Abiomed Announces Q1 FY 2021 Revenue of $165 Million and 21% Operating Margin

August 6, 2020

June Revenue Up 4% Versus Prior Year

DANVERS, Mass.--(BUSINESS WIRE)--Aug. 6, 2020-- Abiomed, Inc. (NASDAQ: ABMD), a leading provider of breakthrough heart support technologies today reported first quarter fiscal 2021 revenue of $164.9 million compared to revenue of $207.7 million for the same period of fiscal 2020 despite a negative impact from the COVID-19 pandemic. The company delivered sequential revenue and patient growth each month within the quarter, with June up 4% versus prior year. Operating income was $34.1 million down 44%, compared to $60.7 million in the same period of fiscal 2020.

Recent financial and operating highlights include:

- Worldwide Impella® heart pump revenue for the quarter totaled $155.4 million, a decrease of 22% compared to revenue of $199.9 million during the same period of the prior fiscal year 2020.
- U.S. Impella product revenue for the quarter totaled $126.2 million, a decrease of 25% compared to revenue of $168.3 million during the same period of the prior fiscal year with U.S. patient usage of the Impella heart pumps down 22%.
- Outside the U.S., Impella product revenue for the quarter totaled $29.2 million, a decrease of 7% compared to revenue of $31.5 million during the same period of the prior fiscal year. European Impella product revenue decreased 13% compared to prior year. Japan Impella product revenue increased 4% compared to prior year.
- Gross margin for the first quarter fiscal 2021 was 78.2% compared to 82.1% during the same period of fiscal 2020.
- Operating income for the first quarter fiscal 2021 was $34.1 million, or 20.7% operating margin, compared to $60.7 million, or 29.2% operating margin in the same period of fiscal 2020.
- First quarter fiscal 2021 GAAP net income was $44.6 million, or $0.98 per diluted share, which includes a $17.9 million, or $0.39 per diluted share, unrealized gain on our investment in Shockwave. This compared to GAAP net income of $88.9 million or $1.93 per diluted share for the prior fiscal year, which benefited from a $30.0 million, or $0.65 per share, unrealized gain on our investment in Shockwave and a $12.8 million, or $0.28 per share, of excess tax benefits.
- The company generated operating cash flow of $31.8 million in the first quarter. As of June 30, 2020, the company had $597.0 million of cash and marketable securities and no debt.
- On May 19, the company announced results presented during the 2020 Society for Cardiovascular Angiography & Interventions (SCAI) Scientific Sessions. Data from more than 1,000 patients demonstrates use of Impella hemodynamic support in high-risk PCI was associated with lower in-hospital mortality when placed before a PCI is performed. The data analyzed from the Global cVAD study found, in the setting of high-risk PCI, that Impella used prophylactically is associated with a ten times lower rate of in-hospital mortality, compared to when Impella is placed emergently as a bailout for patients that hemodynamically decompensate during PCI.
- On May 27, the company hosted a Virtual Investor Day covering clinical data and innovation. The event included presentations from members of Abiomed's senior management team and five physicians experts providing an overview and update on the company's robust clinical data and latest innovations that have been recently launched or are expected to be launched commercially over the next few years.
- On June 1, the company announced that the FDA issued an emergency use authorization (EUA) for Impella RP for use in patients suffering with COVID-19 related right heart failure or decompensation, including pulmonary embolism (PE). Since the onset of the COVID-19 pandemic, Impella RP has become a therapeutic choice for clinicians treating certain COVID-19 patients suffering right heart failure. COVID-19 can create a prothrombotic environment in some patients resulting in acute pulmonary embolism which may lead to acute right ventricular failure.
- On June 5, the company announced that the FDA approved the company's investigational device exemption application to start an early feasibility study with a first-in-human trial of the 9 French (Fr) Impella ECP heart pump. Impella ECP, which stands for expandable cardiac power, will be studied in high-risk PCI patients. The prospective, multi-center, non-randomized early feasibility study will allow Abiomed, the study investigators, and the FDA to make qualitative assessments about the safety and feasibility of Impella ECP use in high-risk patients.
- On June 15, the company announced it appointed Charles (Chuck) Simonton, M.D., as vice president and chief medical officer. Dr. Simonton's appointment comes as the company accelerates its clinical research, including multiple randomized control trials. He will also play an integral role as the company launches new, innovative products and incorporates artificial intelligence (AI).
- On June 16, the company launched CAMP PCI, a cutting-edge digital education platform which stands for Coronary Artery & Myocardial Protected PCI, to improve patient outcomes and quality of life with supported high-risk PCI by utilizing best practices, techniques and technologies to enable safer, more effective and complete revascularization.
- On July 1, the company announced outcomes of the first 55 patients treated with Impella 5.5 with SmartAssist as a featured publication in the July edition of the American Society for Artificial Internal Organs (ASAIO) Journal. This first published United States experience of Abiomed's newest heart pump, Impella 5.5 with SmartAssist in the treatment of acute on chronic heart failure patients in cardiogenic shock, reported an

84% survival to explant with 76% native heart recovery.

- On July 16, the company announced that the FDA approved one-way digital data streaming during patient support from the company's Automated Impella Controller (AIC), the external console used with Impella heart pumps. The data streaming capability is facilitated through the Impella Connect interface, a HIPAA-compliant, cloud-based remote monitoring platform. The approval means console data could be streamed live via Impella Connect to a secure server where AI could provide predictive clinical information to the patient's physician.

- On July 30, the company announced data from a large, multi-center study in Japan. A three-year, investigator-led, prospective study of Japanese patients who received an Impella heart pump finds use of Impella is associated with a 77% survival rate at 30 days in AMI cardiogenic shock patients. The interim analysis examined 819 patients treated with Impella for a variety of conditions, including cardiogenic shock and fulminant myocarditis. Other findings include that Impella therapy is a highly effective treatment for myocarditis, with an 88% survival rate at 30 days. Overall, investigators conclude the favorable 30-day survival data indicates Impella is a beneficial therapy.

- On August 3, the FDA issued an EUA for left-sided Impella heart pumps to provide left ventricular unloading and support to COVID-19 patients who are undergoing ECMO treatment and develop pulmonary edema or myocarditis. Impella combined with ECMO therapy (known as ECpella™) has become an important tool for physicians treating COVID-19 patients suffering from both heart and lung failure.

"I am proud of Abiomed's execution during the COVID-19 pandemic, delivering on our Q1 RED phase commitments and maintaining our focus to recover hearts and save lives. We achieved sequential improvements in revenue and patients, strengthened our clinical data, and advanced our pipeline technology," said Michael R. Minogue, Abiomed's Chairman, President and Chief Executive Officer. "We will make fiscal year 2021 one of the most productive and transformative years for the company as we build Abiomed 2.0 and continue to innovate products that are smaller, smarter and more connected, while we pursue studies for Class I guidelines."

FISCAL YEAR 2021 OUTLOOK

Due to the uncertain scope and duration of the COVID-19 pandemic and the timing of global recovery, the company has not provided full year revenue or operating margin guidance. The company will continue to analyze and monitor this dynamic environment and will continue to provide transparency around results and trends. The company will reassess after each quarter and provide an update on guidance as appropriate.

EARNINGS CONFERENCE CALL DETAILS

The company will host a conference call to discuss the quarterly and full year results at 8:00 a.m. ET on Thursday, August 6, 2020. The conference call 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/u65m8ykc 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. ET August 6, 2020 through 11:00 a.m. ET on August 13, 2020. The replay phone number is (855) 859-2056; the international number is (404) 537-3406. The replay access code is 4367904.

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 ECP, Impella XR Sheath, Impella BTR, CVAD, STEMI DTU and Automated Impella Controller are pending trademarks of Abiomed, Inc. Other

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 scope, scale and duration of the impact of the COVID-19 pandemic, 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, the company's ability to integrate acquired companies into its operations 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.

Abiomed, Inc. and Subsidiaries

Consolidated Balance Sheets

(Unaudited)

(in thousands, except share data)

	June 30, 2020	March 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 214,827	$ 192,341
Short-term marketable securities	212,536	250,775
Accounts receivable, net	82,084	84,650
Inventories	89,284	90,088
Prepaid expenses and other current assets	20,958	18,009
Total current assets	619,689	635,863
Long-term marketable securities	169,668	207,795
Property and equipment, net	170,346	164,931
Goodwill	76,783	31,969
In-process research and development	42,223	14,913
Long-term deferred tax assets, net	30,875	43,336
Other assets	139,928	117,655
Total assets	$ 1,249,512	$ 1,216,462
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 27,747	$ 32,774
Accrued expenses	58,431	75,107
Deferred revenues	19,903	19,147
Other current liabilities	4,298	4,857

Total current liabilities	110,379	131,885
Contingent consideration	23,701	9,000
Long-term deferred tax liabilities	4,204	806
Other long-term liabilities	9,380	9,305
	147,664	150,996
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	450	451
Authorized - 100,000,000 shares; Issued - 47,698,298 shares at June 30, 2020 and 47,542,061 shares at March 31, 2020		
Outstanding - 45,044,760 shares at June 30, 2020 and 45,008,687 shares at March 31, 2020		
Additional paid in capital	749,440	739,133
Retained earnings	647,070	602,482
Treasury stock at cost - 2,653,538 shares at June 30, 2020 and 2,533,374 shares at March 31, 2020	(286,577)	(265,411)
Accumulated other comprehensive loss	(8,535)	(11,189)
Total stockholders' equity	1,101,848	1,065,466
Total liabilities and stockholders' equity	$ 1,249,512	$ 1,216,462

Abiomed, Inc. and Subsidiaries

Consolidated Statements of Operations

(Unaudited)

(in thousands, except per share data)

	For the Three Months Ended June 30,	
	2020	**2019**

Revenue	$ 164,850	$ 207,666
Costs and expenses:		
Cost of revenue	35,983	37,073
Research and development	26,357	23,790
Selling, general and administrative	68,444	86,078
	130,784	146,941
Income from operations	34,066	60,725
Other income (expenses):		
Investment income, net	2,397	3,049
Other income, net	24,613	39,364
	27,010	42,413
Income before income taxes	61,076	103,138
Income tax provision	16,488	14,215
Net income (A)	$ 44,588	$ 88,923
Basic net income per share	$ 0.99	$ 1.97
Basic weighted average shares outstanding	45,010	45,215
Diluted net income per share (B)	$ 0.98	$ 1.93
Diluted weighted average shares outstanding	45,549	46,092
(A) Net income includes the following items:		
Excess tax benefits related to stock-based compensation awards	$ (522)	$ (12,821)
Unrealized gain on investment in Shockwave Medical	(17,934)	(29,998)
	$ (18,456)	$ (42,819)
(B) Diluted net income per share includes the following items:		
Excess tax benefits related to stock-based compensation awards	$ (0.01)	$ (0.28)

Unrealized gain on investment in Shockwave Medical	(0.39)	(0.65)
	$ (0.40)	$ (0.93)

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