

HOLLISTON, Mass., Aug. 13, 2020 /[PRNewswire](#)/ -- [Biostage, Inc.](#) (OTCQB: BSTG) ("Biostage" or the "Company"), a clinical-stage biotechnology company developing bioengineered organ implants based on the Company's novel Cellspan™ technology for the treatment of esophageal atresia and esophageal disease, today announced its financial results for the three and six months ended June 30, 2020.



The Company will not hold an earnings conference call at this time. The Company plans to hold a conference call at a future date to discuss its clinical and business plans.

Operating Highlights

Based on the U.S. Food and Drug Administration (FDA) removing the Company's CEI product candidate, its First in Human (FIH) Clinical study, from clinical hold in March 2020, Biostage focused its main efforts during the second quarter on clinical planning, including engaging with a clinical research organization, in advance of preparing for the start of the clinical trial for our CEI product candidate. Although the Company continues to make progress towards the start of its clinical trial, the COVID-19 pandemic has and will continue to affect the Company's operations, including causing delays or difficulties in its ability to plan for and start its clinical trial.

Summary of Financial Results

For the three months ended June 30, 2020, the Company reported a net loss of \$1.2 million, (\$0.14) per share, compared to a net loss of \$2.4 million, (\$0.37) per share, for the three months ended June 30, 2019. The \$1.2 million year-over-year net loss decrease was due primarily to a \$0.8 million decrease in research and development costs, and a \$0.6 million decrease in general and administrative expenses. Slightly offsetting the lower operating expense was the absence of \$0.2 million of grant income recorded in the prior year quarter for

qualified expenditures from our Fast-Track Small Business Innovation Research (SBIR) grant.

For the six months ended June 30, 2020, the Company reported a net loss of \$3.2 million, (\$0.38) per share, compared to a net loss of \$4.4 million, (\$0.69) per share, for the six months ended June 30, 2019. The \$1.2 million year-over-year net loss decrease was due primarily to \$1.2 million of lower research and development costs, and a \$0.3 million decrease in general and administrative expenses. Slightly offsetting the lower operating expense was the absence of \$0.3 million of grant income recorded in the prior year quarter for qualified expenditures from our SBIR grant.

Balance Sheet and Cash

At June 30, 2020, the Company had operating cash on-hand of \$0.6 million. The Company also had debt of \$0.4 million based on receiving a loan in May 2020 pursuant to the Paycheck Protection Program (PPP), established as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. 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, although there is no assurance that any portion of the loan will be forgiven.

During the six-month period ended June 30, 2020, the Company used net cash in operations of \$2.2 million and received \$1.9 million from financing activities, including approximately \$0.6 million of proceeds from private placement transactions that resulted in the issuance of 151,027 shares of our common stock and warrants to investors in private placement transactions and approximately \$1.0 million from the issuance of 353,533 shares of its common stock to a group of investors in connection with the exercise of previously issued warrants. The Company also received proceeds of approximately \$0.4 million from the aforementioned PPP loan.

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 before the fourth quarter of 2020, it may be forced to curtail or cease its operations.

About Biostage, Inc.

Biostage is a clinical-stage biotechnology company developing bioengineered organ implants based on the Company's novel Cellspan™ technology. The Company's Cellspan technology combines a proprietary, biocompatible scaffold with a patient's own cells to create an esophageal implant that could potentially be used to treat pediatric esophageal atresia and other tubular organ conditions. Our novel technology harnesses the body's response and modulates it toward the healing process to regenerate tissue and restore the continuity and integrity of the organ. These implants have the potential to dramatically improve the quality of

life for children and adults. At Biostage, we believe the future of medicine has been inside us all along.

For more information, please visit www.biostage.com and connect with the Company on [Twitter](#) and [LinkedIn](#).

Biostage, Inc. Social Media

The Company uses its website (www.biostage.com), corporate Twitter account (<https://twitter.com/BiostageInc>), and LinkedIn page (<https://www.linkedin.com/company/biostage-inc>) as channels of distribution of information about the Company and its product candidates. Such information may be deemed material information, and the Company may use these channels to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor Biostage's website and its social media accounts in addition to following its press releases, SEC filings, public conference calls, and webcasts. The social media channels that Biostage intends to use as a means of disclosing the information described above may be updated from time to time.

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 viability of our technology; success with respect to any clinical trials and other development and commercialization efforts of the Company's products, which such success may not be achieved on a timely basis or at all; our financing activities; expectations as to regulatory approval of any of the Company's products, including those utilizing its Cellspan™ and Cellframe™ technology, by the U.S. Food and Drug Administration, the European Medicines Agency or otherwise, which approvals may not be 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 impact of COVID-19 on our business and operations; 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, 2019 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.

Investor Relations Contacts

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Biostage, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value and share data)

	June 30, 2020		December 31, 2019
Assets		<i>(Unaudited)</i>	
Current assets:			
Cash	\$	618	\$ 913
Restricted cash		50	50
Prepaid expenses and other current assets		273	444
Total current assets		941	1,407
Property, plant and equipment, net		300	394
Right-of-use assets		141	191
Total non-current assets		441	585
Total assets	\$	1,382	\$ 1,992

Liabilities and

stockholders' equity

Current liabilities

Accounts payable	\$	141	\$	241
Accrued and other current liabilities		411		438
Current portion of notes payable		157		-
Warrant liability		55		33
Current portion of operating lease liability		100		102
Total current liabilities		864		814
Notes payable, net of current portion		247		-
Operating lease liability, net of current portion		41		89
Total liabilities	\$	1,152	\$	903

Commitments and contingencies

Stockholders' equity:

Undesignated preferred stock, \$0.01 par value; 984,000 shares authorized and none	\$	-	\$	-
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issued and outstanding at June 30, 2020 and

December 31, 2019			
Common stock, par value \$0.01 per share, 60,000,000 shares authorized at	87		82
June 30, 2020 and December 31, 2019; 8,688,083 and 8,155,555 issued and			
outstanding at June 30, 2020 and December 31, 2019, respectively			
Additional paid-in capital	67,419		65,102
Accumulated deficit	(67,276)		(64,095)
Total stockholders' equity	230		1,089
Total liabilities and stockholders' equity	\$ 1,382	\$	1,992

BIOSTAGE, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except per share amounts)

	Three Months Ended June 30,				Nine Months ended June 30,			
	2020		2019		2020		2019	
Revenues	\$	-	\$	-	\$	-	\$	-
Operating expenses								
Research and development		536	\$	1,376		1,179		2,410
Selling, general and administrative		725		1,292		1,975		2,292
Total operating expenses		1,261		2,668		3,157		4,702
Operating loss		(1,261)		(2,668)		(3,157)		(4,702)
Other income (expense)								
Grant income		-		223		-		337
Change in fair value of warrant liability		78		16		(22)		9
Interest		(2)		-		(2)		-

Net income										
Other income (expense), net		76		239		(24)				346
Net loss	\$	(1,185)	\$	(2,429)	\$	(3,181)	\$	(4,356)		
Basic and diluted net loss per share	\$	(0.14)	\$	(0.37)	\$	(0.38)	\$	(0.69)		
Weighted-average common shares, basic and diluted		8,636		6,592		8,462		6,299		

BIOSTAGE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

Basic and diluted net loss per share \$(0.20) \$(0.09)

Nine Months Ended

June 30,

2020

2019

CASH FLOWS FROM OPERATING ACTIVITIES

Net loss	\$ (3,181)	\$ (4,356)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	853	824
Depreciation	94	115
Amortization of right-of-use assets	50	46
Change in fair value of warrant liability	22	(9)
Changes in opera		

ting a ssets and li abiliti es:		
Grant receiv able	-	(47)
Prepa id exp enses and other curre nt ass ets	171	107
Accou nts pa yable	(100)	56
Accru ed and other curre nt liab ilities	(23)	57
Lease liabiliti es	(50)	(46)
Net cash used in op eratin g acti vities	(2,16 4)	(3,25 3)
CAS H FL OWS FRO M INV ESTI NG A CTIVI TIES		
Purch ases of pro perty,	-	(78)

plant and equipment
 Net cash used in investing activities

- (78)

CASH FLOWS FROM FINANCING ACTIVITIES

Proceeds from issuance of common stock and warrants

559 1,277

Proceeds from exercise of warrants

952 2,000

Proceeds from notes payable

404 -

Payments of tax withholding

(46) -

s of s hares repur chase d for v ested stock award s			
Net cash provided by financing activities	1,869		3,277
Net decrease in cash and restricted cash	(295)		(54)
Cash and restricted cash at beginning of period	963		1,355
Cash and restricted cash at end of period	668	\$	\$ 1,301

SOURCE Biostage, Inc.

