Abiomed Announces Record Revenue of $253 Million, Up 53% Year Over Year

August 4, 2021

Full year global revenue guidance increased for fiscal year 2022 to 22% - 24% growth versus prior year

DANVERS, Mass.--(BUSINESS WIRE)--Aug. 4, 2021-- Abiomed, Inc. (NASDAQ: ABMD), a leading provider of breakthrough heart support technologies, today announced financial results for the quarter ended June 30, 2021.

Q1 financial summary and operational highlights:

- Total revenue for the quarter totaled $252.6 million, an increase of 53% compared to $164.9 million during the same period of the prior fiscal year, driven by record global patient utilization with COVID recovery.
- Worldwide Impella® heart pump product revenue for the quarter totaled $241.5 million, an increase of 55% compared to $155.4 million during the same period of the prior fiscal year.
- U.S. Impella product revenue for the quarter totaled $197.5 million, an increase of 56% compared to $126.2 million during the same period of the prior fiscal year, with U.S. patient usage of Impella heart pumps up 43%.
- Outside the U.S., Impella product revenue for the quarter totaled $44.0 million, an increase of 51% compared to $29.2 million during the same period of the prior fiscal year. Specifically, Japan product revenue for the quarter totaled $10.9 million, an increase of 24% compared to $8.8 million during the same period of the prior fiscal year, driven by a 78% increase in patient usage.
- Gross margin for the quarter was 82.1% compared to 78.2% during the same period of the prior fiscal year.
- The company announced the acquisition of the remaining interest of preCARDIA for $82.8 million. preCARDIA is the developer of a proprietary catheter and controller that will complement Abiomed's product portfolio to expand options for upstream heart failure patients acutely decompensating. Annually, more than one million patients are admitted to hospitals in the United States with acute decompensated heart failure (ADHF)[1]. Despite available pharmaceutical treatments, heart failure is the leading cause of hospitalization in patients older than 65 years of age[2]. preCARDIA will provide heart failure specialists a minimally invasive solution with the potential to improve patient outcomes and lower the cost of care by providing early intervention with this new technology.
- Non-GAAP income from operations* increased 94% to $66.2 million, or 26.2% non-GAAP operating margin* for the quarter, compared to $34.1 million non-GAAP income from operations, or 20.7% GAAP operating margin during the same period of the prior fiscal year. GAAP loss from operations for the quarter was $49.3 million, or (19.5%) GAAP operating margin primarily due to the accounting for the preCARDIA acquisition.
- Non-GAAP net income* increased 95% to $51.1 million, or $1.10 per diluted share, compared to non-GAAP net income of $26.1, or $0.58 per diluted share during the same period of the prior fiscal year. GAAP net loss for the quarter was $26.5 million, or $(0.59) per diluted share compared to GAAP net income of $44.6 million, or $0.98 per diluted share during the same period of the prior fiscal year primarily due to the accounting for the preCARDIA acquisition.
- The company generated operating cash flows of $55.4 million during the quarter. As of June 30, 2021, the company had $804.8 million of cash and cash equivalents and marketable securities and no debt.
- On June 29, the company announced Impella RP with SmartAssist received U.S. Food and Drug Administration (FDA) pre-market approval (PMA) as safe and effective to treat acute right heart failure for up to 14 days. Impella RP with SmartAssist is the first single-access temporary percutaneous ventricular support device with sensor technology. The FDA issued an emergency use authorization (EUA) for Impella RP in June 2020 to include patients suffering from 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.
- On August 2, the Centers for Medicare and Medicaid Services (CMS) released final Medicare payment levels for inpatient hospital discharges for fiscal year 2022 which takes effect October 1, 2021. Consistent with the April 2021 proposal and the Form 8-K filed with the SEC, CMS will reassign select ICD-10-PCS codes from MS-DRG 215 to additional cardiovascular related MS-DRGs to align clinical populations and better reflect hospital resources. We are pleased and

supported the final rule coding changes to provide stability for multiple DRG payments. The Final Rule for the Inpatient Prospective Payment System (IPPS) is available on the CMS website.

"Q1 was a solid start with record global revenue and patient utilization in US, Europe and Japan, and we believe we are well-positioned for success in FY22," said Michael R. Minogue, Abiomed's Chairman, President and Chief Executive Officer. "We will continue to create and deliver value by successfully advancing our innovation, clinical research and commercial distribution. We remain steadfast to creating the field of heart recovery and driving a new standard of care for circulatory support."

FISCAL YEAR 2022 OUTLOOK

The company is increasing fiscal year 2022 global revenue and now expects it to be in the range of $1,030 million to $1,050 million, representing 22% to 24% growth compared to fiscal year 2021, an increase from our original guidance of $990 million to $1,030 million, or 17% to 22% growth compared to fiscal year 2021. The company expects its fiscal year 2022 non-GAAP operating margin* to be in the range of 24% to 26%.

***ABOUT NON-GAAP FINANCIAL MEASURES**

To supplement its condensed consolidated financial statements, which are prepared and presented in accordance with accounting principles generally accepted in the United States ("GAAP"), the company uses non-GAAP financial measures as described below. The company uses these non-GAAP financial measures for financial and operational decision-making and to evaluate period-to-period comparisons. The company believes that these non-GAAP financial measures provide meaningful supplemental information regarding its performance and liquidity. The company believes that both management and investors benefit from referring to these non-GAAP financial measures in assessing its performance and when planning, forecasting, and analyzing future periods. The company believes these non-GAAP financial measures are useful to investors because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) they are used by institutional investors and the analyst community to help them analyze the performance of the company's business.

The company uses the following non-GAAP financial measures:

Non-GAAP (loss) income from operations: The company defines non-GAAP (loss) income from operations as (loss) income from operations, excluding the charge for the acquired in-process research and development related to the preCARDIA acquisition.

Non-GAAP operating margin: The company defines non-GAAP operating margin as operating margin, excluding the charge for the acquired in-process research and development related to the preCARDIA acquisition.

Non-GAAP net (loss) income and net (loss) income per diluted share: The company defines non-GAAP net (loss) income and net (loss) income per diluted share as net (loss) income and net (loss) income per diluted share, excluding the charge for the acquired in-process research and development related to the preCARDIA acquisition, the gain recognized on its previously owned minority interest in preCARDIA, the unrealized gain on investment in Shockwave Medical and excess tax benefits associated with stock-based compensation. The company defines non-GAAP EPS as non-GAAP net (loss) income divided by non-GAAP diluted shares, which are calculated as GAAP weighted average outstanding shares plus dilutive potential shares outstanding during the period.

Refer to the *"Reconciliation of GAAP to Non-GAAP Financial Measures"* section of this press release.

The company reports non-GAAP financial measures in addition to, and not as a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. These non-GAAP financial measures are not based on any comprehensive set of accounting rules or principles, differ from GAAP measures with the same names, and may differ from non-GAAP financial measures with the same or similar names that are used by other companies. The company believes it is useful to exclude certain items because such amounts in any specific period may not directly correlate to the underlying performance of its business operations or can vary significantly between periods. The company believes that non-GAAP financial measures should only be used to evaluate our results of operations in conjunction with the corresponding GAAP financial measures. The company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliations between these presentations, to more fully understand its business.

EARNINGS CONFERENCE CALL DETAILS

The company will host a conference call to discuss the quarterly results at 8:00 a.m. ET on Thursday, August 5, 2021. 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://investors.abiomed.com/events-presentations 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 5, 2021 through 11:00 a.m. ET on August 12, 2021. The replay phone number is (855) 859-2056; the international number is (404) 537-3406. The replay access code is 5929017.

ABOUT ABIOMED

Based in Danvers, Massachusetts, USA, Abiomed, Inc. is a leading provider of medical devices that provide circulatory support and oxygenation. 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 Breethe 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, future opportunities and expected regulatory approvals and statements in the paragraph under “Fiscal Year 2022 Outlook” section regarding certain business metrics on either or both a GAAP or non-GAAP basis. 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
Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share data)

	June 30, 2021	March 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 175,454	$ 232,710
Short-term marketable securities	347,577	350,985
Accounts receivable, net	88,645	97,179
Inventories	83,661	81,059
Prepaid expenses and other current assets	34,536	26,032
Total current assets	729,873	787,965
Long-term marketable securities	281,776	264,085

Property and equipment, net	198,234	197,129
Goodwill	79,006	78,568
Other intangibles, net	41,904	42,150
Deferred tax assets	4,958	11,380
Other assets	122,643	113,082
Total assets	$ 1,458,394	$ 1,494,359
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 29,807	$ 34,842
Accrued expenses	56,462	66,046
Deferred revenues	24,094	24,322
Other current liabilities	2,760	3,759
Total current liabilities	113,123	128,969
Other long-term liabilities	11,314	10,162
Contingent consideration	25,577	24,706
Deferred tax liabilities	858	847
Total liabilities	150,872	164,684
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	454	453
Authorized - 100,000,000 shares; Issued 48,070, 443 shares as of June 30, 2021 and 47,929,402 shares as of March 31, 2021		
Outstanding 45,377,715 shares as of June 30, 2021 and 45,270,948 shares as of March 31, 2021		
Additional paid in capital	815,416	800,690
Retained earnings	801,482	828,007
Treasury stock at cost 2,692,728 shares as of June 30, 2021 and 2,658,454 shares as of March 31, 2021	(297,619)	(288,030)
Accumulated other comprehensive loss	(12,211)	(11,445)
Total stockholders' equity	1,307,522	1,329,675
Total liabilities and stockholders' equity	$ 1,458,394	$ 1,494,359

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

	For the Three Months Ended June 30,	
	2021	**2020**
Revenue	$ 252,585	$ 164,850
Costs and expenses:		
Cost of revenue	45,188	35,983
Research and development	37,708	26,357
Selling, general and administrative	103,484	68,444
Acquired in-process research and development	115,490	—
	301,870	130,784
(Loss) income from operations	(49,285)	34,066
Other income:		

Investment income, net	1,050	2,397
Other income, net	38,885	24,613
	39,935	27,010
(Loss) income before income taxes	(9,350)	61,076
Income tax provision	17,175	16,488
Net (loss) income	$ (26,525)	$ 44,588
Net (loss) income per share - basic	$ (0.59)	$ 0.99
Weighted average shares outstanding - basic	45,311	45,010
Net (loss) income per share - diluted	$ (0.59)	$ 0.98
Weighted average shares outstanding - diluted	45,311	45,549

Abiomed, Inc. and Subsidiaries
Reconciliation of GAAP to Non-GAAP Financial Measures
(Unaudited)
(in thousands, except per share data)

	For the Three Months Ended June 30,	
	2021	**2020**
GAAP (loss) income from operations	$ (49,285)	$ 34,066
Acquired in-process research and development (1)	115,490	—
Non-GAAP income from operations	$ 66,205	$ 34,066
GAAP operating margin	(19.5%)	20.7%
Non-GAAP operating margin	26.2%	20.7%
GAAP net (loss) income	$ (26,525)	$ 44,588
Acquired in-process research and development (1)	115,490	—
Gain on previously held interest in preCARDIA (2)	(20,980)	—
Excess tax benefits on stock-based compensation (3)	(3,630)	(522)
Gain on investment in Shockwave Medical (4)	(13,301)	(17,934)
Non-GAAP net income	$ 51,054	$ 26,132
GAAP diluted net (loss) income per share	$ (0.59)	$ 0.98
Acquired in-process research and development (1)	2.52	—
Gain on previously held interest in preCARDIA (2)	(0.46)	—
Excess tax benefits on stock-based compensation (3)	(0.08)	(0.01)
Gain on investment in Shockwave Medical (4)	(0.29)	(0.39)
Non-GAAP diluted net income per share	$ 1.10	$ 0.58
GAAP diluted weighted-average shares outstanding	45,311	45,549
Non-GAAP diluted weighted-average shares outstanding	45,797	45,549

Notes:

(1) In May 2021, the company acquired the remaining interest in preCARDIA for $82.8 million. The company determined that substantially all of the fair value of the acquisition related to the acquired in-process research and development asset, which resulted in accounting for the transaction as an asset acquisition. The fair value of the acquired in-process research and development asset of $115.5 million is primarily comprised of the net consideration paid for the acquired remaining interest of

$82.8 million and our previously owned minority interest in preCARDIA of $32.4 million. Since the acquired technology platform is pre-commercial and has not reached technical feasibility as defined by the accounting rules, the cost of the in-process research and development asset was expensed in the quarter, resulting in a charge of $115.5 million for the three months ended June 30, 2021.

(2) The company recognized a gain of $21.0 million related to its previously owned minority interest in preCARDIA as described in note (1), within the condensed consolidated statement of operations for the three months ended June 30, 2021.

(3) Amount represents the impact of excess tax benefits associated with stock-based compensation in each respective period presented. The company recognized excess tax benefits associated with stock-based compensation of $3.6 million and $0.5 million as an income tax benefit for the three months ended June 30, 2021 and 2020, respectively.

(4) Amount represents the unrealized gain on investment in Shockwave Medical in each respective period presented. The company recognized an unrealized gain on investment in Shockwave Medical of $17.7 million ($13.3 million, net of tax benefit) and $23.9 million ($17.9 million, net of tax benefit) within other income for the three months ended June 30, 2021 and 2020, respectively.

Refer to *"About Non-GAAP Financial Measures"* section of this press release.

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[1] Ponikowski, et al., ESC Heart Fail. 2014 Sep;1(1):4-25.
[2] Olofsson, et al., Journal of Clinical Gerontology and Geriatrics, Volume 7, Issue 2, 2016, Pages 53-59

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