Biostage Reports Q1 2022 Financial Results and Corporate Highlights

HOLLISTON, Mass., May 16, 2022 /PRNewswire/ -- Biostage, Inc. (OTCQB: BSTG) ("Biostage" or the "Company"), a cell-therapy biotechnology company with successful "first-in-human" experience in treating esophageal cancer (conducted at the Mayo Clinic and published last August) and FDA approval to commence a clinical trial of the Biostage Esophageal Implant, or BEI, for severe esophageal disease including cancer, today announced its financial results for the three months ended March 31, 2022, and highlighted recent events.

The Company will be hosting a conference call on Tuesday, May 17, 2022 at 8:30 A.M. Eastern Time. You can access the live conference call by dialing the following phone numbers toll free 877-407-8293 or international +1 201-689-8349.

Closed Private Placement for $5.1 Million to Advance Clinical Trial

On May 12, 2022, Biostage raised approximately $5.1 million from new and existing investors in a private placement of its shares. The funds will be used to accelerate the clinical development of Biostage's lead product candidate, the BEI.

At that time, the Company entered into Securities Purchase Agreements with certain investors (the "Investors") pursuant to which the Investors agreed to purchase in a private placement an aggregate of 854,771 shares of common stock and warrants to purchase 427,390 shares of common stock, subject to adjustment, for the aggregate purchase price of $5.1 million with a purchase price per unit of $5.92. Each unit consisted of one share of common stock and a warrant to purchase one half of one share of common stock, subject to adjustment.

Wrongful Death Complaint Settlement

On April 27, 2022, Biostage settled all claims relating to the litigation. Biostage made no admission of liability or wrongdoing.

David Green, Interim Chief Executive Officer, Chairman, and Director commented "Settling this lawsuit, which has been outstanding against Biostage for almost five years, clears the way for us to complete the financing we need to begin the clinical trial. I look forward to making Biostage a success for both its patients and its shareholders."

As previously disclosed by Biostage in its periodic filings with the Securities and Exchange Commission, 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, against the Company and other defendants, including Harvard Bioscience, Inc. (or HBIO), the former parent of the Company that spun off the Company in 2013, as well as another third party. The complaint sought payment for an unspecified amount of damages and alleges that the plaintiff sustained terminal injuries allegedly caused by products 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 BEI.

On April 27, 2022, the Company and HBIO executed a settlement with the plaintiffs (the "Settlement"), which resolves all claims relating to the litigation and will result in the dismissal with prejudice of the wrongful death claim, and neither the Company nor HBIO admit any fault or liability in connection with the claim. The Settlement also resolves any and all claims by and between the parties and the Company's products liability insurance carriers, which will result in the dismissal with prejudice of all claims asserted by or against those carriers, the Company and HBIO.

In relation to the litigation, Settlement and related legal expenses, the Company estimates that it will incur approximately $6.0 million of costs, of which, approximately $5.5 million remain unpaid. This amount includes the cost of both the accrual for contingency matter of $3.3 million and approximately $2.7 million of legal and related costs incurred by the Company which consist of attorneys' fees and advisor and specialist costs as part of its defense in this matter.

With respect to these costs, the Company is required to either pay such costs directly or indemnify HBIO as to such amounts it incurs. Of such amounts, Company anticipates that HBIO will pay an aggregate amount of $4.0 million by the end of the second quarter of 2022. With respect to these indemnification obligations of the

Company to HBIO, the Company and HBIO have entered into a Preferred Issuance Agreement dated as of April 27, 2022 (or the PIA). In connection with the PIA, the Company and HBIO have agreed that once HBIO has paid at least $4.0 million in such costs to satisfy the Company's indemnification obligations with respect thereto, in lieu of paying cash, the Company will issue senior convertible preferred stock to HBIO.

In addition, the Company will continue to pay, or otherwise indemnify HBIO as to its payment thereof, the remaining legal expenses incurred in connection with the litigation, Settlement and related matters. Assuming the issuance of such senior convertible preferred stock, the Company currently estimates that the remaining aggregate amount of such costs it will be obligated to pay will be approximately $1.5 million.

First Quarter 2022 Financial Results

For the three months ended March 31, 2022, the Company reported a net loss of $2.2 million, ($0.20 per share), compared to a net loss of $0.9 million, ($0.09 per share), for the three months ended March 31, 2021.

The $1.3 million quarter-over-quarter increase in net loss was due primarily to a $1.4 million increase in general and administrative costs from higher legal and related costs relating to the wrong death compliant settlement more fully described in Note 6 to our consolidated financial statements and $0.1 million of lower grant income for qualified expenditures from our SBIR grant. These changes were offset, in part, by a $0.2 million decrease in research and development costs.

As of March 31, 2022, the Company had operating cash on-hand of $0.7 million. The Company used net cash in operations of $0.5 million during the quarter ended March 31, 2022.

As of May 16, 2022, the Company has received aggregate proceeds of approximately $5.1 million from the private placement. Based on the Company's current operating plan and given consideration to this cash infusion, the Company expects that its current cash will be sufficient to fund its operating expenses and capital expenditure requirements through the first quarter of 2023.

About Biostage, Inc.

Biostage is a clinical-stage biotech company that uses cell therapy to regenerate organs inside the human body to treat cancer, trauma and birth defects in the esophagus and bronchus. We have performed the world's first regeneration of an esophagus in a human cancer patient. This surgery was performed at Mayo Clinic and was published in August 2021. We have performed the regeneration of the bronchus in a pig.

Biostage has 8 issued U.S. patents, 2 orphan-drug designations (which provide 7 years of market exclusivity in addition to any patents), and the possibility of 2 Priority Review Vouchers from the FDA.

Biostage's current goals include raising capital, uplisting from the OTC bulletin board to NASDAQ and beginning its clinical trial for regeneration and repair of the esophagus.

For more information, please visit www.biostage.com and connect with the Company on Twitter and LinkedIn.

Forward-Looking Statements

Some of the statements in this press release are "forward-looking" and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These "forward-looking" statements in this press release include, but are not limited to, statements relating to the capabilities and performance of our products and product candidates; our capital raising plans and expectations, including uplifting to NASDAQ; development expectations and regulatory approval of any of the Company's products, including those utilizing its Biostage Esophageal Implant technology, by the U.S. Food and Drug Administration, the European Medicines Agency or otherwise, which expectations or approvals may not be achieved or obtained on a timely basis or at all; and success with respect to any collaborations, clinical trials and other development and commercialization efforts of the Company's products, which such success may not be achieved or obtained on a timely basis or at all. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release, including, among other things, the Company's inability to obtain needed funds in the immediate future; the Company's ability to obtain and maintain regulatory approval for its products; plus other factors described under the heading "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 or described in the Company's other public filings. The Company's results may also be affected by factors of which the Company is not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions or circumstances on which any such statement is based.

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BIOSTAGE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	March 31, 2022	December 31, 2021
Assets		
Cash	$ 723	$ 1,242
Restricted cash	3,105	50
Other assets	340	574
Total assets	$ 4,168	$ 1,866
Liabilities and stockholders' equity		
Other liabilities	$ 2,834	$ 1,645
Accrual for contingency matter	3,250	3,250
Advance from private placement	3,055	-
Total liabilities	9,139	4,895
Total stockholders' deficit	(4,971)	(3,029)
	$ 4,168	$ 1,866

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

	Three Months Ended December 31,	
	2022	2021
Operating expenses		
Research and development	$ 303	$ 473
General and administrative	1,902	522
Total operating expenses	2,205	995
Other income (expense), net		
Sublease income	29	-
Grant income	-	118
Other income (expense), net	(1)	3
Total other income, net	28	121
Net loss	$ (2,177)	$ (874)
Basic and diluted net loss per share	$ (0.20)	$ (0.09)
Weighted average common shares, basic and diluted	10,762	9,388

SOURCE Biostage, Inc.