the esophagus. It is the Company’s understanding that this life saving surgery would not have been attempted without the use of the Company’s Cellspan Esophageal Implant product candidate. The patient remains alive seven months after the surgery.

In August 2017, we announced that we are reprioritizing our product development program based on greatest unmet medical need, analysis of existing surgical options, and physician validation. We believe that, of our two current programs, the Cellspan Esophageal Implant program to treat pediatric esophageal atresia provides a shorter time to a commercial product and the greater overall potential value. We also believe that the pediatric esophageal atresia program needs to advance in the first position with the FDA to ensure eligibility for the pediatric rare disease accelerated review voucher program. Receipt of such a voucher, if achieved, could potentially provide significant value to the company in the future. As a result, we are elevating the pediatric program to our lead program. We plan to continue to advance the Cellspan Esophageal Implant adult program, but have not filed an IND for that product candidate at this time. Our current plan for that product candidate is to update the FDA on the progress and status of our preclinical testing, including our GLP studies, for the adult esophagus program in the near future. Based on the FDA’s feedback, we may amend its preclinical testing plan and continue toward the filing of an IND.

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

February 2017 Public Offering

On February 10, 2017, we completed a public offering of 20,000,000 shares of common stock at a purchase price of $0.40 per share and the issuance of warrants to purchase 20,000,000 shares of common stock at an exercise price of $0.50 per warrant for gross proceeds of $8.0 million and net proceeds of $6.8 million. Additionally, we issued warrants to purchase 1,000,000 shares of common stock to the placement agent for the offering at an exercise price of $0.40 per warrant. As of September 30, 2017, 2,647,338 of those warrants had been exercised for proceeds of $1.1 million. If in the future the stock's market price were to increase and market conditions were such that all of the remaining 18,352,662 warrants were to be exercised, then such exercises could provide approximately $7.4 million of cash proceeds to the Company, net of issuance costs.

First Pecos Securities Purchase Agreement and Breach Notice

On June 26, 2017, we entered into a binding Memorandum of Understanding (the "Pecos MOU") with First Pecos, LLC ("First Pecos"), pursuant to which the we agreed to issue to First Pecos in a private placement (the "Pecos Placement") 9,700,000 shares of its common stock at a purchase price of $0.315 per share or, to the extent First Pecos, following the transaction, would own more than 19.9% of our common stock, shares of a new class of our preferred stock (the "Preferred Stock") with a per-share purchase price of $1,000.

Additionally, First Pecos was to receive warrants (the "Warrants") to purchase 9,700,000 shares of our common stock or, to the extent First Pecos would own more than 19.9% of our common stock, shares of Preferred Stock. The Warrants would have had an exercise price of $0.315 per share and would not have been exercisable until six months after the closing of the Pecos Placement.

Under the Pecos Placement, the Preferred Stock would bear a cumulative annual dividend of 15%, compounding annually, and would be senior to all of our other common stock, but would generally not have any voting rights. Following approval by our stockholders, the Preferred Stock would automatically convert into shares of our common stock. We agreed to include a proposal for such stockholder approval in the definitive proxy statement for our 2018 annual meeting of stockholders and, if not approved at such meeting, would seek approval from our stockholders every six months thereafter.

In connection with the Pecos Placement, First Pecos agreed to serve as a backstopping party with respect to two pro rata rights offerings with aggregate gross proceeds of up to $14.0 million that we could elect to conduct within 24 months following the closing of the Pecos Placement. Additionally, we had agreed to grant board representation and nomination rights to First Pecos that would be proportional to the percentage of our common stock owned by First Pecos and its affiliates.

The Pecos Placement was conditioned on satisfaction of customary closing conditions, including us terminating our Shareholder Rights Plan, and was expected to be consummated on or prior to August 15, 2017. The definitive agreements relating to the Pecos Placement were to include customary representations, warranties and covenants. We agreed to file a resale registration statement promptly after the closing of the Pecos Placement to register the resale of the shares of common stock issued in the Pecos Placement.

The Pecos MOU was intended to be binding upon both us and First Pecos. In the event that we failed to perform any of our obligations under the Pecos MOU or otherwise breached the Pecos MOU, subject to certain exceptions, First Pecos could terminate the Pecos MOU, and we would have been obligated to pay a termination fee of $0.5 million (the “Termination Fee”).

We entered into the Securities Purchase Agreement (the “Purchase Agreement) with First Pecos on August 11, 2017, pursuant to which we agreed to sell to First Pecos, and First Pecos agreed to purchase from us, shares of our common stock, shares of our Preferred Stock and Warrants on the terms described above. The aggregate gross proceeds from the private placement of common stock, Preferred Stock and the Warrant would have been $3,055,500 (the “Purchase Price”). We did not receive the Purchase Price from First Pecos.

On October 5, 2017, we delivered a notice (the “Notice”) to First Pecos and its manager, Leon “Chip” Greenblatt III, stating that First Pecos was in breach of the Purchase Agreement as a result of its failure to deliver the Purchase Price to us following satisfaction of all closing conditions in the Purchase Agreement. None of the shares of common stock, shares of Preferred Stock or Warrants have been issued to First Pecos.

On October 10, 2017, First Pecos delivered a notice to us stating that, as a result of alleged breaches by us of our obligations pursuant to the Purchase Agreement, First Pecos has terminated the Purchase Agreement and demanded that we pay the Termination Fee pursuant to the terms of the Purchase Agreement.

We believe that we were not in breach of the Purchase Agreement at any time, and that First Pecos’s notice was unjustified and without any legal merit or factual basis. Accordingly, we believe that First Pecos is not entitled to terminate the Purchase Agreement, and is not entitled to the Termination Fee thereunder, as the failure to consummate the Pecos Placement resulted from First Pecos’s breach of the Purchase Agreement. We are reviewing all of its rights and remedies against First Pecos that may be available to us.

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NASDAQ Delisting and OTCQB Quotation

We had been operating under an extension period from November 18, 2016 through May 17, 2017 with respect to non-compliance of the listing requirements on NASDAQ. We then requested a hearing with the NASDAQ Hearings Panel (the "Panel"), and on June 29, 2017, presented its plan to regain compliance with the NASDAQ listing requirements, including Listing Rule 5550(a)(2), which requires an issuer to maintain a closing bid price of at least $1.00 per share, and Listing Rule 5550(b)(1), which requires minimum stockholders' equity of $2.5 million. The Panel accepted our plan and continued listing was subject to a number of conditions, with the Panel's decision ultimately requiring that we evidence full compliance with all requirements for continued listing on The NASDAQ Capital Market, including the minimum bid price and stockholders' equity requirements, by no later than November 13, 2017.

We determined that as a result of the termination of the Purchase Agreement, we could not regain compliance with The NASDAQ Capital Market listing standards by the deadline imposed by NASDAQ, and on October 4, 2017 we withdrew our appeal from the Panel.

On October 4, 2017, following the withdrawal by us of our appeal to the Panel, we received written notification from NASDAQ indicating that the Panel had determined to delist our common stock from The NASDAQ Capital Market, and suspended it from trading on that marketplace effective with the open of business on October 6, 2017. NASDAQ has also informed us that it would file a Form 25-NSE with the Securities and Exchange Commission (the "SEC") to remove the Company's common stock from listing on NASDAQ, which was filed with the SEC on December 7, 2017.

Our common stock began trading on the OTCQB marketplace at the open of business on October 6, 2017. Our common stock continues to trade under the symbol "BSTG".

December 2017 Private Placement MOU

On December 11, 2017, we entered into a binding Memorandum of Understanding (the "MOU") with Bin Zhao, pursuant to which we will issue to Ms. Zhao and her designees in a private placement (the "Private Placement") 40,000,000 shares of our common stock at a purchase price of $0.10 per share or, to the extent Ms. Zhao and her designees, following the transaction, would own more than 49.99% of our common stock, shares of a new class of our preferred stock (the "Preferred Stock") with a per-share purchase price of $1,000.

Additionally, Ms. Zhao and her designees will receive warrants (the "Warrants") to purchase 60,000,000 shares of our common stock (or, to the extent Ms. Zhao and her designees would more than 49.99% of our common stock, shares of Preferred Stock). The Warrants will have an exercise price of $0.10 per share.

The investor advanced a $300,000 deposit on the private placement proceeds concurrently with the MOU's execution.

The Preferred Stock will be entitled to vote on any matters to which shares of our common stock are entitled to vote, on an as-if-converted basis. The Preferred Stock will include an ownership limitation that will limit Ms. Zhao and her affiliates to owning no more than 49.99% of our common stock. Additionally, we have agreed to grant board representation and nomination rights to Ms. Zhao and her affiliates, with two director nominees initially and, to the extent that Ms. Zhao and her affiliates beneficially own more than 50% of our common stock (assuming conversion of all shares of Preferred Stock held by such persons), enough director nominees such that the director nominees of Ms. Zhao and her affiliates shall constitute a majority of our board of directors (but no more than is necessary to constitute such a majority).

Pursuant to the MOU, we may identify other investors who may participate in the Private Placement on the same financial terms as Ms. Zhao and her designees, for gross proceeds of up to $2.0 million. In the event such other investors participate in the Private Placement, then Ms. Zhao and her designees may elect to purchase additional securities in the Private Placement, on the same terms, to the extent necessary to maintain the same post-transaction percentage of voting power that Ms. Zhao and her designees would have received if no such additional parties participated in the Private Placement.

The Private Placement is conditioned on satisfaction of customary closing conditions and on us completing a reverse stock split, as previously approved by our stockholders, such that we will have sufficient authorized but unissued shares of common stock to accommodate the issuance of shares of common stock in the Private Placement, along with all shares of common stock issuable upon exercise of the Warrants or conversion of the Preferred Stock. The numbers of securities, purchase price per share of common stock and exercise price of the Warrants will be adjusted to reflect such reverse stock split. The definitive agreements relating to the Private Placement will include customary representations, warranties and covenants.

The MOU is intended to be binding upon both us and Ms. Zhao. The shares of common stock, the Warrants (including shares of common stock issuable upon exercise of the Warrants) and the shares of Preferred Stock (including shares of common stock issuable upon conversion of the Preferred Stock) will be sold and issued without registration under the Securities Act of 1933 (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and Rule 506 promulgated under the Securities Act as sales to accredited investors, and in reliance on similar exemptions under applicable state laws.

Operating Losses and Cash Requirements

We have incurred substantial operating losses since our inception, and as of September 30, 2017 had an accumulated deficit of approximately $47.0 million. We are currently investing significant resources in development of products for use by clinicians in the field of regenerative medicine. We expect to continue to incur operating losses and negative cash flows from operations for the remainder of 2017 and in future years. As a result of First Pecos's refusal to deliver the Purchase Price, we are facing significant capital issues, as our current financial obligations exceed our cash on hand, and are exploring financing and other strategic alternatives, including the Private Placement. We cannot provide any assurance that it will be able to obtain sufficient financing. Therefore, these conditions raise substantial doubt about our ability to continue as a going concern.

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

Results of Operations

Components of Operating Loss

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

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

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

Comparison of the three months ended September 30, 2017 to the three months ended September 30, 2016

Research and Development Expense

Research and development expense increased by approximately $0.1 million, to $2.4 million or 6.2% for the three months ended September 30, 2017 compared to $2.2 million for the three months ended September 30, 2016. The increase was primarily due increases of $0.2 million in compensation and related expenses offset by a $0.1 million decrease in stock-based compensation.

Selling, General and Administrative Expense

Selling, general and administrative expense remained unchanged at $0.9 million for the three months ended September 30, 2017 and the three months ended September 30, 2016.

Expense or income from change in fair value of liability warrants, net of issuance costs

The change in fair value of the warrant liability decreased $0.1 million for the three months ended September 30, 2017 due to a decrease in the fair value of the warrants, specifically with respect to the value of the underlying common shares and a decrease due to the exercise or modification of warrants. Holders agreed to the modification of 2,474,850 warrants in the third quarter of 2017 such that the modified warrants now meet the definition of an equity instrument. The exercise of warrants to purchase 2,647,338 shares of common stock in the three months ended September 30, 2017 included 1,672,338 warrants that had not been modified.

Comparison of the nine months ended September 30, 2017 to the nine months ended September 30, 2016

Research and Development Expense

Research and development expense increased $1.8 million, to $7.1 million or 34.9% for the nine months ended September 30, 2017 compared to $5.3 million for the nine months ended September 30, 2016. The increase was

primarily due to increases of $0.9 million in compensation and related expenses, reflecting increased headcount as of September 30, 2017 compared to September 30, 2016, $0.7 million of outsourced research and consulting costs, $0.3 million of costs associated with scientific conferences and related travel and $0.2 million of other research and development expenses, offset by a decrease in stock-based compensation of $0.3 million.

Selling, General and Administrative Expense

Selling, general and administrative expense decreased $0.4 million, or 10.9%, to $2.9 million for the nine months ended September 30, 2017 compared with $3.3 million for the nine months ended September 30, 2016. The decrease was due primarily to $0.2 million of costs related to the Company's name change to Biostage and greater investor communication efforts, which occurred during the nine months ended September 30, 2016 as well as a $0.2 million decrease in stock-based compensation primarily due to options previously issued becoming fully vested during the first quarter of 2017.

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

The gain on the change in fair value of the warrant liability of $0.3 million in the nine months ended September 2016 became a loss of $0.7 million during the nine months ended September 30, 2017. The $1.0 million change primarily due to the addition of 21,000,000 warrants issued in the first quarter of 2017 in connection with the issuance of 20,000,000 shares of common stock, offset by the modification of 19,043,696 warrants and the exercise of 2,647,338 warrants.

Financial Condition, Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of September 30, 2017, we had an accumulated deficit of approximately $47.0 million. We are currently investing significant resources in the development 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.

As a result of First Pecos's refusal to deliver the Purchase Price pursuant to the Pecos Placement, the we are facing significant capital issues, as its current financial obligations exceed its cash on hand, and is exploring financing and other strategic alternatives, including the Private Placement, as described above under “Overview—December 2017 Private Placement MOU”. We cannot provide any assurance we it will be able to obtain sufficient financing.

We need to raise additional funds to fund our operations. In the event that we do not raise additional capital from outside sources in the near future, we may be forced to further curtail or cease our operations. Cash requirements and cash resource needs will vary significantly depending upon the timing of clinical and animal studies and other resource needs that will be required to complete ongoing development and pre-clinical and clinical testing of products as well as regulatory efforts and collaborative arrangements necessary for our products that are currently under development. We 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 $9.4 million for the nine months ended September 30, 2017 was primarily a result of our $10.7 million net loss, partially offset by a $1.6 million add-back of non-cash expenses related to the change in the fair value of warrant liability, stock-based compensation and depreciation.

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 and $1.0 million of cash provided for working capital and $1.1 million add-back of non-cash expenses of stock-based compensation and depreciation, partially offset by a favorable change in the fair value of warrant liability.

Investing activities. Net cash used in investing activities during the nine months ended September 30, 2017 and 2016 of $0.1 million and $0.2 million, respectively, reflects cash used for additions to property and equipment.

Financing activities Net cash generated from financing activities during the nine months ended September 30, 2017 of $7.9 million consisted of the net proceeds from the issuance of 20,000,000 shares of our common stock at a purchase price of $0.40 per share, the issuance of warrants to purchase 20,000,000 shares of common stock at an exercise price of $0.40 per warrant and warrants issued to placement agents for the offering to purchase 1,000,000 shares of common stock at an exercise price of $0.50 per warrant and $1.1 million from the conversion of warrants for 2,647,338 shares of common stock at $0.40 per share.

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 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, 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 Capital Purchase Agreement.

Recent Authoritative Accounting Guidance

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

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

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

In November 2016, the FASB issued ASU 2016-18 *Statement of Cash Flows* ("ASU 2016-18") which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company is in the process of evaluating the impact of ASU 2016-17 on its consolidated financial statements.

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

Critical Accounting Policies and Estimates

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2017. Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer have concluded that they believe that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

On April 14, 2017, representatives for the estate of a deceased individual filed a civil lawsuit in the Suffolk Superior Court, in Boston, Massachusetts, against the Company, Harvard Bioscience and other defendants. The complaint alleges that the decedent was harmed by two tracheal implants that incorporated synthetic trachea scaffolds and a biologic component combined by the implanting surgeon with a bioreactor, and surgically implanted in the decedent in two surgeries performed in 2012 and 2013, which harm caused her injury and death. The civil complaint seeks a non-specific sum of money to compensate the plaintiffs. This civil lawsuit relates to the Company's first generation trachea scaffold technology for which the Company discontinued development in 2014, and not to the Company's current Cellframe technology nor to its lead development product candidate, the Cellspan esophageal implant. The litigation is at an early stage and the Company intends to vigorously defend this case. While the Company believes that such claim lacks merit, and has filed a motion seeking dismissal of the lawsuit, the Company is unable to predict the ultimate outcome of such litigation. In accordance with a separation and distribution agreement between Harvard Bioscience and the Company relating to the Separation, the Company would be required to indemnify Harvard Bioscience against losses that Harvard Bioscience may suffer as a result of this litigation. The Company has been informed by its insurance provider that the case has been accepted as an insurable claim under the Company's product liability insurance policy.

Item 1A. Risk Factors

In addition to the risk factor below and the other risks described herein, Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 17, 2017, contains risk factors identified by the Company. Except for the risk factor below and the other risks described herein, there have been no material changes to the risk factors we previously disclosed. Our operations could also be affected by additional factors that are not presently known to us or by factors that we currently consider immaterial to our business.

Risks Related to the Ownership of Shares of Our Common Stock

Our common stock has been delisted on The NASDAQ Capital Market, which may negatively impact the trading price of our common stock and the levels of liquidity available to our stockholders.

Our common stock was suspended from trading on The NASDAQ Capital Market, prior to the opening of the market on October 6, 2017 and began quotation on the OTCQB Venture Market on that date, retaining the symbol "BSTG". On December 7, 2017, NASDAQ filed a Form 25-NSE with the SEC to complete the delisting process. The trading of our common stock on the OTCQB rather than NASDAQ may negatively impact the trading price of our common stock

and the levels of liquidity available to our stockholders.

Upon such delisting, our common stock became subject to the regulations of the SEC relating to the market for pennystocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of shareholders to sell securities in the secondary market. Accordingly, investors in our common stock may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be continue to be eligible for trading or quotation on the OTCQB Venture Market or any other alternative exchanges or markets.

The delisting of our common stock from NASDAQ may adversely affect our ability to raise additional financing through public or private sales of equity securities, may significantly affect the ability of investors to trade our securities, and may negatively affect the value and liquidity of our common stock. Such delisting from NASDAQ may also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. Furthermore, because of the limited market and low volume of trading in our common stock that could occur, the share price of our common stock could more likely be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market’s perception of our business, and announcements made by us, our competitors, parties with whom we have business relationships or third parties.

Item 6. Exhibits

Exhibit

Index

10.1(1)	Memorandum of Understanding, dated December 11, 2017, between Biostage, Inc. and Bin Zhao.
31.1+	Certification of Chief Financial Officer of Biostage, Inc., pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Executive Officer of Biostage, Inc., pursuant to Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Financial Officer of Biostage, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

(1) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on December 14, 2017) and incorporated by reference thereto.

+Filed herewith.

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

SIGNATURES

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

Date: December 15, 2017

BIOSTAGE, INC.

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

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

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