
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 June 30, 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

(State or Other Jurisdiction of
Incorporation or Organization)

45-5210462

(IRS Employer
Identification No.)

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

01746
(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 August 13, 2021, there were 9,688,407 shares of common stock, par value \$0.01 per share, outstanding.

Biostage, Inc.
Form 10-Q
For the Quarter Ended June 30, 2021

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

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

| | June 30, 2021 | December 31, 2020 |
|---|--------------------|----------------------|
| ASSETS | <i>(Unaudited)</i> | |
| Current assets: | | |
| Cash | \$ 451 | \$ 1,026 |
| Restricted cash | 50 | 50 |
| Grant receivable | 70 | 77 |
| Prepaid expenses and other current assets | 263 | 524 |
| Total current assets | 834 | 1,677 |
| Property, plant and equipment, net | 151 | 217 |
| Right-of-use assets | 130 | 182 |
| Total assets | <u>\$ 1,115</u> | <u>\$ 2,076</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 39 | \$ 31 |
| Accrued and other current liabilities | 213 | 317 |
| Current portion of notes payable | — | 284 |
| Warrant liability | 5 | 17 |
| Current portion of operating lease liability | 104 | 107 |
| Total current liabilities | 361 | 756 |
| Notes payable, net of current portion | — | 120 |
| Operating lease liability, net of current portion | 26 | 75 |
| Total liabilities | <u>387</u> | <u>951</u> |
| Commitments and contingencies (Note 7) | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.01 par value; 2,000,000 shares authorized as of June 30, 2021 and December 31, 2020, 0 issued and outstanding | — | — |
| Common stock, par value \$0.01 per share, 60,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 9,688,407 and 9,388,407 issued and outstanding at June 30, 2021 and December 31, 2020, respectively | 97 | 94 |
| Additional paid-in capital | 70,847 | 69,991 |
| Accumulated deficit | (70,216) | (68,960) |
| Total stockholders' equity | <u>728</u> | <u>1,125</u> |
| Total liabilities and stockholders' equity | <u>\$ 1,115</u> | <u>\$ 2,076</u> |

See accompanying notes to unaudited consolidated financial statements.

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|-------------------|------------------------------|-------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Revenues | \$ — | \$ — | \$ — | \$ — |
| Operating expenses: | | | | |
| Research and development | 300 | 536 | 773 | 1,179 |
| General and administrative | 618 | 725 | 1,140 | 1,978 |
| Total operating expenses | <u>918</u> | <u>1,261</u> | <u>1,913</u> | <u>3,157</u> |
| Operating loss | <u>(918)</u> | <u>(1,261)</u> | <u>(1,913)</u> | <u>(3,157)</u> |
| Other income (expense): | | | | |
| Forgiveness of notes payable | 408 | — | 408 | — |
| Grant income | 47 | — | 165 | — |
| Change in fair value of warrant liability | 10 | 78 | 13 | (22) |
| Other income (expense), net | 71 | (2) | 71 | (2) |
| Total other income (expense), net | <u>536</u> | <u>76</u> | <u>657</u> | <u>(24)</u> |
| Net loss | <u>\$ (382)</u> | <u>\$ (1,185)</u> | <u>\$ (1,256)</u> | <u>\$ (3,181)</u> |
| Basic and diluted net loss per share | <u>\$ (0.04)</u> | <u>\$ (0.14)</u> | <u>\$ (0.13)</u> | <u>\$ (0.38)</u> |
| Weighted-average common shares, basic and diluted | <u>9,435</u> | <u>8,636</u> | <u>9,412</u> | <u>8,462</u> |

See accompanying notes to unaudited consolidated financial statements.

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

| Three Months Ended June 30, 2021 | | | | | |
|---------------------------------------|--|-----------------|----------------------------------|------------------------|----------------------------------|
| | Number of Common Shares Outstanding | Common Stock | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
| Balance at March 31, 2021 | 9,388 | \$ 94 | \$ 70,121 | \$ (69,834) | \$ 381 |
| Net loss | — | — | — | (382) | (382) |
| Share-based compensation expense | — | — | 131 | — | 131 |
| Issuance of common stock and warrants | 300 | 3 | 595 | — | 598 |
| Balance at June 30, 2021 | 9,688 | \$ 97 | \$ 70,847 | \$ (70,216) | \$ 728 |

| Three Months Ended June 30, 2020 | | | | | |
|--|--|-----------------|----------------------------------|------------------------|----------------------------------|
| | Number of Common Shares Outstanding | Common Stock | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
| Balance at March 31, 2020 | 8,533 | \$ 85 | \$ 66,650 | \$ (66,091) | \$ 644 |
| Net loss | — | — | — | (1,185) | (1,185) |
| Share-based compensation expense | — | — | 265 | — | 265 |
| Issuance of fully vested common shares | 14 | — | (18) | — | (18) |
| Issuance of common stock from exercise of warrants | 141 | 2 | 522 | — | 524 |
| Balance at June 30, 2020 | 8,688 | \$ 87 | \$ 67,419 | \$ (67,276) | \$ 230 |

See accompanying notes to unaudited consolidated financial statements.

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

Six Months Ended June 30, 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 | — | — | — | (1,256) | (1,256) |
| Share-based compensation expense | — | — | 261 | — | 261 |
| Issuance of common stock and warrants | 300 | 3 | 595 | — | 598 |
| Balance at June 30, 2021 | 9,688 | \$ 97 | \$ 70,847 | \$ (70,216) | \$ 728 |

Six Months Ended June 30, 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 | — | — | — | (3,181) | (3,181) |
| Share-based compensation expense | — | — | 853 | — | 853 |
| Issuance of fully vested common shares | 26 | — | (42) | — | (42) |
| Issuance of common stock and warrants to purchase common stock | 151 | 1 | 558 | — | 559 |
| Issuance of common stock from exercise of warrants | 355 | 4 | 948 | — | 952 |
| Balance at June 30, 2020 | 8,688 | \$ 87 | \$ 67,419 | \$ (67,276) | \$ 230 |

See accompanying notes to unaudited consolidated financial statements.

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

| | Six Months Ended June 30, | |
|---|------------------------------|----------------|
| | 2021 | 2020 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net loss | \$ (1,256) | \$ (3,181) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Forgiveness of notes payable | (408) | — |
| Share-based compensation expense | 261 | 853 |
| Depreciation | 66 | 94 |
| Change in fair value of warrant liability | (12) | 22 |
| Changes in operating assets and liabilities: | | |
| Grant receivable | 7 | — |
| Prepaid expenses and other current assets | 261 | 171 |
| Accounts payable | 8 | (100) |
| Accrued and other current liabilities | (100) | (23) |
| Net cash used in operating activities | <u>(1,173)</u> | <u>(2,164)</u> |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Net cash used in investing activities | <u>—</u> | <u>—</u> |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Proceeds from issuance of common stock and warrants | 598 | 559 |
| Proceeds from exercise of warrants | — | 952 |
| Proceeds from notes payable | — | 404 |
| Acquisition of common stock for tax withholding obligations | — | (46) |
| Net cash provided by financing activities | <u>598</u> | <u>1,869</u> |
| Net decrease in cash and restricted cash | (575) | (295) |
| Cash and restricted cash at beginning of period | 1,076 | 963 |
| Cash and restricted cash at end of period | <u>\$ 501</u> | <u>\$ 668</u> |
| Supplemental disclosure of non-cash investing and financing activities: | | |
| Issuance of vested stock | <u>\$ —</u> | <u>\$ 42</u> |

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 Cellspan™ and Cellframe™ 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 the 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 June 30, 2021 has an accumulated deficit of approximately \$70.2 million and will require additional financing to fund future operations.

The Company expects that its operating cash on-hand as of June 30, 2021 of \$0.5 million, which includes cash proceeds of approximately \$0.6 million received in May and June 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 third 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.

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.

Principles of Consolidation

The consolidated financial statements include the accounts of Biostage, and three wholly-owned subsidiaries, Harvard Apparatus Regenerative Technology Limited (Hong Kong), Harvard Apparatus Regenerative Technology GmbH (Germany) and Biostage Limited (UK). The three wholly-owned subsidiaries do not have any net assets as of June 30, 2021. The functional currency for these subsidiaries is the U.S dollar. All intercompany balances and transactions have been eliminated in consolidation.

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 the Company's consolidated financial statements requires the Company to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, equity, expenses and related disclosures. On an ongoing basis the Company evaluates its estimates, judgments and methodologies. The Company bases its estimates on historical experience and on various other assumptions that the Company believes 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 June 30, 2021, consolidated interim statements of operations and stockholders' equity for the three and six months ended June 30, 2021 and 2020, and consolidated statements of cash flows for the six months ended June 30, 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 consolidated financial statements and, in the opinion of management, reflect all adjustments necessary for a fair statement of the Company's financial position as of June 30, 2021, its consolidated results of operations and consolidated stockholders' equity for the three and six months ended June 30, 2021 and 2020 and consolidated statements of cash flows for the six months ended June 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2021 and 2020 are unaudited. The results for the three and six months ended June 30, 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.

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 October 26, 2018, the Company was awarded the Phase II Fast-Track SBIR grant from the Eunice Kennedy NICHD grant aggregating approximately \$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 approximately \$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 and six months ended June 30, 2021, the Company recognized approximately \$47,000 and \$165,000 of grant income, respectively, from Phase II of the SBIR grant. The aggregate SBIR grant to date provides a total award of approximately \$1.8 million, of which, approximately \$1.5 million has been recognized through June 30, 2021. There was no grant income for qualified expenditures from an SBIR grant for the three and six months ended June 30, 2020 as the modified Phase II grant development plan the Company submitted to the NICHD has not yet been approved as of June 30, 2020.

Restricted Cash

Restricted cash consists of \$50,000 held as collateral for the Company's credit card program as of June 30, 2021 and December 31, 2020. The Company's consolidated 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 consolidated statements of cash flows is as follows:

| | <u>June 30,</u> <u>2021</u> | <u>December 31,</u> <u>2020</u> |
|--|--------------------------------|------------------------------------|
| | (In thousands) | |
| Cash | \$ 451 | \$ 1,026 |
| Restricted cash | 50 | 50 |
| Total cash and restricted cash as shown in the consolidated statements of cash flows | <u>\$ 501</u> | <u>\$ 1,076</u> |

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 consolidated financial statements upon adoption.

3. Capital Stock

During the three months ended June 30, 2021, the Company issued a total of 300,000 shares of its common stock and warrants to purchase 150,000 shares of common stock with an exercise price of \$2.00 per share, at a purchase price of \$2.00 per unit. Each unit consisted of one share of common stock and a warrant to purchase one half of one share of common stock. The shares and warrants were sold 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 classified these warrants on its consolidated balance sheets as equity as the warrants do not have any redemption features nor a right to put for cash that is outside the control of the Company, and valued using the Black-Scholes model based on the following weighted average assumptions:

| | |
|------------------------------|---------|
| Risk-free interest rate | 0.88 % |
| Expected volatility | 134.3 % |
| Expected term | 5 years |
| Expected dividend yield | — |
| Exercise price | \$ 2.00 |
| Market value of common stock | \$ 1.21 |

During the six months ended June 30, 2020, the Company issued a total of 151,027 shares of its common stock and warrants to purchase 151,027 shares of common stock with an exercise price of \$3.70 per share, at a purchase price of \$3.70 per unit. Each unit consisted of one share of common stock and a warrant to purchase one share of common stock. The shares and warrants were sold 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 classified these warrants on its consolidated balance sheets as equity as the warrants do not have any redemption features nor a right to put for cash that is outside the control of the Company, 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 six months ended June 30, 2020, the Company issued 141,533 shares of its common stock to a group of investors in connection with the exercise of 141,533 previously issued warrants at \$3.70 per share for aggregate gross and net proceeds of approximately \$0.5 million.

During the six months ended June 30, 2020, the Company issued 214,000 shares of its 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 six months ended June 30, 2020, the Company issued a total of 25,948 shares of its common stock to employees due to the vesting of restricted stock units and issuance of a common stock award.

Warrants to purchase common stock activity for the six months ended June 30, 2021 was as follows:

| | Amount | Weighted-Average Exercise Price |
|----------------------------------|------------------|------------------------------------|
| Outstanding at December 31, 2020 | 1,893,201 | \$ 6.44 |
| Issued | 150,000 | 2.00 |
| Exercised | — | — |
| Outstanding at June 30, 2021 | <u>2,043,201</u> | <u>\$ 6.11</u> |

4. Notes Payable

On May 4, 2020, the Company obtained a loan (Loan) from the Bank of America (Lender) in the aggregate amount of approximately \$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*. As of December 31, 2020, repayment amounts due within one year were 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 approximately \$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. On May 23, 2021, the Company was notified that the SBA determined that the application for PPP loan forgiveness was approved, and that the SBA remitted the forgiven amount to the Lender.

In accordance with *FASB ASC 470, Debt*, the Notes Payable and applicable accrued interest have been recorded as forgiveness of notes payable resulting in a gain of approximately \$408,000 for the three and six months ended June 30, 2021.

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 June 30, 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 Company had no outstanding Notes Payable as of June 30, 2021 due to the approval for forgiveness by the SBA (see Note 4). The Company's Notes Payable carrying value at December 31, 2020 approximated fair value due to the relatively small amount of principal and the short duration of the underlying promissory note.

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis at June 30, 2021:

| | Fair Value Measurement as of June 30, 2021 | | | |
|---------------------|--|-------------|-------------|--------------|
| | (In thousands) | | | |
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Restricted cash | \$ 50 | \$ — | \$ — | \$ 50 |
| Total | \$ 50 | \$ — | \$ — | \$ 50 |
| Liabilities: | | | | |
| Warrant liability | \$ — | \$ — | \$ 5 | \$ 5 |
| Total | \$ — | \$ — | \$ 5 | \$ 5 |

The following fair value hierarchy table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis at December 31, 2020:

| | Fair Value Measurement as of December 31, 2020 | | | |
|---------------------|--|-------------|--------------|--------------|
| | (In thousands) | | | |
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Restricted cash | \$ 50 | \$ — | \$ — | \$ 50 |
| Total | \$ 50 | \$ — | \$ — | \$ 50 |
| Liabilities: | | | | |
| Warrant liability | \$ — | \$ — | \$ 17 | \$ 17 |
| Total | \$ — | \$ — | \$ 17 | \$ 17 |

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 six months ended June 30, 2021:

| | Warrant Liability (In thousands) |
|--|-------------------------------------|
| Balance at December 31, 2020 | \$ 17 |
| Change in fair value upon re-measurement | (12) |
| Balance at June 30, 2021 | \$ 5 |

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:

| | June 30, 2021 | December 31, 2020 |
|---|------------------|----------------------|
| Risk-free interest rate | 0.07 % | 0.12 % |
| Expected volatility | 134.28 % | 137.89 % |
| Expected term (in years) | 0.6 | 1.1 |
| Expected dividend yield | — | — |
| Exercise price | \$ 8.00 | \$ 8.00 |
| Market value of common stock | \$ 1.26 | \$ 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 3,545,299 shares available for issuance as of June 30, 2021.

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 six months ended June 30, 2021 was as follows:

| | Stock Options | |
|----------------------------------|----------------------|--|
| | Amount | Weighted – Average Exercise Price |
| Outstanding at December 31, 2020 | 1,599,720 | \$ 6.33 |
| Granted | 16,416 | 1.80 |
| Canceled | (81,242) | 18.43 |
| Outstanding at June 30, 2021 | <u>1,534,894</u> | <u>\$ 6.31</u> |

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 June 30, 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 six months ended June 30, 2021 was \$0 based on the Company's closing stock price of \$1.26 per share as of June 30, 2021. As of June 30, 2021, unrecognized compensation cost related to unvested nonperformance-based awards amounted to approximately \$0.5 million, which will be recognized over a weighted average period of 0.2 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 six months ended June 30, 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.

In March 2020, the Company issued 35,000 common stock awards to an employee to be earned upon the achievement of certain milestones. Such milestones were achieved as of June 30, 2020 and the Company issued 23,793 fully vested share of common stock to the employee with 11,207 common shares withheld to cover taxes. The Company recognized share-based compensation of \$65,200 and \$140,000 for the three and six months ended June 30, 2020, respectively.

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--------------------------------|-----------------------------|--------|---------------------------|--------|
| | 2021 | 2020 | 2021 | 2020 |
| | (In thousands) | | (In thousands) | |
| Research and development | \$ 69 | \$ 69 | \$ 149 | \$ 161 |
| General and administrative | 62 | 196 | 112 | 692 |
| Total share-based compensation | \$ 131 | \$ 265 | \$ 261 | \$ 853 |

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 an individual plaintiff filed a wrongful death complaint with the Suffolk Superior Court, in the County of Suffolk, Massachusetts (the "Court"), against the Company and other defendants, including Harvard Bioscience, Inc. ("Harvard Bioscience"), our former parent entity prior to the spin-off of the Company in 2013, as well as another third party. The complaint seeks payment for an unspecified amount of damages and alleges that the plaintiff sustained terminal injuries allegedly caused by products, including one synthetic trachea scaffold and two bioreactors, provided by certain of the named defendants and utilized in connection with surgeries performed by third parties in Europe in 2012 and 2013. This 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 Cellspan Esophageal Implant product candidate.

On October 1, 2019, the Court entered an order granting plaintiffs' motion to compel the defendants to produce discovery. Subsequently, the plaintiff filed a motion for sanctions against the Company on January 6, 2020 claiming failure to produce the required discovery. The Company's counsel at the time, which had been selected for the case by its liability insurance carrier, never notified the Company of plaintiffs' motion and never responded to plaintiff motion. As a result of the failure of the Company's former counsel to respond, on January 29, 2020, the Court entered an order allowing plaintiffs' sanctions against the Company and the other defendants, which establishes a sanction of admitted liability. In June 2021, the Company was informed of these 2019 and 2020 court actions by new defense counsel appointed by its liability insurance carrier. On June 9, 2021, the Company, together with the other defendants, filed a motion to vacate the Court's order allowing plaintiff's motion for sanctions, and following a hearing on such motion, on August 6, 2021 the Court issued a ruling in our favor, vacating the sanctions. This case will now proceed on the merits, which the Company will continue to oppose vigorously. While there can be no assurance that the Company and other defendants will prevail, the Company continues to believe that the claims made in this lawsuit are without merit, however, an estimate of potential liability cannot be made at this time.

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 or estimable 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 3.3 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 31st 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:

| <u>(In thousands)</u> | <u>Balance Sheet Classification</u> | <u>June 30, 2021</u> | <u>December 31, 2020</u> |
|---|---|--------------------------|------------------------------|
| <i>Assets:</i> | | | |
| Operating lease assets | Right-of-use asset | \$ 130 | \$ 182 |
| <i>Liabilities:</i> | | | |
| Current operating lease liabilities | Current portion of operating lease liabilities | 104 | 107 |
| Non-current operating lease liabilities | Operating lease liabilities, net of current portion | 26 | 75 |
| Total operating lease liabilities | | <u>\$ 130</u> | <u>\$ 182</u> |

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

| | <u>Three Months Ended June 30,</u> | | <u>Six Months Ended June 30,</u> | |
|-------------------------------|------------------------------------|--------------|----------------------------------|--------------|
| | <u>2021</u> | <u>2020</u> | <u>2021</u> | <u>2020</u> |
| | <u>(In thousands)</u> | | <u>(In thousands)</u> | |
| Research and development | \$ 19 | \$ 19 | \$ 38 | \$ 39 |
| General and administrative | 11 | 11 | 22 | 22 |
| Total operating lease expense | <u>\$ 30</u> | <u>\$ 30</u> | <u>\$ 60</u> | <u>\$ 61</u> |

Cash paid included in the computation of the right of use asset and lease liability during the six months ended June 30, 2021 and 2020 amounted to approximately \$60,000 and \$61,000, respectively.

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

| | <u>As of June 30,</u> | |
|---------------------------------|-----------------------|-------------|
| | <u>2021</u> | <u>2020</u> |
| Remaining lease term (in years) | 1.53 | 2.07 |
| Discount rate | 10.36 % | 13.13 % |

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

| <u>(In thousands)</u> | <u>As of June 30,</u> |
|--|---------------------------|
| 2021 | \$ 61 |
| 2022 | 62 |
| 2023 | 12 |
| 2024 | 7 |
| 2025 | — |
| Total lease payments | 142 |
| Less: imputed interest | 12 |
| Present value of operating lease liabilities | <u>\$ 130</u> |

9. Net Loss Per Share

The following potential common shares were excluded from the calculation of diluted net loss per share attributable to common stockholders for the six months ended June 30, 2021 and 2020 because including them would have had an anti-dilutive effect:

| | <u>Six Months Ended June 30,</u> | |
|-----------------------------------|----------------------------------|------------------|
| | <u>2021</u> | <u>2020</u> |
| Warrants to purchase common stock | 2,043,201 | 2,468,525 |
| Options to purchase common stock | 1,534,894 | 1,704,721 |
| Total | <u>3,578,095</u> | <u>4,173,246</u> |

10. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the three and six months ended June 30, 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.

The Company maintains the Harvard Apparatus Regenerative Technology GmbH (Germany) subsidiary whereas in fiscal years 2013, 2014 and 2015 certain withholding taxes were paid to the German tax authorities. In June of 2021, the Company received a refund payment of approximately \$71,000 for certain withholding taxes paid during those fiscal years. This amount has been recorded in other income (expense), net, for the three and six months ended June 30, 2021.

11. Subsequent Events

The Company has performed an evaluation of subsequent events through the time of filing this Quarterly Report on Form 10-Q with the Securities Exchange Commission and has determined that there are no such events to report.

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 bio-compatible 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 The 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 June 30, 2021 had an accumulated deficit of approximately \$70.2 million and will require additional financing to fund future operations. We expect that our operating cash on-hand as of June 30, 2021 of approximately \$0.5 million which includes cash proceeds of approximately \$0.6 million received in May and June 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 third 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 continue 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.

Capital Transactions

During 2021 we had the following financing transactions:

- On May 4, 2020, we obtained a loan (Loan) from Bank of America (Lender) in the aggregate amount of approximately \$0.4 million, pursuant to the Paycheck Protection Plan (PPP), established as part of the CARES Act. The Loan was evidenced by a promissory note dated May 4, 2020 issued by us whereas certain amounts of the Loan were eligible for forgiveness if used for qualifying expenses. On December 18, 2020, we submitted the loan forgiveness application for the entire borrowings of approximately \$0.4 million to the Lender and were notified on January 7, 2021 that the application was submitted to the Small Business Administration (SBA) for review. On May 23, 2021, we were notified by Bank of America that the Small Business Administration determined that the application for PPP loan forgiveness was approved, and the SBA remitted the forgiven amount to the Lender. We have accounted for this loan forgiveness as an extinguishment (See Note 4 in the Consolidated Financial Statements included in Part I "Financial Information", Item 1 of this report for further discussion).
- On June 17, 2021, we issued a total of 300,000 shares of our common stock and warrants to purchase 150,000 shares of common stock with an exercise price of \$2.00 per share, at a purchase price of \$2.00 per unit. Each unit consisted of one share of common stock and a warrant to purchase one half of one share of common stock. The shares and warrants were sold to a group of investors for aggregate gross and net proceeds of approximately \$0.6 million.

During 2020 we had the following financing transactions:

- During the six months ended June 30, 2020, we issued a total of 151,027 shares of our common stock and warrants to purchase 151,027 shares of common stock with an exercise price of \$3.70 per share, at a purchase price of \$3.70 per unit. Each unit consisted of one share of common stock and a warrant to purchase one share of common stock. The shares and warrants were sold to a group of investors for aggregate gross and net proceeds of approximately \$0.6 million.
- During the six months ended June 30, 2020, we 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 six months ended June 30, 2020, we issued 141,553 shares of our common stock to a group of investors in connection with the exercise of 141,553 previously issued warrants at \$3.70 per share for aggregate gross and net proceeds of approximately \$0.5 million.
- On May 4, 2020, we were granted a loan from the Bank of America in the aggregate amount of \$0.4 million, pursuant to the Paycheck Protection Program (PPP), established as part of the CARES Act (See Note 4 in the Consolidated Financial Statements included in Part I "Financial Information", Item 1 of this report for further discussion).
- During the six months ended June 30, 2020, we issued a total of 25,948 shares of our common stock to former chief executive officer and an employee due to the vesting of restricted stock units and issuance of a common stock award.

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 approximately \$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 approximately \$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 and six months ended June 30, 2021, we recognized approximately \$47,000 and \$165,000 of grant income, from Phase II of the SBIR grant, respectively. The aggregate SBIR grant to date provides a total award of approximately \$1.8 million, of which, approximately \$1.5 million has been recognized through June 30, 2021.

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.

Forgiveness of notes payable. On May 23, 2021, we were notified by the Lender that provided our PPP Loan that the Small Business Administration determined that our application for PPP loan forgiveness was approved, and the SBA remitted the forgiven amount to the Lender. We have accounted for this loan forgiveness as an extinguishment.

Grant income. 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. 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 and six months ended June 30, 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 and six months ended June 30, 2021 and 2020 (in thousands):

| | <u>Three Months Ended June 30,</u> | | <u>Change 2021 vs. 2020</u> | | <u>Six Months Ended June 30,</u> | | <u>Change 2021 vs. 2020</u> | |
|---|------------------------------------|-------------------|-----------------------------|--------------|----------------------------------|-------------------|-----------------------------|----------------|
| | <u>2021</u> | <u>2020</u> | <u>Change</u> | <u>%</u> | <u>2021</u> | <u>2020</u> | <u>Change</u> | <u>%</u> |
| Operating expenses | | | | | | | | |
| Research and development | \$ 300 | \$ 536 | \$ (236) | (44)% | \$ 773 | \$ 1,179 | \$ (406) | (34)% |
| General and administrative | 618 | 725 | (107) | (15)% | 1,140 | 1,978 | (838) | (42)% |
| Total operating expenses | <u>918</u> | <u>1,261</u> | <u>(343)</u> | <u>(27)%</u> | <u>1,913</u> | <u>3,157</u> | <u>(1,244)</u> | <u>(39)%</u> |
| Other income (expense) | | | | | | | | |
| Forgiveness of notes payable | 408 | — | 408 | nm | 408 | — | 408 | nm |
| Grant income | 47 | — | 47 | nm | 165 | — | 165 | nm |
| Change in fair value of warrant liability | 10 | 78 | (68) | (87)% | 13 | (22) | 35 | 159 % |
| Other income (expense), net | 71 | (2) | 73 | 3,650 % | 71 | (2) | 73 | 3,650 % |
| Total other income (expense), net | <u>536</u> | <u>76</u> | <u>460</u> | <u>605 %</u> | <u>657</u> | <u>(24)</u> | <u>681</u> | <u>2,838 %</u> |
| Net loss | <u>\$ (382)</u> | <u>\$ (1,185)</u> | <u>\$ (803)</u> | <u>(68)%</u> | <u>\$ (1,256)</u> | <u>\$ (3,181)</u> | <u>\$ (1,925)</u> | <u>(61)%</u> |

nm = not meaningful

Comparison of the three months ended June 30, 2021 compared to the three months ended June 30, 2020

Research and Development Expense

Research and development expense decreased approximately \$0.2 million, or 44%, to \$0.3 million for the three months ended June 30, 2021 as compared to approximately \$0.5 million for the three months ended June 30, 2020. This decrease was due to lower headcount resulting in lower salary and share-based compensation expenses period over period.

General and Administrative Expense

General and administrative expense decreased approximately \$0.1 million, or 15%, to \$0.6 million for the three months ended June 30, 2021 compared to approximately \$0.7 million for the three months ended June 30, 2020. This decrease was due to lower headcount resulting in lower salary and share-based compensation expenses period over period.

Forgiveness of notes payable

On May 23, 2021, we were notified by the Lender that provided our PPP Loan that the Small Business Administration determined that our application for PPP loan forgiveness was approved, and the SBA remitted the forgiven amount to the Lender. As a result, we recorded a gain from forgiveness of our notes payable of approximately \$0.4 million.

Grant income

For the three months ended June 30, 2021, we recorded grant income of approximately \$47,000 for qualified expenditures under our SBIR grant. There was no grant income for qualified expenditures from an SBIR grant for the three months ended June 30, 2020 as the modified Phase II grant development plan we submitted to the NICHD had not yet been approved as of June 30, 2020.

Change in fair value of warrant liability

During the three months ended June 30, 2021, the change in fair value of our warrant liability resulted in other income of approximately \$10,000 due primarily to a lower stock price of the underlying common shares. This compared to approximately \$78,000 of other income for three months ended June 30, 2020 due to a decrease in the price of the underlying common shares.

Other income (expense), net

In June of 2021, we received a refund payment of approximately \$71,000 for certain withholding taxes paid in previous years to the German tax authorities which were remitted on to us on behalf of Harvard Apparatus Regenerative Technology GmbH, our German subsidiary.

Comparison of the six months ended June 30, 2021 to the six months ended June 30, 2020

Research and Development Expense

Research and development expense decreased approximately \$0.4 million, or 34%, to \$0.8 million for the six months ended June 30, 2021 as compared to approximately \$1.2 million for the six months ended June 30, 2020. This decrease was due to lower headcount resulting in \$0.3 million in lower salary and share-based compensation expenses and approximately \$0.1 million of lower operating expenses.

General and Administrative Expense

General and administrative expense decreased approximately \$0.8 million, or 42%, to \$1.1 million for the six months ended June 30, 2021 compared to approximately \$2.0 million for the six months ended June 30, 2020. This decrease was due to approximately \$0.3 million lower salary and related expenses and approximately \$0.5 million in lower share-based compensation costs due to the separation of our former chief executive officer and chief financial officer in 2020.

Forgiveness of notes payable

On May 23, 2021, we were notified by the Lender that provided our PPP Loan that the Small Business Administration determined that our application for PPP loan forgiveness was approved, and the SBA remitted the forgiven amount to the Lender. As a result, we recorded a gain from forgiveness of our notes payable of approximately \$0.4 million.

Grant income

For the six months ended June 30, 2021, we recorded grant income of approximately 165,000 for qualified expenditures under our SBIR grant. There was no grant income for qualified expenditures from an SBIR grant for the six months ended June 30, 2020 as the modified Phase II grant development plan we submitted to the NICHD has not yet been approved as of June 30, 2020.

Change in fair value of warrant liability

During the six months ended June 30, 2021, the change in fair value of our warrant liability resulted in other income of approximately \$13,000 due primarily to a lower stock price of the underlying common shares. This compared to approximately \$22,000 of other expense for six months ended June 30, 2020 due to an increase in the price of the underlying common shares.

Other income (expense), net

In June of 2021, we received a refund payment of approximately \$71,000 for certain withholding taxes paid in previous years to the German tax authorities which were remitted on to us on behalf of Harvard Apparatus Regenerative Technology GmbH, our German subsidiary.

Liquidity and Capital Resources

Sources of liquidity. We have incurred operating losses since inception, and as of June 30, 2021 we had an accumulated deficit of approximately \$70.2 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 six months ended June 30, 2021 and 2020 (in thousands):

| | Six Months Ended June 30, | |
|---|----------------------------------|-------------|
| | 2021 | 2020 |
| Net Cash Used in Operating Activities | \$ (1,173) | \$ (2,164) |
| Net Cash Used by Investing Activities | \$ — | \$ — |
| Net Cash Provided by Financing Activities | \$ 598 | \$ 1,869 |

Comparison of Six Months Ended June 30, 2021 and 2020

Operating activities. Net cash used in operating activities of approximately \$1.2 million for the six months ended June 30, 2021 was due primarily to our net loss of approximately \$1.3 million and adjustments for non-cash items of approximately \$0.1 million due to the add-back for a gain from forgiveness of our notes payable, offset, in part, by non-cash expenses including share-based compensation, depreciation and the change in fair value of our warrant liability. These cash outflows were offset, in part, by an approximately \$0.2 million increase to cash from changes in working capital due to the timing of payments for prepaid expenses and accounts payable.

Net cash used in operating activities of approximately \$2.2 million for the six months ended June 30, 2020 was due primarily to our net loss of approximately \$3.2 million, partially offset by approximately \$1.0 million add-back for non-cash expenses including share-based compensation, depreciation and the change in fair value of warrant liability. The cash impact of working capital due to the timing of prepaid expenses and accounts payable was negligible during the period.

Investing activities. There were no investing activities for the six months ended June 30, 2021 and 2020.

Financing activities. Net cash generated from financing activities during the six months ended June 30, 2021 of approximately \$0.6 million consisted of net proceeds received from private placement transactions that resulted in the issuance of 300,000 shares of our common stock at a purchase price of \$2.00 per share and warrants to purchase 150,000 shares of common stock at an exercise price of \$2.00 per share to a group of investors.

Net cash generated from financing activities during the six months ended June 30, 2020 of \$1.9 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, \$1.0 million received from the issuance of 355,553 shares of our common stock to a group of investors in connection with previously issued warrants, and \$0.4 million from a loan granted to us in May 2020 pursuant to the PPP established as part of the CARES Act. These proceeds were offset slightly by \$46,000 of payments for employee tax withholdings for common shares repurchased for vested stock awards.

Off-Balance Sheet Arrangements

We do not have any material off-balance sheet arrangements as of June 30, 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 June 30, 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 June 30, 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 June 30, 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 March 27, 2020, our Form 8-K filed with the SEC on June 24, 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.

As previously disclosed, including in the Form 8-K referenced above, representatives for the estate of an individual plaintiff filed a wrongful death complaint on April 14, 2017 with the Suffolk Superior Court, in the County of Suffolk, Massachusetts (the "Court"), against us and other defendants, including Harvard Bioscience, Inc. ("Harvard Bioscience"), our former parent entity prior to the spin-off of the Company in 2013, as well as another third party. The complaint seeks payment for an unspecified amount of damages and alleges that the plaintiff sustained terminal injuries allegedly caused by products, including one synthetic trachea scaffold and two bioreactors, provided by certain of the named defendants and utilized in connection with surgeries performed by third parties in Europe in 2012 and 2013. This lawsuit relates to our first-generation trachea scaffold technology for which we discontinued development in 2014, and not to our current Cellframe technology nor to our lead development Cellspan Esophageal Implant product candidate.

On October 1, 2019, the Court entered an order granting plaintiffs' motion to compel the defendants to produce discovery. Subsequently, the plaintiff filed a motion for sanctions against us on January 6, 2020 claiming failure to produce the discovery. Our counsel at the time, which had been selected for the case by our liability insurance carrier, never notified us of plaintiffs' motion and never responded to plaintiff motion. As a result of the failure of our former counsel to respond, on January 29, 2020, the Court entered an order allowing plaintiffs' sanctions against us and the other defendants, which establishes a sanction of admitted liability. In June 2021, we were informed of these 2019 and 2020 court actions by new defense counsel appointed by our liability insurance carrier. On June 9, 2021, we, together with the other defendants, filed a motion to vacate the Court's order allowing plaintiff's motion for sanctions, and following a hearing on such motion, on August 6, 2021 the Court issued a ruling in our favor, vacating the sanctions. This case will now proceed on the merits, which we will continue to oppose vigorously.

While there can be no assurance that we and the other defendants will prevail, we continue to believe that the claims made in this lawsuit are without merit. If we face a trial on damages and lose on the merits, we do not know the exact amount of compensatory and, potentially, punitive damages that could be awarded. In all events, we believe that available product liability insurance coverage will reimburse us for all or a significant portion of such damages, although there can be no assurance that the damages awarded will be within the limits of our insurance. We are also evaluating possible malpractice claims as an additional source of recovery. We cannot provide assurance that our losses will not exceed our insurance or such recoveries. Further, in accordance with a separation and distribution agreement between Harvard Bioscience and the Company relating to the spin-off, we would be required to indemnify Harvard Bioscience against losses that Harvard Bioscience may suffer as a result of this litigation.

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 June 30, 2021 with approximately \$0.5 million of operating cash on-hand, which include cash proceeds of approximately \$0.6 million received in May and June 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 before the fourth 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

| | |
|-------------|---|
| 4.1 | Form of Warrant (previously filed as an exhibit to Form 8-k, filed on June 22, 2021, and incorporated herein by reference) |
| 10.1 | Form of Securities Purchase Agreement, dated as of June 17, 2021 (previously filed as an exhibit to Form 8-k, filed on June 22, 2021, and incorporated herein by reference) |
| 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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 |
| Exhibit 104 | Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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: August 13, 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)

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 consolidated 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 the consolidated 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: August 13, 2021

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

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 consolidated 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 consolidated 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: August 13, 2021

/s/ Hong Yu

Hong Yu
President

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 June 30, 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: August 13, 2021

/s/ Peter A. Pellegrino Jr.

Name: Peter A. Pellegrino Jr.

Title: Interim Vice President of Finance

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 June 30, 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: August 13, 2021

/s/ Hong Yu

Name: Hong Yu

Title: President
