October 30, 2014

Abiomed Announces Second Quarter Fiscal 2015 Revenue of $51.9 Million, Up 17% Over Prior Year

Abiomed on Track for Impella 2.5 and Impella RP FDA Approvals by February/March 2015

DANVERS, Mass., Oct. 30, 2014 (GLOBE NEWSWIRE) -- Abiomed, Inc. (Nasdaq:ABMD), a leading provider of breakthrough heart support technologies, today reports second quarter fiscal 2015 revenue of $51.9 million, an increase of 17% compared to revenue of $44.3 million for the same period of fiscal 2014. Second quarter fiscal 2015 GAAP net income was $3.8 million or $0.09 per diluted share, compared to GAAP net income of $1.1 million or $0.03 per diluted share for the prior year period.

Today, Abiomed announces that the Company and the Food & Drug Administration (FDA) have agreed on the indication for use for high-risk PCI for the Impella® 2.5 Pre-Market Approval (PMA). Based on the information available to the Company to date, including multiple discussions with the FDA, the Company no longer anticipates the requirement for an FDA panel and expects PMA approval for the safety and effectiveness of the Impella 2.5 by February/March 2015.

Following approval of the Impella 2.5, the Impella® 5.0 and Impella CP® will be submitted as PMA supplements. Until the 515 process is completed, the Impella 5.0 and Impella CP will remain on the market under the existing 510(k) clearances.

The totality of data in the Impella 2.5 PMA submission includes two FDA approved studies: PROTECT I and PROTECT II totaling 472 patients which includes randomized data, 637 new high-risk PCI patients from the U.S. Impella registry, and clinical data from 215 publications, for a total of 1,638 Impella patients. The submission also contains a medical device reporting analysis from approximately 14,000 patients, and comes after six years of real-world U.S. Impella experience with over 24,000 patients treated post 510(k) clearance.

Financial and operating highlights during the second quarter of fiscal 2015 and fiscal year to date include:

- Fiscal second quarter worldwide Impella revenue totaled $46.9 million, an increase of 17% compared to revenue of $40.2 million during the same period of the prior fiscal year.
- U.S. Impella revenue grew 14% to $42.0 million from $37.0 million in the prior fiscal year with U.S. Impella patient usage up 19% and U.S. Impella reorder revenue up 20%.
- An additional 27 hospitals purchased the Impella 2.5 during the quarter, compared to 30 in the prior year, bringing the installed customer base to 910 sites. An additional 56 hospitals purchased Impella CP, compared to 65 in the prior year, bringing the total number of Impella CP U.S. sites to 507.
- Outside the U.S., Impella revenue was $4.9 million, an increase of 53% over the prior year.
- Gross margin rate for the second quarter of fiscal 2015 was 81.5% compared to 79.6% in the second quarter of fiscal 2014. There were 140 Automated Impella Controller (AIC) consoles placed during the quarter compared to 172 in the same period of the prior year.
- Income from operations for the second quarter of fiscal 2015 was $4.2 million or 8.0% of revenue, compared to $1.4 million or 3.2% of revenue in the prior year period.
- Cash, cash equivalents, short and long-term marketable securities totaled $111.9 million as of September 30, 2014, compared to $118.3 million at March 31, 2014. During the quarter, $15.7 million in cash was used for the acquisition of ECP. The Company continues to have no debt and a U.S. federal net operating loss carry-forward of approximately $193 million as of September 30, 2014.
- In September, Abiomed attended the annual Transcatheter Cardiovascular Therapeutics (TCT) 2014 scientific meeting in Washington, D.C., where the Impella devices were featured in over 25 presentations during the scientific sessions.
- At TCT 2014, Abiomed announced results from RECOVER RIGHT, an Investigational Device Exemption (IDE) study of the Impella RP™ (Right Percutaneous) System. The results of the clinical trial, which was designed to evaluate the safety and probable benefit of the Impella RP in patients with right ventricular failure (RVF) refractory to medical treatment and deemed to require hemodynamic support, demonstrated a survival rate of 73% in the overall patient population at 30 days.

- There were 11 peer-reviewed clinical papers published concerning the Impella platform of devices during the second quarter. Most notably:
    - A clinical paper titled, "National Trends in the Utilization of Short-Term Mechanical Circulatory Support (MCS)," authored by Yale physicians was published in the Journal of the American College of Cardiology. The article reviews upward trends in utilization of percutaneous devices for short-term mechanical circulatory support, noting a subsequent drop in mortality rates and hospital costs that is potentially attributable to the increased use of these devices.

    - Another paper titled, "Comparison of the Use of Hemodynamic Support in Patients ≥80 Years Versus Patients < 80 Years During High-Risk Percutaneous Coronary Interventions (from the Multicenter PROTECT II Randomized Study)," was published in the American Journal of Cardiology. The article determined that the use of percutaneous circulatory support is reasonable and feasible in a selected octogenarian population with similar outcomes as those of younger selected patients.

"Abiomed achieved the highest quarterly revenue to date at $51.9 million, and has now grown top line revenue by double digits, year over year, for 20 straight quarters," said Michael R. Minogue, Chairman, President & Chief Executive Officer, Abiomed. "Abiomed's investment in clinical research, new products and patent portfolio, along with our disciplined approach in execution continue to provide Abiomed the opportunity to become the new standard of care and recognized leader in percutaneous circulatory support."

FISCAL YEAR 2015 OUTLOOK

The Company is increasing the lower end of its fiscal year 2015 revenue guidance with the new range of $209 million to $212 million from the original range of $205 million to $212 million. The Company is reiterating its fiscal year 2015 guidance for GAAP operating margin of 1% - 4%.

CONFERENCE CALL

The Company will host a conference call to discuss the results on Thursday, October 30, 2014, at 8:00 a.m. ET. Michael R. Minogue, Chairman, President and Chief Executive Officer and Robert L. Bowen, Vice President and Chief Financial Officer, will host the conference call.

To listen to the call live, please tune into the webcast via http://investor.abiomed.com or dial (855) 212-2361; the international number is (678) 809-1538. A replay of this conference call will be available beginning at 11 a.m. ET October 30, 2014 through 11:59 p.m. ET on November 6, 2014. The replay phone number is (855) 859-2056; the international number is (404) 537-3406. The replay access code is 5150124.

***** The Impella RP is the subject of an investigational device exemption (IDE) clinical study and is limited by federal law to investigational use. The Impella RP currently is not available for sale in the United States.

ABOUT ABIOMED

Based in Danvers, Massachusetts, 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

FORWARD-LOOKING STATEMENTS

This press release contains "forward-looking statements," including 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 about 2015 financial guidance. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," forecast," "intend, "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. These forward-looking statements include all matters that are not historical facts. The Company's actual results may differ materially from those results anticipated in these forward-looking statements based upon a number of factors, risks and uncertainties, including uncertainties associated with development, testing and related regulatory approvals, including the potential for future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, litigation matters, future capital needs and uncertainty of additional financing, and other risks and challenges detailed in the Company's filings with the Securities and Exchange Commission, including the most recently filed Annual Report on Form 10-K and Quarterly Report on Form 10-Q. As a result of the foregoing, readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. The Company undertakes no obligation to publicly update or revise these forward-looking statements whether as a result of new information, future events or otherwise, unless otherwise required by law.

Abiomed, Inc. and Subsidiaries

Consolidated Balance Sheets

(Unaudited)

(in thousands, except share data)

	September 30, 2014	March 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,483	$ 20,916
Short-term marketable securities	77,981	55,663
Accounts receivable, net	23,072	24,357
Inventories	13,445	13,948
Prepaid expenses and other current assets	3,310	3,082
Total current assets	135,291	117,966
Long-term marketable securities	16,473	41,761
Property and equipment, net	7,351	6,889
Goodwill	38,476	37,990
In-process research and development	17,198	--
Other assets	1,551	801
Total assets	$ 216,340	$ 205,407
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,616	$ 7,746
Accrued expenses	13,762	17,899
Deferred revenue	5,756	4,766
Total current liabilities	27,134	30,411
Other long-term liabilities	210	228
Contingent consideration	5,797	--
Long-term deferred tax liability	7,661	6,415
Total liabilities	40,802	37,054
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	417	411
Authorized - 100,000,000 shares; Issued - 41,831,077 shares at September 30, 2014 and 41,122,695 shares at March 31, 2014; Outstanding - 40,577,134 shares at September 30, 2014 and 39,916,328 shares at March 31, 2014		
Additional paid in capital	447,433	436,136
Accumulated deficit	(248,780)	(250,910)
Treasury stock at cost - 1,253,943 shares at September 30, 2014 and 1,206,367 shares at March 31, 2014	(17,567)	(16,554)
Accumulated other comprehensive loss	(5,965)	(730)
Total stockholders' equity	175,538	168,353
Total liabilities and stockholders' equity	$ 216,340	$ 205,407

Abiomed, Inc. and Subsidiaries

Consolidated Statements of Operations

(Unaudited)

(in thousands, except share data)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Revenue:				
Product revenue	$ 51,774	$ 44,288	$ 100,434	$ 86,897
Funded research and development	164	57	315	118
	51,938	44,345	100,749	87,015
Costs and expenses:				
Cost of product revenue	9,612	9,027	19,301	17,750
Research and development	8,693	7,721	17,755	15,008
Selling, general and administrative	29,455	26,199	61,053	54,166
	47,760	42,947	98,109	86,924
Income from operations	4,178	1,398	2,640	91
Other income (loss):				
Investment income, net	36	25	80	41
Other (loss) income, net	(39)	6	(28)	(15)
	(3)	31	52	26
Income before income tax provision	4,175	1,429	2,692	117
Income tax provision	336	370	562	781
Net income (loss)	$ 3,839	$ 1,059	$ 2,130	$ (664)
Basic net income (loss) per share	$ 0.09	$ 0.03	$ 0.05	$ (0.02)
Basic weighted average shares outstanding	40,448	39,260	40,256	38,971
Diluted net income (loss) per share	$ 0.09	$ 0.03	$ 0.05	$ (0.02)
Diluted weighted average shares outstanding	42,239	41,337	42,069	38,971

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