



Abiomed Announces Q2 FY 2021 Revenue of \$210 Million, Up 27% Over Q1 FY 2021 and Up 2% Over Q2 FY 2020 With 29.2% Operating Margin

October 29, 2020

DANVERS, Mass.--(BUSINESS WIRE)--Oct. 29, 2020-- Abiomed, Inc. (NASDAQ: ABMD), a leading provider of breakthrough heart support technologies today reported second quarter fiscal 2021 revenue of \$209.8 million, a sequential increase of 27% compared to Q1 fiscal year 2021 and a year over year increase of 2% compared to Q2 fiscal year 2020 despite the negative impact of COVID-19. Operating income was \$61.3 million up 2%, compared to \$60.2 million in the same period of fiscal 2020.

Recent financial and operating highlights include:

- Worldwide Impella® heart pump revenue for the quarter totaled \$199.7 million, a sequential increase of 29% compared to revenue of \$155.4 million during Q1 fiscal year 2021 and a 1% increase compared to revenue of \$196.9 million during Q2 fiscal year 2020.
- U.S. Impella product revenue for the quarter totaled \$163.2 million, a sequential increase of 29% compared to revenue of \$126.2 million during Q1 fiscal year 2021 and a decrease of 1% compared to revenue of \$164.7 million during Q2 fiscal year 2020 with U.S. patient usage of the Impella heart pumps up 24% over prior fiscal quarter and down 4% over prior fiscal year.
- Outside the U.S., Impella product revenue for the quarter totaled \$36.5 million, a sequential increase of 25% compared to revenue of \$29.2 million during Q1 fiscal year 2021 and an increase of 13% compared to revenue of \$32.2 million during Q2 fiscal year 2020. European Impella product revenue increased 29% compared to the prior fiscal quarter and 16% compared to the prior fiscal year. Japan Impella product revenue increased 14% compared to the prior fiscal quarter and 5% compared to the prior fiscal year.
- Gross margin for the second quarter fiscal 2021 was 81.5% compared to 83.0% during the same period of fiscal 2020.
- Operating income for the second quarter fiscal 2021 was \$61.3 million, or 29.2% operating margin, compared to \$60.2 million, or 29.4% operating margin in the same period of fiscal 2020.
- Second quarter fiscal 2021 GAAP net income was \$62.2 million, or \$1.36 per diluted share, which includes a \$8.2 million, or \$0.18 per diluted share, gain on our investment in Shockwave and a \$7.9 million, or \$0.17 per diluted share, of excess tax benefits related to employee share-based compensation awards. This compared to GAAP net income of \$13.1 million or \$0.28 per diluted share for the prior fiscal year.
- The company generated operating cash flow of \$77.2 million in the second quarter. As of September 30, 2020, the company had \$735.7 million of cash and marketable securities and no debt.
- At the end of second quarter fiscal 2021, Abiomed has 929 patents and 835 patents pending due to our continued innovation and expanding our global reach.
- In October, at TCT Connect, more than 20 presentations and abstracts were presented validating the benefits of a more complete revascularization with Impella heart pumps in high-risk percutaneous coronary intervention (PCI) patients and the value of Impella protocol-based treatment for survival and native heart recovery in cardiogenic shock and right heart failure patients. Key data presented includes:
 - New [PROTECT III study data](#) demonstrates reduced rates of MACCE (composite of death, stroke, myocardial infarction and repeat procedures) compared to the Protect II dataset (15% vs. 21.9%, p=0.035).
 - The [Restore EF Study](#) demonstrates the use of contemporary best practices with Impella-supported high-risk PCI enables a more complete revascularization and is associated with significant improvement of left ventricular ejection fraction (45% relative improvement), heart failure symptoms (80% reduction in NYHA Class III, IV), and anginal symptoms at follow up (99% reduction in CCS Angina Class III, IV).
 - Data from the [RECOVER III](#) post-market approval (PMA) study of AMI cardiogenic shock (AMICS) patients was presented in two studies. The first study, presented by Hemindermeet Singh, MD, of Ascension St. John Hospital, found an 18% relative improvement in overall survival in the recent cohort (2017 – 2019) versus a pre-PMA cohort (2008 – 2014), indicating increased adoption of the cardiogenic shock best practices, including placing Impella pre-PCI has led to an improvement in overall survival rates. The second study, presented by Tayyab Shah, MD, of the Yale School of Medicine, found that placing Impella pre-PCI in AMICS patients is associated with higher survival, particularly in women, as compared to post-PCI (74% relative survival benefit).
 - [Two Impella RP studies](#) find that early identification of right heart failure and early use of Impella RP is associated with significantly higher survival rates. The ongoing PMA post-approval study, RECOVER RIGHT, presented by Mark Anderson, MD, found patients who received Impella RP support within 48 hours of cardiogenic shock onset had a significantly higher survival rate than those who received delayed right-heart support (73% vs. 14%, p<0.001). Another study, presented by Babar Basir, DO, found persistent diastolic suction alarms on the Automated Impella Controller (AIC) and an elevated central venous pressure of greater than 12mmHg can be an early indication of Right Ventricular Failure.
- On October 20, the company hosted a [virtual investor meeting](#) to review new clinical data presented at TCT Connect. The virtual meeting included a presentation from Chuck A. Simonton, MD, Vice President and Chief Medical Officer.
- On October 26, [the company announced](#) the United States Food and Drug Administration (FDA) granted a 510(k) clearance for Abiomed's Breeze OXY-1 cardiopulmonary bypass support system.

- On October 28, [the company announced](#) the first two patients have been treated with the Impella ECP expandable percutaneous heart pump as part of an FDA Early Feasibility Study. Impella ECP is the smallest heart pump in the world.

"I am proud to report that we achieved our Q2 'Yellow' phase goals and grew sequentially, stabilized revenue in the US and increased revenue double digits outside of the U.S while advancing our regulatory, clinical and engineering milestones," said Michael R. Minogue, Abiomed's Chairman, President and Chief Executive Officer. "I am also proud of the Patients First commitment and leadership from our employees and customers to recover hearts and save lives every day."

THIRD QUARTER 2021 REVENUE OUTLOOK

Similar to the revenue performance in the second quarter of fiscal year 2021, the company anticipates sequential improvement in revenue in the third quarter fiscal year 2021. At this time, the company anticipates third quarter fiscal year 2021 global revenue to be in the range of \$221 million to \$230 million, representing flat to 4% growth compared to third quarter fiscal year 2020.

EARNINGS CONFERENCE CALL DETAILS

The company will host a conference call to discuss the quarterly results at 8:00 a.m. ET on Thursday, October 29, 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/or57h3yi> 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 October 29, 2020 through 10:00 a.m. ET on November 5, 2020. The replay phone number is (855) 859-2056; the international number is (404) 537-3406. The replay access code is 5992445.

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, Automated Impella Controller and Abiomed Breathe OXY-1 System 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 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)

September 30, 2020	March 31, 2020
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ASSETS

Current assets:

Cash and cash equivalents	\$ 202,241	\$ 192,341
Short-term marketable securities	330,843	250,775
Accounts receivable, net	80,909	84,650
Inventories	83,209	90,088
Prepaid expenses and other current assets	19,419	18,009
Total current assets	716,621	635,863
Long-term marketable securities	202,613	207,795
Property and equipment, net	175,582	164,931
Goodwill	78,122	31,969
In-process research and development	42,895	14,913
Deferred tax assets	29,547	43,336
Other assets	82,594	117,655
Total assets	\$ 1,327,974	\$ 1,216,462

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 21,734	\$ 32,774
Accrued expenses	57,227	75,107
Deferred revenues	21,314	19,147
Other current liabilities	4,938	4,857
Total current liabilities	105,213	131,885
Contingent consideration	24,417	9,000
Deferred tax liabilities	4,251	806
Other long-term liabilities	11,684	9,305
Total liabilities	145,565	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	452	451
Authorized - 100,000,000 shares; Issued - 47,847,023 shares at September 30, 2020 and 47,542,061 shares at March 31, 2020		
Outstanding - 45,189,883 shares at September 30, 2020 and 45,008,687 shares at March 31, 2020		
Additional paid in capital	767,527	739,133
Retained earnings	709,283	602,482
Treasury stock at cost - 2,657,140 shares at September 30, 2020 and 2,533,374 shares at March 31, 2020	(287,654)	(265,411)
Accumulated other comprehensive loss	(7,199)	(11,189)
Total stockholders' equity	1,182,409	1,065,466
Total liabilities and stockholders' equity	\$ 1,327,974	\$ 1,216,462

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,	
	2020	2019	2020	2019
Revenue	\$ 209,764	\$ 204,974	\$ 374,614	\$ 412,640
Costs and expenses:				
Cost of revenue	38,736	34,867	74,719	71,940
Research and development	30,525	23,969	56,882	47,759
Selling, general and administrative	79,167	85,956	147,611	172,034
	148,428	144,792	279,212	291,733

Income from operations	61,336	60,182	95,402	120,907
Other income (expense):				
Investment income, net	1,822	2,932	4,219	5,981
Other income (expense), net	9,757	(45,756)	34,370	(6,392)
	11,579	(42,824)	38,589	(411)
Income before income taxes	72,915	17,358	133,991	120,496
Income tax provision	10,702	4,287	27,190	18,502
Net income (A)	\$ 62,213	\$ 13,071	\$ 106,801	\$ 101,994
Basic net income per share	\$ 1.38	\$ 0.29	\$ 2.37	\$ 2.25
Basic weighted average shares outstanding	45,104	45,319	45,057	45,267
Diluted net income per share (B)	\$ 1.36	\$ 0.28	\$ 2.34	\$ 2.22
Diluted weighted average shares outstanding	45,661	45,912	45,609	46,031

(A) Net income includes the following items:

Excess tax benefits related to stock-based compensation awards	\$ (7,932)	\$ (469)	\$ (8,454)	\$ (13,290)
(Gain) loss on investment in Shockwave Medical	(8,167)	34,508	(26,101)	4,496
	\$ (16,099)	\$ 34,039	\$ (34,555)	\$ (8,794)

(B) Diluted net income per share includes the following items:

Excess tax benefits related to stock-based compensation awards	\$ (0.17)	\$ (0.01)	\$ (0.19)	\$ (0.29)
(Gain) loss on investment in Shockwave Medical	(0.18)	0.75	(0.57)	0.10
	\$ (0.35)	\$ 0.74	\$ (0.76)	\$ (0.19)

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