

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 31, 2019



ABIOMED, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-09585
(Commission File Number)

04-2743260
(IRS Employer Identification No.)

22 Cherry Hill Drive
Danvers, Massachusetts 01923
(Address of Principal Executive Offices, including Zip Code)

(978) 646-1400
(Registrant's Telephone Number, including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Common Stock, \$0.01 par value

Trading symbol
ABMD

Name of each exchange on which registered
The NASDAQ Stock Market LLC

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On October 31, 2019, ABIOMED, Inc. (the “Company,” “we” or “us”) issued a press release reporting our financial results for our second quarter ended September 30, 2019. A copy of the press release is set forth as Exhibit 99.1 and is incorporated herein by reference. The information contained in this report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Act of 1934, whether made before or after the date hereof and regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

<u>Exhibit</u>	<u>Description</u>
99.1	Q2 FY2020 earnings press release dated October 31, 2019

Exhibit Index

Exhibit	Description
99.1	Q2 FY2020 earnings press release dated October 31, 2019
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

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 the undersigned thereunto duly authorized.

ABIOMED, Inc.

By: /s/ Todd A. Trapp
Todd A. Trapp
Vice President and Chief Financial Officer
(Authorized Signatory)

Date: October 31, 2019



ABIOMED ANNOUNCES Q2 FY 2020 REVENUE OF \$205 MILLION AND 29.4% OPERATING MARGIN

DANVERS, Mass. — October 31, 2019 – Abiomed, Inc. (NASDAQ: ABMD), a leading provider of breakthrough heart recovery and support technologies, today reported second quarter fiscal 2020 revenue of \$205.0 million, an increase of 13% compared to revenue of \$181.8 million for the same period of fiscal 2019. Operating income was \$60.2 million, up 20%, compared to \$50.3 million in the same period of fiscal 2019.

Financial and operating highlights for the second quarter fiscal 2020 include:

- U.S. revenue totaled \$172.0 million, an increase of 9% compared to revenue of \$158.2 million during the same period of fiscal 2019 with U.S. patient usage of Impella heart pumps up 14%. In the second quarter, we opened 62 new sites, compared to 135 sites in the prior year, which impacted our U.S. growth rate by \$3 million in revenue, or approximately two points of growth.
 - Outside the U.S., revenue totaled \$33.0 million, an increase of 40% compared to revenue of \$23.5 million during the same period of fiscal 2019. Specifically, Japan revenue was \$9.6 million in the quarter, up 135% compared to the same period of fiscal 2019.
 - Gross margin was 83.0% compared to 83.6% during the same period of fiscal 2019.
 - Operating income was \$60.2 million, or 29.4% operating margin compared to \$50.3 million, or 27.7% operating margin in the same period of fiscal 2019.
 - GAAP net income was \$13.1 million, or \$0.28 per diluted share, which includes a \$34.5 million, or \$0.75 per share, unrealized loss from our investment in Shockwave. This compared to GAAP net income of \$50.1 million or \$1.09 per diluted share for the prior fiscal year, which benefited from \$12.9 million, or \$0.28 per share, of excess tax benefits.
 - The company generated operating cash flow of \$74.3 million in the second quarter and \$138.9 million year to date, an increase of 30% versus prior year. As of September 30, 2019, the company had \$551.3 million of cash and marketable securities and maintains no debt.
 - On September 23, the company announced that the highest court in Germany, the Federal Court of Justice, ruled in favor of Abiomed in a patent challenge, specifically around the pigtail and design for insertion, filed by Thoratec in 2015, validating the strengths of Abiomed's Impella-related patents. Abiomed has invested more than \$500 million and 20 years of research and development for Impella and owns a robust world-wide portfolio of 715 patents and 622 patents pending, covering all aspects of its existing and future products.
 - On September 25, the company announced that the Impella 5.5 with SmartAssist received U.S. Food and Drug Administration (FDA) pre-market approval (PMA) for safety and efficacy in the therapy of cardiogenic shock for up to 14 days. Impella 5.5 with SmartAssist is a minimally invasive, forward flow, fully unloading heart pump designed for heart surgeons, implanted via axillary artery or direct to the aorta.
 - On September 26, the company announced the results of PROTECT III, the ongoing, prospective, single-arm FDA post-approval study for the PMA approval of Impella 2.5 and Impella CP in high-risk PCI. PROTECT III follows the PROTECT II Randomized Controlled Trial (RCT). The findings of this interim analysis on 898 patients demonstrates a reduction in the primary endpoint of death, stroke, myocardial infarction and repeat procedures at 90 days with Impella-supported Protected PCI, compared to PROTECT II.
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- On September 27, the company announced that data presented from the National Cardiogenic Shock Initiative Study (NCSI) on 250 consecutive AMI cardiogenic shock patients from 49 sites demonstrates 72% survival at discharge with 98% native heart recovery. The patients were treated with the NCSI protocol, which includes placing Abiomed's Impella heart pump before revascularization via percutaneous coronary intervention (PCI). Investigators also now plan to institute new escalation protocols that will be applied in the cath lab immediately after Impella-supported PCI in order to further increase patient survival and native heart recovery.
- On October 7, the company announced that the 1,000th patient has been treated with the Impella heart pump in Japan. Procedural outcomes data, available on the first 580 Japanese cases, demonstrates improvements in AMI cardiogenic shock and myocarditis survival rates during the procedure, compared to traditional therapies. The protocols used to introduce Impella in Japan were developed based on best practices learned from the experience treating patients in Europe and the United States, including the National Cardiogenic Shock Initiative, the Impella Quality (IQ) Database and the cVAD Study.
- On October 25, the company announced that the FDA Post Approval Study demonstrates timely identification of right heart failure and early use of Impella RP leads to higher survival. When physicians followed the FDA's approved protocol for Impella RP use they achieved 72% patient survival and 88% native heart recovery. These results, from the Impella RP's post-approval study, match the survival rate in the Impella RP's pre-approval study.
- Today, the company announces the first U.S. patients treated with Impella 5.5 with SmartAssist. The first 10 patients were treated at the Cleveland Clinic, Hackensack Meridian Health and Cedars-Sinai Medical Center in Los Angeles. The Impella 5.5 with SmartAssist is being introduced in the U.S. through a controlled rollout at hospitals with established heart recovery protocols.

“We are pleased that this quarter demonstrated our ability to leverage best practices and support strategies to improve clinical outcomes overall for high risk PCI, cardiogenic shock and right heart failure,” said Michael R. Minogue, Chairman, President and Chief Executive Officer, Abiomed, Inc. “We have made progress on our key initiatives in the quarter, but we still have more work to do. Our innovation and ability to improve clinical outcomes remains the driver for Impella adoption through a function of training, data and time.”

FISCAL YEAR 2020 OUTLOOK

The company is maintaining its fiscal year 2020 guidance for total revenue to be in the range of \$885 million to \$925 million, an increase of 15% to 20% over the prior year. The company is also maintaining its fiscal year 2020 guidance for GAAP operating margin to be in the range of 28% to 30%.

EARNINGS CONFERENCE CALL DETAILS

The company will host a conference call to discuss the results at 8:00 a.m. EDT on Thursday, October 31, 2019. The conference call releasing full quarterly results will be hosted by Michael R. Minogue, Chairman, President and Chief Executive Officer and Todd A. Trapp, Vice President and Chief Financial Officer.

To listen to the call live, please tune into the webcast via <https://edge.media-server.com/mmc/p/7yfbz5bxh> or dial (855) 212-2361; the international number is (678) 809-1538. A replay of this conference call will be available beginning at 11:00 a.m. EDT October 31, 2019 through 11:00 a.m. EST on November 7, 2019. The replay phone number is (855) 859-2056; the international number is (404) 537-3406. The replay access code is 7594662.

ABOUT ABIOMED

Based in Danvers, Massachusetts, USA, Abiomed, Inc. is a leading provider of medical devices that provide circulatory support. Our products are designed to enable the heart to rest by improving blood flow and/or performing the pumping of the heart. For additional information, please visit: www.abiomed.com. Abiomed, Impella, Impella 2.5, Impella 5.0, Impella LD, Impella CP, Impella RP, and Impella Connect are registered trademarks of Abiomed, Inc., and are registered in the U.S. and certain foreign countries. Impella BTR, Impella 5.5, Impella ECP, CVAD Study, and SmartAssist are pending trademarks of Abiomed, Inc.

FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including, without limitation, statements regarding development of Abiomed's existing and new products, the company's progress toward commercial growth, and future opportunities and expected regulatory approvals. All statements, other than statements of historical facts, may be forward-looking statements. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "should," "likely," "will" and other words and terms of similar meaning. The company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including, without limitation: the company's dependence on Impella® products for all of its revenues; the company's ability to successfully compete against its existing or potential competitors; the acceptance of the company's products by cardiac surgeons and interventional cardiologists; long sales and training cycles associated with expansion into new hospital cardiac centers; reduced market acceptance of the company's products due to lengthy clinician training process; the company's ability to effectively manage its growth; the company's ability to successfully commercialize its products; the company's ability to obtain regulatory approvals and market and sell its products in certain jurisdictions; enforcement actions and product liability suits relating to off-label uses of the company's products; unsuccessful clinical trials or procedures relating to products under development; the company's ability to maintain compliance with regulatory requirements; the failure of third-party payers to provide reimbursement of the company's products; the company's ability to increase manufacturing capacity to support continued demand for its products; the company or its vendors' failure to achieve and maintain high manufacturing standards; the failure of the company's suppliers to provide the components the company requires; the company's ability to expand its direct sales activities into international markets; the outcome of ongoing securities class action litigation relating to our public disclosures and other risks and challenges detailed in the company's filings with the Securities and Exchange Commission (the "SEC"), including the most recently filed Annual Report on Form 10-K and the filings subsequently filed with or furnished to the SEC. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. Unless otherwise required by law, the company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

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Abiomed, Inc. and Subsidiaries
Consolidated Balance Sheets
(Unaudited)
(in thousands, except share data)

	September 30, 2019	March 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 150,279	\$ 121,021
Short-term marketable securities	295,041	370,677
Accounts receivable, net	94,319	90,809
Inventories	90,295	80,942
Prepaid expenses and other current assets	17,498	13,748
Total current assets	647,432	677,197
Long-term marketable securities	106,025	21,718
Property and equipment, net	157,896	145,005
Goodwill	31,727	32,601
In-process research and development	14,800	15,208
Long-term deferred tax assets, net	67,277	77,502
Other assets	99,191	85,115
Total assets	<u>\$ 1,124,348</u>	<u>\$ 1,054,346</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 31,736	\$ 32,185
Accrued expenses	57,907	57,420
Deferred revenues	19,322	16,393
Other current liabilities	3,264	—
Total current liabilities	112,229	105,998
Contingent consideration	10,236	9,575
Long-term deferred tax liabilities	800	822
Other long-term liabilities	9,626	1,061
Total liabilities	<u>132,891</u>	<u>117,456</u>
Commitments and contingencies		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value	—	—
Authorized - 1,000,000 shares; Issued and outstanding - none		
Common stock, \$.01 par value	452	451
Authorized - 100,000,000 shares; Issued - 47,484,911 shares at September 30, 2019 and 47,026,226 shares at March 31, 2019		
Outstanding - 45,238,952 shares at September 30, 2019 and 45,122,985 shares at March 31, 2019		
Additional paid in capital	722,020	690,507
Retained earnings	501,467	399,473
Treasury stock at cost - 2,245,959 shares at September 30, 2019 and 1,903,241 shares at March 31, 2019	(214,926)	(138,852)
Accumulated other comprehensive loss	(17,556)	(14,689)
Total stockholders' equity	<u>991,457</u>	<u>936,890</u>
Total liabilities and stockholders' equity	<u>\$ 1,124,348</u>	<u>\$ 1,054,346</u>

Abiomed, Inc. and Subsidiaries
Consolidated Statements of Operations
(Unaudited)
(in thousands, except per share data)

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2019	2018	2019	2018
Revenue	\$ 204,974	\$ 181,778	\$ 412,640	\$ 361,788
Costs and expenses:				
Cost of revenue	34,867	29,846	71,940	60,696
Research and development	23,969	22,717	47,759	43,990
Selling, general and administrative	85,956	78,895	172,034	160,034
	<u>144,792</u>	<u>131,458</u>	<u>291,733</u>	<u>264,720</u>
Income from operations	60,182	50,320	120,907	97,068
Other (expenses) income:				
Investment income, net	2,932	1,671	5,981	3,222
Other (expense) income, net	(45,756)	(158)	(6,392)	30
	<u>(42,824)</u>	<u>1,513</u>	<u>(411)</u>	<u>3,252</u>
Income before income taxes	17,358	51,833	120,496	100,320
Income tax provision (benefit)	4,287	1,706	18,502	(39,873)
Net income (A)	<u>\$ 13,071</u>	<u>\$ 50,127</u>	<u>\$ 101,994</u>	<u>\$ 140,193</u>
Basic net income per share	\$ 0.29	\$ 1.11	\$ 2.25	\$ 3.13
Basic weighted average shares outstanding	45,319	44,961	45,267	44,754
Diluted net income per share (B)	\$ 0.28	\$ 1.09	\$ 2.22	\$ 3.04
Diluted weighted average shares outstanding	45,912	46,153	46,031	46,164
(A) Net income includes the following items:				
Excess tax benefits related to stock-based compensation awards (1)	\$ (469)	\$ (12,928)	\$ (13,290)	\$ (66,765)
Unrealized loss on investment in Shockwave Medical - net of tax (2)	34,508	—	4,496	—
	<u>\$ 34,039</u>	<u>\$ (12,928)</u>	<u>\$ (8,794)</u>	<u>\$ (66,765)</u>
(B) Diluted net income per share includes the following items:				
Excess tax benefits related to stock-based compensation awards (1)	\$ (0.01)	\$ (0.28)	\$ (0.29)	\$ (1.45)
Unrealized loss on investment in Shockwave Medical (2)	0.75	—	0.10	—
	<u>\$ 0.74</u>	<u>\$ (0.28)</u>	<u>\$ (0.19)</u>	<u>\$ (1.45)</u>

(1) Amount represents the impact of excess tax benefits and shortfalls associated with stock-based awards in each respective period presented.

(2) In the second quarter of fiscal 2020, the company recorded an unrealized loss on its investment in Shockwave Medical of \$45.8 million (\$34.5 million, net of tax benefit) and is recorded within other income (expense), net.