UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended March 31, 2021

☐ **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)

Securities registered pursuant to Section 12(b) of the Act: None

Title of each class	Trading Symbol(s)	Name of each exchange on which registered

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. ☒ YES ☐ NO

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). ☒ 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 ☒ Smaller reporting company ☒

Emerging growth company ☐

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 ☒ NO

As of May 21, 2021, there were 9,388,407 shares of common stock, par value $0.01 per share, outstanding.

Biostage Inc.
Form 10-Q
For the Quarter Ended March 31, 2021

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements.

BIOSTAGE, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value and share data)

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash	$ 466	$ 1,026
Restricted cash	50	50
Grant receivable	22	77
Prepaid expenses and other current assets	388	524
Total current assets	926	1,677
Property, plant and equipment, net	174	217
Right-of-use assets	156	182
Total assets	$ 1,256	$ 2,076
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 81	$ 31
Accrued and other current liabilities	220	317
Current portion of notes payable	346	284
Warrant liability	14	17
Current portion of operating lease liability	110	107
Total current liabilities	771	756
Notes payable, net of current portion	58	120
Operating lease liability, net of current portion	46	75
Total liabilities	$ 875	$ 951
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 2,000,000 shares authorized as of March 31, 2021 and December 31, 2020, 0 issued and outstanding	$ -	$ -
Common stock, par value $0.01 per share, 60,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 9,388,407 issued and outstanding at March 31, 2021 and December 31, 2020	94	94
Additional paid-in capital	70,121	69,991
Accumulated deficit	(69,834)	(68,960)
Total stockholders' equity	381	1,125
Total liabilities and stockholders' equity	$ 1,256	$ 2,076

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2021	2020
Revenues	$ -	$ -
Operating expenses:		
Research and development	473	643
Selling, general and administrative	522	1,253
Total operating expenses	995	1,896
Operating loss	(995)	(1,896)
Other income (expense):		
Grant income	118	-
Change in fair value of warrant liability	3	(100)
Total other income (expense), net	121	(100)
Net loss	$ (874)	$ (1,996)
Basic and diluted net loss per share	$ (0.09)	$ (0.24)
Weighted-average common shares, basic and diluted	9,388	8,287

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands)

	Three Months Ended March 31, 2021				
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2020	**9,388**	**$ 94**	**$ 69,991**	**$ (68,960)**	**$ 1,125**
Net loss	-	-	-	(874)	(874)
Share-based compensation	-	-	130	-	130
Balance at March 31, 2021	**9,388**	**$ 94**	**$ 70,121**	**$ (69,834)**	**$ 381**

	Three Months Ended March 31, 2020				
	Number of Common Shares Outstanding	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2019	**8,156**	**$ 82**	**$ 65,102**	**$ (64,095)**	**$ 1,089**
Net loss	-	-	-	(1,996)	(1,996)
Share-based compensation	-	-	588	-	588
Issuance of fully vested common shares	12	-	(24)	-	(24)
Issuance of common stock and warrants to purchase common stock	151	1	558	-	559
Issuance of common stock from exercise of warrants	214	2	426	-	428
Balance at March 31, 2020	**8,533**	**$ 85**	**$ 66,650**	**$ (66,091)**	**$ 644**

See accompanying notes to unaudited consolidated financial statements.

BIOSTAGE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2021	2020
OPERATING ACTIVITIES		
Net loss	$ (874)	$ (1,996)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	130	588

Depreciation	43	48
Change in fair value of warrant liability	(3)	100
Changes in operating assets and liabilities:		
Grant receivable	55	-
Prepaid expenses and other current assets	136	98
Accounts payable	50	(14)
Accrued and other current liabilities	(97)	82
Net cash used in operating activities	(560)	(1,094)
INVESTING ACTIVITIES		
Net cash used in investing activities	$ -	$ -
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and warrants	-	559
Proceeds from exercise of warrants	-	428
Net cash provided by financing activities	-	987
Net decrease in cash and restricted cash	(560)	(107)
Cash and restricted cash at beginning of period	1,076	963
Cash and restricted cash at end of period	$ 516	$ 856

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 the Company's novel Cellframe ™ and Cellspan ™ technology. The Company's technology is comprised of a proprietary biocompatible scaffold, which is the foundation of the Company's Cellframe technology, that is seeded with the recipient's own mesenchymal stromal cells to form the Company's Cellspan implant. The Company believes that this technology may provide surgeons a new paradigm to address life-threatening conditions of the esophagus, bronchus, and trachea due to congenital abnormalities, diseases, infections and traumas. Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, and acquiring operating assets. The Company has one business segment and does not have significant costs or assets outside the United States.

On October 31, 2013, Harvard Bioscience, Inc. (Harvard Bioscience) contributed its regenerative medicine business assets, plus $15 million of cash, into Biostage (formerly "Harvard Apparatus Regenerative Technologies" at time of spin-off.) 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 stockholders of Harvard Bioscience (the "Distribution").

The Company's common stock is currently traded on the OTCQB Venture Market under the symbol "BSTG".

Going Concern

The Company has incurred substantial operating losses since its inception, and as of March 31, 2021 has an accumulated deficit of approximately $69.8 million and will require additional financing to fund future operations.

The Company expects that its operating cash on-hand as of March 31, 2021 of $0.5 million, along with cash proceeds of approximately $0.3 million received in May of 2021 from existing investors, will enable it to fund its operating expenses and capital expenditure requirements into the third quarter of 2021. 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 to fund its operations. In the event the Company does not raise additional capital from outside sources in the second quarter, it may be forced to curtail or cease its operations. Cash requirements and cash resource needs will vary significantly depending upon the timing of the financial and other resource needs that will be required to complete ongoing development, 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 is currently seeking and will continue to seek financings from other existing and/or new investors to raise necessary funds through a combination of public or private equity offerings. The Company may also pursue debt financings, other financing mechanisms, research grants, or strategic collaborations and licensing arrangements. The Company may not be able to obtain additional financing on favorable terms, if at all.

The Company's operations will be adversely affected if it is unable to raise or obtain needed funding and such circumstance may materially affect the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and therefore, the consolidated 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.

Basis of Presentation

The consolidated 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).

Use of Estimates

The preparation of our consolidated financial statements requires us to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, expenses and related disclosures. On an ongoing basis we evaluate our estimates, judgments and methodologies. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and equity and the amount of expenses. Actual results may differ from these estimates.

Net Loss Per Share

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

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

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

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

Unaudited Interim Financial Information

The accompanying interim consolidated balance sheet as of March 31, 2021, consolidated interim statements of operations and stockholders' equity for the three months ended March 31, 2021 and 2020, and consolidated statements of cash flows for the three months ended March 31, 2021 and 2020 are unaudited. The interim unaudited consolidated financial statements have been prepared in accordance with GAAP on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company's financial position as of March 31, 2021, its consolidated results of operations, consolidated statement of cash flows, and consolidated stockholders' equity for the three-month periods ended March 31, 2021 and 2020. The financial data and other information disclosed in these notes related to the three-month periods ended March 31, 2021 and 2020 are unaudited. The results for the three months ended March 31, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, 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 consolidated financial statements for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K.

SBIR Award

Grant income is recognized when qualified research and development costs are incurred and recorded in other income (expense), net in the consolidated statements of operations. When evaluating grant revenue from the SBIR grant, the Company considered accounting requirements under the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 606, *Revenue From Contracts With Customers*. The Company concluded that ASC 606 did not apply as there is no exchange of goods or services or an exchange of intellectual property between the parties; therefore, the Company presents grant income in other income.

On March 28, 2018, the Company was awarded a Fast-Track Small Business Innovation Research (SBIR) grant by the Eunice Kennedy National Institute of Child Health and Human Development (NICHD) to support testing of pediatric Cellspan™ Esophageal Implants (CEIs). The award for Phase I provided for the reimbursement of approximately $0.2 million of qualified research and development costs which was received and recognized as grant income during 2018.

On October 26, 2018, the Company was awarded the Phase II Fast-Track SBIR grant from the Eunice Kennedy NICHD grant aggregating $1.1 million to support development, testing, and translation to the clinic through September 2019 and represented years one and two of the Phase II portion of the award. On August 3, 2020, the Company was awarded a third year of the Phase II grant totaling $0.5 million for support of development, testing, and translation to the clinic covering qualified expenses incurred from October 1, 2019 through September 30, 2020. In September of 2020, the Company filed and was granted a one year, no-cost extension for the Phase II grant period extending through September 30, 2021.

For the three months ended March 31, 2021, the Company recognized $0.1 million of grant income, from Phase II of the SBIR grant. The aggregate SBIR grant to date provides a total award of $1.8 million, of which, approximately $1.4 million has been recognized through March 31, 2021.

The Company did not recognize any grant income during the three months ended March 31, 2020.

Restricted Cash

Restricted cash consists of $50,000 held as collateral for the Company's credit card program as of March 31, 2021 and December 31, 2020. The Company's statements of cash flows include restricted cash with cash when reconciling the beginning-of-period and end-of-period total amounts shown on such statements.

A reconciliation of the cash and restricted cash reported within the balance sheet that sum to the total of the same amounts shown in the statements of cash flows is as follows:

	March 31, 2021	December 31, 2020
	(In thousands)	
Cash	$ 466	$ 806
Restricted cash	50	50
Total cash and restricted cash as shown in the statements of cash flows	$ 516	$ 856

Recently Adopted Accounting Pronouncements

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

3. Notes Payable

On May 4, 2020, the Company obtained a loan (Loan) from the Bank of America (Lender) in the aggregate amount of $0.4 million, pursuant to the Paycheck Protection Plan (PPP), established as part of the CARES Act. The Loan is evidenced by a promissory note dated May 4, 2020 issued by the Company and will accrue interest at a fixed interest rate of 1% per annum from the funding date of May 4, 2020. Payments of principal and interest have been deferred since the funding under the original terms of the promissory note. However, the Loan and accrued interest may be forgivable at the conclusion of this period.

Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. The terms of the promissory note, including eligibility and forgiveness, may be subject to additional requirements adopted by the SBA. Any unforgiven portion of the PPP loan, including principal and interest, will mature on May 4, 2022 and will be required to be payable monthly. The Note may be prepaid by the Company at any time prior to maturity with no prepayment penalties.

The Company has accounted for the loan under FASB ASC 470, Debt. Repayment amounts due within one year have been recorded as current liabilities, and the remaining amounts due in more than one year as long-term liabilities. On December 18, 2020, the Company submitted the loan forgiveness application for the entire borrowings of $0.4 million to the Lender and was notified on January 7, 2021 that the application was submitted to the Small Business Administration (SBA) for review. The SBA had up to 90 days from the date of submittal to make a final decision on loan forgiveness. The Company has yet to be notified of the SBA's forgiveness decision.

If the Company is successful in receiving forgiveness for any portion of the loan used for qualifying expenses, those amounts will be recorded as a gain upon extinguishment.

4. Capital Stock

During the three months ended March 31, 2020, the Company issued a total of 151,027 shares of our common stock at a purchase price of $3.70 per share and warrants to purchase 151,027 shares of common stock at an exercise price of $3.70 per share to a group of investors for aggregate gross and net proceeds of approximately $0.6 million, of which, $0.5 million and $0.1 million was allocated to the common stock and warrants, respectively. The Company has classified these warrants on its consolidated balance sheets as equity and valued using the Black-Scholes model based on the following weighted average assumptions:

Risk-free interest rate		0.88%
Expected volatility		106.7%
Expected term		2 months
Expected dividend yield		-
Exercise price	$	3.70
Market value of common stock	$	3.11

During the three months ended March 31, 2020, the Company also issued 214,000 shares of our common stock to a group of investors in connection with the exercise of 214,000 previously issued warrants at $2.00 per share for aggregate gross and net proceeds of approximately $0.4 million.

During the three months ended March 31, 2020, the Company issued a total of 11,950 shares of our common stock to employees due to the vesting of restricted stock units and issuance of a common stock award.

5. Fair Value Measurements

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

The Company utilizes a valuation hierarchy for disclosure of the inputs to the valuations used to measure fair value that prioritizes the inputs into three broad levels. 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 2 as of March 31, 2021 and December 31, 2020. The Company's restricted cash that serves as collateral for the Company's credit card program is held in a demand money market account and is measured at fair value based on quoted prices, which are Level 1 inputs. The Company classifies warrants to purchase common stock that are accounted for as liabilities as Level 3 liabilities, as discussed below.

The following table presents a reconciliation of the Company's liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the three months ended March 31, 2021:

	Warrant Liability (In thousands)
Balance at December 31, 2020	$ 17
Change in fair value upon re-measurement	(3)
Balance at March 31, 2021	$ 14

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

	March 31, 2021	December 31, 2020
Risk-free interest rate	0.16%	0.12%
Expected volatility	140.08%	137.89%
Expected term (in years)	0.9	1.1
Expected dividend yield	-	-
Exercise price	$ 8.00	$ 8.00
Market value of common stock	$ 1.34	$ 1.25
Warrants to purchase shares of common stock	92,212	92,212

6. Share-Based Compensation

Biostage Amended and Restated Equity Incentive Plan

The Company maintains the Amended and Restated Equity Incentive Plan (the Plan) for the benefit of certain 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's policy is to issue stock available from its registered but unissued stock pool through its transfer agent to satisfy stock option exercises and the vesting of restricted stock units. The vesting period for awards is generally four years and the contractual life is ten years. Canceled and forfeited options and awards are available to be reissued under the Plan.

In June 2020, the Company's shareholders approved the Plan to, among other things, increase of the number of shares of the Company's common stock available for issuance pursuant thereto by 3,000,000 shares, which increased the total shares authorized to be issued under the Plan to 5,098,000. There were 3,461,091 shares available for issuance as of March 31, 2021.

The Company has granted options to purchase common stock under the Plan. Stock option activity during the three months ended March 31, 2021 was as follows:

	Stock Options	
	Amount	Weighted–average exercise price
Outstanding at December 31, 2020	1,599,720	$ 6.33
Granted	16,413	1.80
Canceled	-	-
Outstanding at March 31, 2021	1,616,134	$ 6.31

The Company's outstanding stock options include 338,663 performance-based awards that have vesting provisions subject to the achievement of certain business milestones. Total unrecognized compensation expense for the remaining 243,532 performance-based awards is approximately $0.8 million. No expense has been recognized for these unvested awards as of March 31, 2021 given that the milestone achievements for these awards have not yet been deemed probable for accounting purposes.

Aggregate intrinsic value for outstanding options and exercisable options for the year ended March 31, 2021 was $0 based on the Company's closing stock price of $1.34 per share as of March 31, 2021. As of March 31, 2021, unrecognized compensation cost related to unvested nonperformance-based awards amounted to $0.3 million, which will be recognized over a weighted average period of 0.3 years.

The Company uses the Black-Scholes option pricing model to value its stock options. The weighted average assumptions for valuing options granted during the three months ended March 31, 2021 were as follows:

Risk-free interest rate	0.47%
Expected volatility	123.20%
Expected term	5.3 years
Expected dividend yield	n/a

In February 2020, as part of the termination arrangement with the Company's former chief executive officer, the Company modified certain options to purchase 236,970 shares of common stock, issued an 80,000 fully vested stock option grant, and accelerated the vesting of 3,300 restricted stock units resulting in recording $153,000, $70,000, and $4,000, respectively, of share-based compensation during the three months ended March 31, 2020.

In March 2020, the Company issued 35,000 common stock awards to an employee that was earned upon the achievement of certain milestones. One of the milestones for 15,000 common shares was achieved on March 27, 2020, and the Company issued 9,795 fully vested share of common stock to the employee with 5,205 common shares withheld to cover taxes. During the three months ended March 31, 2020, the Company recognized a total of $74,800 of share-based compensation with the remaining expense of $65,200 recognized upon the achievement of certain milestones over the requisite service period during the three months ended June 30, 2020.

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

	Three Months Ended March 31,	
	2021	2020
	(In thousands)	
Research and development	$ 80	$ 92
General and administrative	50	496
Total share-based compensation	$ 130	$ 588

The Company estimates the fair value of non-employee share options using the Black-Scholes option pricing model reflecting the same assumptions as applied to employee and director options in each of the reporting periods, other than the expected life, which is assumed to be the remaining contractual life of the options.

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 and Harvard Bioscience. The complaint alleges that the decedent's injury and death were caused by two tracheal implants that incorporated synthetic trachea scaffolds and a biologic component combined by the implanting surgeon with a bioreactor, and surgically implanted in the decedent in two surgeries performed in 2012 and 2013. The civil complaint seeks a non-specific sum of money to compensate the plaintiffs. This civil lawsuit relates to the Company's first-generation trachea scaffold technology for which the Company discontinued development in 2014, and not to the Company's current Cellspan technology nor to its lead development product candidate, the Cellspan Esophageal Implant. The Company intends to vigorously defend this case. While the Company believes that such claim lacks merit, the Company is unable to predict the ultimate outcome of such litigation. In accordance with a separation and distribution agreement between Harvard Bioscience and the Company relating to the spin-off, 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. The Company does not believe a loss is probable at this time and therefore has not accrued any amounts for this contingent liability.

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, results of operations, or cash flows.

8. Leases

The Company leases laboratory and office space and certain equipment with remaining terms ranging approximately from 1 year to 3.5 years.

The laboratory and office space arrangement is under a sublease that was renewed in December of 2020 and currently extends through May 31, 2022. This lease automatically renews annually for a one-year period unless the Company or the counterparty provides a notice of termination within one hundred and eighty days prior to May 31 of each year.

All of the Company's leases qualify as operating leases. The following table summarizes the presentation of the Company's operating leases in its consolidated balance sheets:

		For the Quarter ended March 31	
(In thousands)	**Balance Sheet Classification**	**2021**	**2020**
Assets:			
Operating lease assets	Right-of-use asset	$ 156	$ 166
Liabilities:			
Current operating lease liabilities	Current portion of operating lease liabilities	$ 110	$ 105
Non-current operating lease liabilities	Operating lease liabilities, net of current portion	$ 46	$ 61
Total operating lease liabilities		$ 156	$ 166

Cash paid included in the computation of the right of use asset and lease liability during the three months ended March 31, 2021 and 2020 amounted to approximately $30,000, respectively.

The weighted average remaining lease term and weighted average discount rate of the Company's operating leases are as follows:

	As of March 31,	
	2021	**2020**
Weighted average remaining lease term (in years)	1.72	2.20
Weighted average discount rate	10.24%	13.13%

The Company recorded lease expense in the following expense categories of its consolidated statements of operations:

		For the Three Months Ended March 31,	
(In thousands)	**Statement of Operations Classification**	**2021**	**2020**
Operating lease expense	Research and development	$ 19	$ 19
	Selling, general and administrative	11	11
		$ 30	$ 30

The minimum lease payments for the next five years are expected to be as follows:

(In thousands)	**As Of March 31, 2021**
2020	$ 91
2021	62
2022	12
2023	7
2024	-
Total lease payments	$ 172
Less: imputed interest	16
Present value of operating lease liabilities	$ 156

9. Net Loss Per Share

Basic and diluted loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding.

The following potential common shares were excluded from the calculation of diluted net loss per share attributable to common stockholders for the three months ended March 31, 2021 and 2020 because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2021	**2020**
Warrants to purchase common stock	1,893,201	2,610,078
Options to purchase common stock	1,616,134	1,607,570
Common stock awards	-	20,000
Total	3,509,335	4,237,648

10. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the three months ended March 31, 2021 and 2020, respectively, due to the expected loss before income taxes to be incurred for the years ended December 31, 2021 and 2020, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

11. Subsequent Events

Equity Transactions

In May 2021, the Company received aggregate gross and net proceeds of approximately $0.3 million from a group of existing investors.

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 and the potential impact of COVID-19 on our business and operations. 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 our ability to access debt and equity markets and raise additional funds when needed; 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; the number of patients who can be treated with our products; the amount and timing of costs associated with our development of implant products, bioreactors, scaffolds and other devices; our failure to comply with regulations and any changes in regulations; unpredictable difficulties or delays in the development of new technology; our collaborators or other third parties we contract with, including with respect to conducting any clinical trial or pre-clinical development efforts, not devoting sufficient time and resources to successfully carry out their duties or meet expected deadlines; our ability to attract and retain qualified personnel and key employees and retain senior management; potential liability exposure with respect to our products; the availability and price of acceptable raw materials and components from third-party suppliers; difficulties in obtaining or retaining the management and other human resource competencies that we need to achieve our business objectives; increased competition in the field of regenerative medicine and bioengineering, and the financial resources of our competitors; our ability to obtain and maintain intellectual property protection for our device and product candidates; our inability to implement our growth strategy; the control our principal stockholders can exert based on holding a majority of voting power; plus factors described under the heading "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (the "SEC") on April 13, 2021 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.

Biostage, Inc. is referred to herein as "we," "our," "us," and "the Company".

Business Overview

We are a biotechnology company developing bioengineered organ implants based on our novel technology. Our technology is comprised of a proprietary biocompatible scaffold, which is the foundation of our Cellframe ™ technology, that is seeded with the recipient's own mesenchymal stromal cells to form our Cellspan ™ implant, combining the clinically proven principles of tissue engineering, cell biology and materials science. This technology is being developed to treat life-threatening conditions of the esophagus, trachea and bronchus with the objective of dramatically improving the treatment paradigm for those patients.

We believe our technology will provide surgeons with new ways to address damage to the esophagus, bronchus, and trachea due to congenital abnormalities, diseases, infections and traumas. Products being developed based on our technology for those indications are called Cellspan products. We are pursuing our Cellspan Esophageal Implant (CEI) technology as our first product candidate to address both esophageal disease and pediatric esophageal atresia, and we are also developing our technology's applications to address conditions of the bronchus and trachea.

In collaboration with world-class institutions, such as Mayo Clinic and Connecticut Children's Medical Center, we are advancing our technology. Our product development program is based on the greatest medical unmet needs, analysis of existing surgical options and physician validation.

In October 2019, we filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) to treat patients with esophageal disease, absent of cancer, in adults that would require a short segment esophageal implant following clinically indicated short segment resection of the thoracic esophagus with our CEI product candidate. In November 2019, we received notice from the FDA placing our IND on clinical hold and providing a preliminary list of clinical hold and non-clinical hold questions. In December 2019, we received the formal letter with clinical hold and non-clinical hold questions and submitted our response to the clinical hold questions on February 18, 2020. On March 19, 2020, the FDA notified us that the IND for our CEI product candidate has been removed from clinical hold and that we can proceed with our study. This FDA approval enables us to start our transition to a clinical-stage biotechnology company, and start clinical planning, engaging with a clinical research organization and site readiness in advance of starting the clinical trial for our CEI product candidate. On May 7, 2020, we submitted responses to certain non-clinical hold questions and finalized a majority of remaining non-clinical hold responses in the third quarter of 2020, and submitted the remaining responses in the fourth quarter of 2020, except for responses to our clinical trial details that we will submit once a clinical research organization is selected. The COVID-19 pandemic could adversely impact our business, including planned clinical trials, as discussed elsewhere in this document.

We believe that receiving regulatory approval to treat pediatric esophageal atresia with our CEI may provide a shorter time to a commercial product and the greater overall potential value in the U.S. market. In addition to providing a novel solution for a great medical need, approval of our pediatric esophageal atresia product candidate may result in receipt of a priority review voucher, which if achieved, could potentially provide significant value and non-dilutive funding to Biostage in the future. We have continued to advance our CEI pediatric esophagus program and plan to file a protocol amendment with the FDA to update our CEI esophageal disease clinical program after the initial adult patients are treated in the esophageal disease trial, subject to FDA approval.

We have also formed a subsidiary in Hong Kong, Harvard Apparatus Regenerative Technology Limited, as we continue to assess the market and regulatory approval pathway in China as to our implant products. We are not certain at this time as to which market, including U.S. or China for example, may provide the most viable initial pathway for regulatory approval to a commercial product. This will depend on a number of factors, including the approval and development processes, related costs, ability to raise capital and the terms

and conditions thereof, as well as the ongoing impact of the COVID-19 pandemic, among other factors. Any development and capital raising efforts in China may include a joint venture in relation to our Hong Kong subsidiary, and would also involve a number of commercial variables, including rights and obligations pertaining to licensing, development and financing, among others. Our failure to receive or obtain such clearances or approvals on a timely basis or at all, whether that be in the U.S., China or otherwise, would have an adverse effect on our results of operations.

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

Financial Condition and Need for Additional Funds

We expect to continue to incur operating losses and negative cash flows from operations for 2021 and in future years.

Operating Losses and Cash Requirements

We have incurred substantial operating losses since our inception, and as of March 31, 2021 had an accumulated deficit of approximately $69.8 million and will require additional financing to fund future operations. We expect that our operating cash on-hand as of March 31, 2021 of approximately $0.5 million along with cash proceeds of approximately $0.3 million received in May of 2021 from existing investors, will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2021. We expect to continue to incur operating losses and negative cash flows from operations for 2021 and in future years. Therefore, as disclosed in Note 1 to our consolidated financial statements, these conditions raise substantial doubt about our ability to continue as a going concern.

We will need to raise additional funds to fund our operations. In the event we do not raise additional capital from outside sources in the second quarter, we may be forced to curtail or cease its operations. Cash requirements and cash resource needs will vary significantly depending upon the timing of the financial and other resource needs that will be required to complete ongoing development, 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 are currently seeking and will continue to seek financings from other existing and/or new investors to raise necessary funds through a combination of public or private equity offerings. We may also pursue debt financings, other financing mechanisms, research grants, or strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on favorable terms, if at all.

Our operations will be adversely affected if it is unable to raise or obtain needed funding and may materially affect our ability to continue as a going concern. Our consolidated financial statements have been prepared assuming that we will continue as a going concern and therefore, the consolidated 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.

Small Business Innovation Research Grant

On March 28, 2018, we were awarded a Fast-Track Small Business Innovation Research (SBIR) grant by the Eunice Kennedy National Institute of Child Health and Human Development (NICHD) to support testing of pediatric Cellspan™ Esophageal Implants (CEIs). The award for Phase I provided for the reimbursement of approximately $0.2 million of qualified research and development costs which was received and recognized as grant income during 2018.

On October 26, 2018, we were awarded the Phase II Fast-Track SBIR grant from the Eunice Kennedy NICHD grant aggregating $1.1 million to support development, testing, and translation to the clinic through September 2019 and represented years one and two of the Phase II portion of the award. On August 3, 2020, we were awarded a third year of the Phase II grant totaling $0.5 million for support of development, testing, and translation to the clinic covering qualified expenses incurred from October 1, 2019 through September 30, 2020. In September of 2020, we filed and were granted a one year, no-cost extension for the Phase II grant period extending through September 30, 2021.

For the three months ended March 31, 2021 and 2020, we recognized $0.1 million and $0.0 million of grant income, respectively, from Phase II of the SBIR grant. The aggregate SBIR grant to date provides a total award of $1.8 million, of which, approximately $1.4 million has been recognized through March 31, 2021.

Management

We disclosed in our Current Report on Form 8-K dated February 7, 2020 that James McGorry, our former Chief Executive Officer, resigned from his role effective February 7, 2020. We also disclosed in our Current Report on Form 8-K dated August 31, 2020 that Peter Chakoutis, our Vice President of Finance, had taken a leave of absence from his role for personal reasons effective August 24, 2020. We disclosed in our Current Report on Form 8-K dated October 30, 2020 that Mr. Chakoutis would not be returning to the Company. In April 2021, we appointed Peter Pellegrino as Interim Vice President of Finance and Mr. Pellegrino is our current principal accounting officer and principal financial officer.

Components of Operating Loss

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

Selling, general and administrative expense. Selling, general and administrative expense consists primarily of salaries and other related expenses, including share-based compensation, for personnel in executive, accounting, information technology and human resources roles. Other costs include professional fees for legal and accounting services, insurance, investor relations and facility costs.

Other income (expense). Grant income reflects income earned under the SBIR grant. Grant income is recognized based on timing of when qualified research and development costs are incurred. Changes in fair value of warrant liability represent the change in the fair value of common stock warrants classified as liability awards during the three months March 31, 2021 and 2020. 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.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States, or. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are discussed in more detail in Note 2 to our financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Share-based Compensation

We account for our share-based compensation in accordance with the fair value recognition provisions of current authoritative guidance. Share-based awards, including stock options, are measured at fair value as of the grant date and recognized as expense over the requisite service period (generally the vesting period), which we have elected to amortize on a straight-line basis. Expense on share-based awards for which vesting is performance or milestone based is recognized on a straight-line basis from the date when we determine the achievement of the milestone is probable to the vesting/milestone achievement date. Since share-based compensation expense is based on awards ultimately expected to vest, it has been reduced by an estimate for future forfeitures. We estimate forfeitures at the time of grant and revise our estimate, if necessary, in subsequent periods. We estimate the fair value of options granted using the Black-Scholes option valuation model. Significant judgment is required in determining the proper assumptions used in these models. The assumptions used include the risk-free interest rate, expected term, expected volatility and expected dividend yield. We base our assumptions on historical data when available or, when not available, on a peer group of companies. However, these assumptions consist of estimates of future market conditions, which are inherently uncertain and subject to our judgment, and therefore any changes in assumptions could significantly impact the future grant date fair value of share-based awards.

Warrant Liability

Most of the warrants to purchase shares of our common stock have been classified on our condensed consolidated balance sheets as equity. We classify warrants as a liability in our condensed consolidated balance sheets if the warrant is a free-standing financial instrument that may require us to transfer cash consideration upon exercise and that cash transfer event would be out of our control. Such a "liability warrant" is initially recorded at fair value on the date of grant using the Black-Scholes model, net of issuance costs, and it is subsequently re-measured to fair value at each subsequent balance sheet date. Changes in fair value of the warrant are recognized as a component of other income (expense) in the condensed consolidated statements of operations. We will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant.

Results of Operations

The following table summarizes the results of our operations for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,		Change 2021 vs. 2020	
	2021	**2020**	**Change**	**%**
Operating expenses				
Research and development	$ 473	$ 643	$ (170)	(26)%
Selling, general and administrative	522	1,253	(731)	(58)%
Total operating expenses	995	1,896	(901)	(48)%
Other income (expense)				
Grant Income	118	-	118	nm
Change in fair value of warrant liability	3	(100)	103	103%
Other income (expense), net	121	(100)	221	221%
Net loss	$ (874)	$ (1,996)	$ 1,122	56%

nm = not meaningful

Research and development expense

Research and development expense decreased approximately $0.2 million, or 24%, to $0.5 million for the three months ended March 31, 2021 as compared to $0.6 million for the same period in 2020. This decrease was due to lower headcount resulting in lower salary and share-based compensation expenses period over period.

Selling, general and administrative expense

Selling, general and administrative expense decreased approximately $0.7 million, or 59%, to $0.5 million for the three months ended March 31, 2021 compared to $1.3 million for the same period in 2020. This decrease was due to lower headcount resulting in lower salary expense of $0.3 million and lower share-based compensation expense of $0.4 million associated with the separation arrangement with our former Chief Executive Officer during the three months ended March 31, 2020.

Grant income

For the three months ended March 31, 2021, we recorded grant income of $0.1 million for qualified expenditures under the SBIR grant. There was no grant income for qualified expenditures from an SBIR grant for the three-month period ended March 31, 2020 as the modified Phase II grant development plan we submitted to the NICHD had not yet been approved as of March 31, 2020.

Change in fair value of warrant liability

During the three months ended March 31, 2021, the change in fair value of our warrant liability resulted in income of $4,000 due primarily to an increase in stock price and volatility of the underlying common shares. This compared to expense of $0.1 million for three months ended March 31, 2020 due to a higher stock price and volatility of the underlying common shares.

Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of March 31, 2021, we had an accumulated deficit of approximately $69.8 million. We are currently investing significant resources in the development and commercialization of our products for use by clinicians and researchers in the fields of regenerative medicine and bioengineering. As a result, we expect to incur operating losses and negative operating cash flows for the foreseeable future.

The following table sets forth the primary uses of cash for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net Cash Used in Operating Activities	$ (560)	$ (1,094)
Net Cash Used by Investing Activities	$ -	$ -
Net Cash Provided by Financing Activities	$ -	$ 987

Comparison of Three Months Ended March 31, 2021 and 2020

Operating activities. Net cash used in operating activities of $0.6 million for the three months ended March 31, 2021 was due primarily to our net loss of $0.9 million, partially offset by a $0.2 million add-back for non-cash expenses including share-based compensation, depreciation, and change in fair value of warrant liability and $0.1 million of cash provided by working capital due to the timing of prepaid expenses and accounts payable.

Net cash used in operating activities of $1.1 million for the three months ended March 31, 2020 was primarily due to our net loss of $2.0 million, partially offset by $0.7 million add-back for non-cash expenses including share-based compensation, depreciation, and change in fair value of warrant liability, and $0.2 million of cash impact of working capital due to the timing of prepaid expenses and accounts payable.

Investing activities. There were no investing activities for the three months ended March 31, 2021 and 2020.

Financing activities. There were no financing activities for the three months ended March 31, 2021.

Net cash generated from financing activities during the three months ended March 31, 2020 of approximately $1.0 million consisted of $0.6 million of net proceeds received from private placement transactions that resulted in the issuance of 151,027 shares of our common stock and warrants to purchase 151,027 shares of common stock to a group of investors at an exercise price of $3.70 per share, and $0.4 million received from the issuance of 214,000 shares of our common stock to a group of investors in connection with the exercise of a portion of the warrants previously issued on December 27, 2017.

Off-Balance Sheet Arrangements

We do not have any material off-balance sheet arrangements as of March 31, 2021.

Other Information

JOBS Act

Effective December 31, 2020, we are no longer considered an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company is a smaller reporting company and is not required to provide this information pursuant to Item 305(e), Regulation S-K.

Item 4. Controls and Procedures.

This Report includes the certifications of our President (who is our principal executive officer) and our Interim Vice President of Finance (who is our principal financial and accounting officer) required by Rule 13a-14 of the Exchange Act. See Exhibits 31.1 and 31.2. This Item 4 includes information concerning the controls and control evaluations referred to in those certifications.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that such information is accumulated and communicated to management, including the President and Interim Vice President of Finance, to allow timely decisions regarding required disclosures.

In connection with the preparation of this Quarterly Report on Form 10-Q, our management, under the supervision and with the participation of our President and Interim Vice President of Finance, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2021. Based upon the evaluation described above, our President and Interim Vice President of Finance have concluded that they believe our disclosure controls and procedures were not effective as of the end of the period covered by this Quarterly Report on Form 10-Q due to the material weakness identified as of December 31, 2020 that has not yet been remediated.

Changes in Internal Control over Financial Reporting

Our management, with the participation of the President and Interim Vice President of Finance, has evaluated whether any change in our internal control over financial accounting and reporting occurred during the quarter ended March 31, 2021. 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 accounting and reporting.

Remediation Plan

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on April 13, 2021, our management concluded that a material weakness in internal control over financial reporting existed as of December 31, 2020 and continues to exist as of March 31, 2021, being that we did not design or maintain effective internal controls over the timely identification and recording of financial statement adjustments. Specifically, we did not identify, analyze, record, and disclose certain non-routine accounting matters, such as a lease extension and a grant contract, timely and accurately. We are committed to remediating such material weaknesses in a timely fashion, including through the engagement of Point Providence Consulting and related appointment of Mr. Pellegrino as our Interim Vice President of Finance. As management continues to evaluate and work to improve its internal control over financial reporting, management may determine it is necessary to take additional measures to address the material weakness. Until the controls have been operating for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively, the material weakness described above will continue to exist.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings arising in the ordinary course of business. Other than the ongoing civil lawsuit described in Item 3 of Part I of our Annual Report on Form 10-K filed with the SEC on April 13, 2021, there are no such matters pending that we expect to be material in relation to our business, financial condition, and results of operations or cash flows.

Item 1A. Risk Factors

To our knowledge and except to the extent additional factual information disclosed in this Quarterly Report on Form 10-Q relates to such risk factors, and the additional risk factors noted below, there have been no material changes in the risk factors described in Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on April 13, 2021.

Our audited financial statements for the year ended December 31, 2020 contain a going concern qualification. Our financial status creates doubt whether we will continue as a going concern. We will need additional funds in the near future and our operations will be adversely affected if we are unable to obtain needed funding.

We ended March 31, 2021 with approximately $0.5 million of operating cash on-hand and received cash proceeds of approximately $0.3 million in May of 2021 from existing investors. This will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2021. We will need to raise additional capital in the in or before the third quarter and beyond to fund operations. If we do not raise sufficient additional capital from outside sources in such timeframe, we will be forced to further curtail or cease our operations. Based on these circumstances, our ability to continue as a going concern is at risk and our independent registered public accounting firm included a "going concern" qualification as to our ability to continue as a going concern in their audit report dated April 13, 2021, included in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on April 13, 2021. Our cash requirements and cash resources will vary significantly depending upon the timing, and the financial and other resources that will be required to complete ongoing development and pre-clinical and clinical testing of our products as well as regulatory efforts and collaborative arrangements necessary for our products that are currently under development. In addition to development and other costs, we expect to incur capital expenditures from time to time. These capital expenditures will be influenced by our regulatory compliance efforts, our success, if any, at developing collaborative arrangements with strategic partners, our needs for additional facilities and capital equipment and the growth, if any, of our business in general. We will require additional funding to continue our anticipated operations and support our capital and operating needs. We are currently seeking and will continue to seek financings from other existing and/or new investors to raise necessary funds through a combination of public or private equity offerings. We may also pursue debt financings, other financing mechanisms, strategic collaborations and licensing arrangements. We may not be able to obtain additional financing on terms favorable to us, if at all. In addition, general market conditions, including the effect of the COVID-19 pandemic on financial markets, as well as the effects of laws and regulations on foreign investment in the United States under the jurisdiction of the Committee on Foreign Investment in the United States (CFIUS), and other agencies and related regulations, including the Foreign Investment Risk Review Modernization Act (FIRRMA), adopted in August 2018, may make it difficult for us to seek financing from the capital markets.

Any additional equity financings could result in significant dilution to our stockholders and possible restrictions on subsequent financings. Debt financing, if available, could result in agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or paying dividends. Other financing mechanisms may involve selling intellectual property rights, payment of royalties or participation in our revenue or cash flow. In addition, in order to raise additional funds through strategic collaborations or licensing arrangements, we may be required to relinquish certain rights to some or all of our technologies or products. If we cannot raise funds or engage strategic partners on acceptable terms when needed, we may not be able to continue our research and development activities, develop or enhance our products, take advantage of future opportunities, grow our business, respond to competitive pressures or unanticipated requirements, or at worst may be forced to curtail or cease our operations.

Item 6. Exhibits

Exhibit Index

31.1+	Certification of Interim Vice President of Finance of Biostage, Inc., pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of President of Biostage, Inc., pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Interim Vice President of Finance of Biostage, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of President of Biostage, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\+ Filed herewith.

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

SIGNATURES

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

Date: May 24, 2021

BIOSTAGE, INC.

By: /s/ Hong Yu

Name: Hong Yu
Title: President
(principal executive officer)

By: /s/ Peter A. Pellegrino Jr.

Name: Peter A. Pellegrino Jr.
Title: Interim Vice President of Finance
(principal financial officer)

Exhibit 31.1

Certification

I, Peter A. Pellegrino Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biostage, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 24, 2021

/s/ Peter A. Pellegrino Jr.
Peter A. Pellegrino Jr.
Interim Vice President of Finance

Exhibit 31.2

Certification

I, Hong Yu, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biostage, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 24, 2021

/s/ Hong Yu
Hong Yu
President

Exhibit 32.1

CERTIFICATION OF PERIODIC FINANCIAL REPORT
PURSUANT TO 18 U.S.C. SECTION 1350

The undersigned officer of Biostage, Inc. (the "Company") hereby certifies to his knowledge that the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021 (the "Report") to which this certification is being furnished as an exhibit, as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. This certification is provided solely pursuant to 18 U.S.C. Section 1350 and Item 601(b)(32) of Regulation S-K (Item 601(b)(32)) promulgated under the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act. In accordance with clause (ii) of Item 601(b) (32), this certification (A) shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and (B) shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Date: May 24, 2021

/s/ Peter A. Pellegrino Jr.
Name: Peter A. Pellegrino Jr.
Title: Interim Vice President of Finance

Exhibit 32.2

CERTIFICATION OF PERIODIC FINANCIAL REPORT
PURSUANT TO 18 U.S.C. SECTION 1350

The undersigned officer of Biostage, Inc. (the "Company") hereby certifies to his knowledge that the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021 (the "Report") to which this certification is being furnished as an exhibit, as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company. This certification is provided solely pursuant to 18 U.S.C. Section 1350 and Item 601(b)(32) of Regulation S-K (Item 601(b)(32)) promulgated under the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act. In accordance with clause (ii) of Item 601(b) (32), this certification (A) shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and (B) shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Date: May 24, 2021

/s/ Hong Yu
Name: Hong Yu
Title: President