

**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): February 6, 2020



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 February 6, 2020, ABIOMED, Inc. (the "Company," "we" or "us") issued a press release reporting our financial results for our third quarter ended December 31, 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 | Q3 FY2020 earnings press release dated February 6, 2020 |

Exhibit Index

| Exhibit | Description |
|---------|---|
| 99.1 | Q3 FY2020 earnings press release dated February 6, 2020 |
| 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: February 6, 2020



ABIOMED ANNOUNCES Q3 FY 2020 REVENUE OF \$222 MILLION AND 31.7% OPERATING MARGIN

DANVERS, Mass. — February 6, 2020 – Abiomed, Inc. (NASDAQ: ABMD), a leading provider of breakthrough heart recovery and support technologies, today reported third quarter fiscal 2020 revenue of \$221.6 million, an increase of 10% compared to revenue of \$200.6 million for the same period of fiscal 2019. Operating income was \$70.3 million, up 13%, compared to \$62.4 million in the same period of fiscal 2019.

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

- U.S. revenue totaled \$185.6 million, an increase of 8% compared to revenue of \$172.6 million during the same period of fiscal 2019 with U.S. patient usage of Impella heart pumps up 5%.
 - Abiomed had a strong start to the quarter across all geographies, highlighted by 24% global revenue growth and 16% growth in U.S. patient usage in October. The company was negatively impacted at a conference by two misleading presentations from observational databases representing less than 4% of our patients over the time period and excluded patients requiring escalation on IABP and all ECMO patients. These conclusions conflict with scientific protocols for observational databases and Impella outcomes reported in more robust, previously published, FDA-audited, peer-reviewed, real-world studies and randomized controlled trials. The totality of the Impella clinical data with 7 FDA studies, 5 post-approval studies and numerous physician-initiated studies demonstrates Impella is safe and effective for high-risk PCI, cardiogenic shock, and right heart failure. The response is detailed in our [press release](#) and [video publication review](#).
 - Outside the U.S., revenue totaled \$36.0 million, an increase of 29% compared to revenue of \$28.0 million during the same period of fiscal 2019. Specifically, Japan revenue was \$8.7 million in the quarter, up 61% compared to the same period of fiscal 2019.
 - Gross margin was 82.0% compared to 83.0% during the same period of fiscal 2019.
 - Operating income was \$70.3 million, or 31.7% operating margin compared to \$62.4 million, or 31.1% operating margin in the same period of fiscal 2019.
 - GAAP net income was \$69.2 million, or \$1.51 per diluted share, which includes a \$17.8 million, or \$0.39 per share, unrealized gain from our investment in Shockwave. This compares to GAAP net income of \$44.9 million or \$0.97 per diluted share for the prior fiscal year.
 - The company generated operating cash flow of \$89.4 million in the third quarter and \$228.3 million year to date, an increase of 26.0% versus prior year. As of December 31, 2019, the company had \$595.5 million of cash and marketable securities and maintains no debt.
 - On October 31, the company announced the first U.S. patients treated with Impella 5.5 with SmartAssist. Designed for heart surgeons, Impella 5.5 with SmartAssist is the first and only forward flow heart pump designed for axillary implant with a smaller profile, weaning algorithms and gives patients the ability to ambulate which has been shown to improve outcomes. The Impella 5.5 with SmartAssist is being introduced in the U.S. through a controlled rollout at hospitals with established heart recovery protocols.
 - On November 14, the [company announced](#) a comprehensive publication review of cost and comparative effectiveness of Impella in high-risk PCI and cardiogenic shock. The data, from a robust body of US and European evidence from 2004 - 2019, includes the PROTECT II FDA randomized controlled trial, data from the Centers
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for Medicare & Medicaid Services MedPAR database and more than 20 peer-reviewed clinical publications on cost-effectiveness. It demonstrates that Impella use in high-risk PCI (Protected PCI) and cardiogenic shock, when compared to intra-aortic balloon pump (IABP) or other therapies, is associated with improved patient outcomes and reduced costs.

- On December 16, the company announced the initiation of the ST-Elevation Myocardial Infarction Door-to-Unloading (STEMI DTU) Pivotal Randomized Controlled Trial (RCT), which will explore whether unloading the heart's left ventricle for 30 minutes with an Impella heart pump prior to opening blocked arteries will reduce infarct size after a heart attack and lead to a reduction in future heart failure rates. Abiomed announces today 12 patients have been enrolled and 10 of the 60 hospitals have IRB approval. If the STEMI DTU trial is successful, it could annually benefit 200,000 heart attack patients in the United States and more than 4 million patients outside the United States.
- On January 13, the company presented at the 38th Annual J.P. Morgan Healthcare Conference. A [webcast](#) of the presentation with automatic slide advance and animations is available on the [investor section](#) of our website.

“Abiomed remains steadfast on our goal of creating the new field of heart recovery and becoming the standard of care for circulatory support for high-risk PCI and cardiogenic shock,” said Abiomed Chairman, President and CEO, Michael R. Minogue. “Today, we are announcing the start of the next wave of clinical studies designed by the true experts in the field with best practice protocols derived from 15 years of clinical experience and studies. In the history of the company, I feel most confident now about the strength of our innovation, clinical outcomes with protocols, and field team. We will remember this time and recognize the opportunity to propel us forward on our path for CLASS I guidelines for percutaneous unloading heart pumps called Impella.”

FISCAL YEAR 2020 OUTLOOK

As previously announced in January, the company revised its 2020 revenue guidance to be in the range of \$846 million to \$877 million, an increase of 10% to 14%, respectively. The company maintains its fiscal year 2020 guidance for GAAP operating margin within 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. EST on Thursday, February 6, 2020. 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/v667km57> 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. EST February 6, 2020 through 11:00 a.m. EST on February 13, 2020. The replay phone number is (855) 859-2056; the international number is (404) 537-3406. The replay access code is 8974195.

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, Impella 5.5, Impella Connect, and SmartAssist are registered trademarks of Abiomed, Inc., and are registered in the U.S. and certain foreign countries. Impella BTR, Impella ECP, CVAD Study, and Automated Impella Controller 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.

For further information please contact:

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

| | <u>December 31, 2019</u> | <u>March 31, 2019</u> |
|--|--------------------------|-----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 117,970 | \$ 121,021 |
| Short-term marketable securities | 309,569 | 370,677 |
| Accounts receivable, net | 100,994 | 90,809 |
| Inventories | 91,193 | 80,942 |
| Prepaid expenses and other current assets | 16,850 | 13,748 |
| Total current assets | 636,576 | 677,197 |
| Long-term marketable securities | 167,981 | 21,718 |
| Property and equipment, net | 162,060 | 145,005 |
| Goodwill | 32,594 | 32,601 |
| In-process research and development | 15,205 | 15,208 |
| Long-term deferred tax assets, net | 47,028 | 77,502 |
| Other assets | 135,167 | 85,115 |
| Total assets | <u>\$ 1,196,611</u> | <u>\$ 1,054,346</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 31,566 | \$ 32,185 |
| Accrued expenses | 71,876 | 57,420 |
| Deferred revenues | 19,156 | 16,393 |
| Other current liabilities | 3,661 | — |
| Total current liabilities | 126,259 | 105,998 |
| Contingent consideration | 10,440 | 9,575 |
| Long-term deferred tax liabilities | 822 | 822 |
| Other long-term liabilities | 12,227 | 1,061 |
| Total liabilities | 149,748 | 117,456 |
| 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 | 451 | 451 |
| Authorized - 100,000,000 shares; Issued - 47,498,385 shares at December 31, 2019 and 47,026,226 shares at March 31, 2019 | | |
| Outstanding - 45,112,835 shares at December 31, 2019 and 45,122,985 shares at March 31, 2019 | | |
| Additional paid in capital | 733,054 | 690,507 |
| Retained earnings | 570,683 | 399,473 |
| Treasury stock at cost - 2,385,550 shares at December 31, 2019 and 1,903,241 shares at March 31, 2019 | (240,330) | (138,852) |
| Accumulated other comprehensive loss | (16,995) | (14,689) |
| Total stockholders' equity | 1,046,863 | 936,890 |
| Total liabilities and stockholders' equity | <u>\$ 1,196,611</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 December 31, | | For the Nine Months Ended December 31, | |
|--|--|-------------------|---|--------------------|
| | 2019 | 2018 | 2019 | 2018 |
| Revenue | \$ 221,584 | \$ 200,563 | \$ 634,225 | \$ 562,351 |
| Costs and expenses: | | | | |
| Cost of revenue | 39,996 | 34,023 | 111,937 | 94,718 |
| Research and development | 25,655 | 23,965 | 73,413 | 67,955 |
| Selling, general and administrative | 85,674 | 80,220 | 257,708 | 240,254 |
| | <u>151,325</u> | <u>138,208</u> | <u>443,058</u> | <u>402,927</u> |
| Income from operations | 70,259 | 62,355 | 191,167 | 159,424 |
| Other income (expenses): | | | | |
| Investment income, net | 3,086 | 2,175 | 9,066 | 5,397 |
| Other income (expense), net | 23,671 | (20) | 17,279 | 10 |
| | <u>26,757</u> | <u>2,155</u> | <u>26,345</u> | <u>5,407</u> |
| Income before income taxes | 97,016 | 64,510 | 217,512 | 164,831 |
| Income tax provision (benefit) | 27,799 | 19,648 | 46,301 | (20,225) |
| Net income (A) | <u>\$ 69,217</u> | <u>\$ 44,862</u> | <u>\$ 171,211</u> | <u>\$ 185,056</u> |
| Basic net income per share | \$ 1.53 | \$ 1.00 | \$ 3.79 | \$ 4.13 |
| Basic weighted average shares outstanding | 45,140 | 45,046 | 45,225 | 44,852 |
| Diluted net income per share (B) | \$ 1.51 | \$ 0.97 | \$ 3.73 | \$ 4.01 |
| Diluted weighted average shares outstanding | 45,695 | 46,136 | 45,935 | 46,147 |
| (A) Net income includes the following items: | | | | |
| Excess tax benefits related to stock-based compensation awards (1) | \$ (485) | \$ (1,704) | \$ (13,775) | \$ (68,469) |
| Unrealized gain on investment in Shockwave Medical (2) | (17,775) | — | (13,272) | — |
| | <u>\$ (18,260)</u> | <u>\$ (1,704)</u> | <u>\$ (27,047)</u> | <u>\$ (68,469)</u> |
| (B) Diluted net income per share includes the following items: | | | | |
| Excess tax benefits related to stock-based compensation awards (1) | \$ (0.01) | \$ (0.04) | \$ (0.30) | \$ (1.48) |
| Unrealized gain on investment in Shockwave Medical (2) | (0.39) | — | (0.29) | — |
| | <u>\$ (0.40)</u> | <u>\$ (0.04)</u> | <u>\$ (0.59)</u> | <u>\$ (1.48)</u> |

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

(2) In the third quarter of fiscal 2020, the company recorded an unrealized gain on its investment in Shockwave Medical of \$23.5 million (\$17.8 million, net of tax benefit) and is recorded within other income (expense), net.