

ABIOMED INC
Form 10-Q
February 05, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended December 31, 2015

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-09585

ABIOMED, INC.

(Exact name of registrant as specified in its charter)

DELAWARE 04-2743260
(State or other jurisdiction of (IRS Employer

incorporation or organization) 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)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is, a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of January 31, 2016, 42,437,354 shares of the registrant's common stock, \$.01 par value, were outstanding.

ABIOMED, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

	Page
<u>PART I - FINANCIAL INFORMATION:</u>	
Item 1. <u>Condensed Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets as of December 31, 2015 and March 31, 2015</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended December 31, 2015 and 2014</u>	4
<u>Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended December 31, 2015 and 2014</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended December 31, 2015 and 2014</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
Item 4. <u>Controls and Procedures</u>	28
<u>PART II - OTHER INFORMATION:</u>	
Item 1. <u>Legal Proceedings</u>	30
Item 1A. <u>Risk Factors</u>	30
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
Item 3. <u>Defaults Upon Senior Securities</u>	31
Item 4. <u>Mine Safety Disclosures</u>	31
Item 5. <u>Other Information</u>	31
Item 6. <u>Exhibits</u>	32
<u>SIGNATURES</u>	34

NOTE REGARDING COMPANY REFERENCES

Throughout this report on Form 10-Q (the “Report”), “Abiomed, Inc.,” the “Company,” “we,” “us” and “our” refer to ABIOMED, Inc. and its consolidated subsidiaries.

NOTE REGARDING TRADEMARKS

ABIOMED, ABIOCOR, IMPELLA, IMPELLA CP, IMPELLA RP and Symphony are trademarks of ABIOMED, Inc., and are registered in the U.S. and certain foreign countries. BVS is a trademark of ABIOMED, Inc. and is registered in the U.S. AB5000, IMPELLA 2.5, IMPELLA 5.0, and IMPELLA LD are trademarks of ABIOMED, Inc. RECOVER is a trademark of Abiomed Europe GmbH, a subsidiary of ABIOMED, Inc., and is registered in certain foreign countries.

PART 1. FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS
ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except share data)

	December 31, 2015	March 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$53,226	\$22,401
Short-term marketable securities	142,968	109,557
Accounts receivable, net	36,842	31,828
Inventories	25,535	16,774
Prepaid expenses and other current assets	4,115	4,479
Deferred tax assets, net	19,059	35,100
Total current assets	281,745	220,139
Long-term marketable securities	—	13,996
Property and equipment, net	15,020	9,127
Goodwill	31,697	31,534
In-process research and development	14,786	14,711
Long-term deferred tax assets, net	43,956	45,206
Other assets	4,422	3,654
Total assets	\$391,626	\$338,367
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$8,836	\$10,389
Accrued expenses	21,921	21,894
Deferred revenue	6,913	7,036
Total current liabilities	37,670	39,319
Other long-term liabilities	236	183
Contingent consideration	7,392	6,510
Long-term deferred tax liabilities	799	795
Total liabilities	46,097	46,807
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value	—	—
Authorized - 1,000,000 shares; Issued and outstanding - none		
Common stock, \$.01 par value	424	413
Authorized - 100,000,000 shares; Issued - 43,777,675 shares at December 31, 2015		

and 42,618,717 shares at March 31, 2015;

Outstanding - 42,437,354 shares at December 31, 2015 and 41,335,773

shares at March 31, 2015		
Additional paid in capital	495,991	465,046
Accumulated deficit	(110,073)	(137,222)
Treasury stock at cost - 1,340,321 shares at December 31, 2015 and 1,282,944		
shares at March 31, 2015	(23,255)	(19,347)
Accumulated other comprehensive loss	(17,558)	(17,330)
Total stockholders' equity	345,529	291,560
Total liabilities and stockholders' equity	\$391,626	\$338,367

The accompanying notes are an integral part of the condensed consolidated financial statements (unaudited)

ABIOMED, INC. AND SUBSIDIARIES

CONDENSED 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,	
	2015	2014	2015	2014
Revenue:				
Product revenue	\$ 85,789	\$ 61,966	\$ 235,569	\$ 162,400
Funded research and development	6	39	17	354
	85,795	62,005	235,586	162,754
Costs and expenses:				
Cost of product revenue	12,744	9,838	35,756	29,139
Research and development	13,755	8,365	35,534	26,120
Selling, general and administrative	41,853	30,139	119,005	91,192
	68,352	48,342	190,295	146,451
Income from operations	17,443	13,663	45,291	16,303
Other income:				
Investment income, net	84	48	209	128
Other (loss) income, net	(29)	(10)	111	(38)
	55	38	320	90
Income before income taxes	17,498	13,701	45,611	16,393
Income tax provision	6,943	1,017	18,462	1,579
Net income	\$ 10,555	\$ 12,684	\$ 27,149	\$ 14,814
Basic net income per share	\$ 0.25	\$ 0.31	\$ 0.64	\$ 0.37
Basic weighted average shares outstanding	42,427	40,856	42,118	40,456
Diluted net income per share	\$ 0.23	\$ 0.30	\$ 0.61	\$ 0.35
Diluted weighted average shares outstanding	44,949	42,884	44,805	42,345

The accompanying notes are an integral part of the condensed consolidated financial statements (unaudited)

ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(in thousands)

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2015	2014	2015	2014
Net income	\$10,555	\$12,684	\$27,149	\$14,814
Other comprehensive (loss) income:				
Foreign currency translation losses	(2,520)	(2,944)	(212)	(8,184)
Net unrealized losses on marketable securities	(32)	(23)	(16)	(18)
Other comprehensive loss	(2,552)	(2,967)	(228)	(8,202)
Comprehensive income	\$8,003	\$9,717	\$26,921	\$6,612

The accompanying notes are an integral part of the condensed consolidated financial statements (unaudited)

ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	For the Nine Months Ended December 31,	
	2015	2014
Operating activities:		
Net income	\$27,149	\$14,814
Adjustments required to reconcile net income to net cash provided by		
operating activities:		
Depreciation and amortization	2,214	1,796
Bad debt expense	78	43
Stock-based compensation	21,731	12,696
Write-down of inventory	1,356	1,135
Excess tax benefit from stock-based awards	(488)	—
Deferred tax provision	17,382	675
Change in fair value of contingent consideration	882	365
Changes in assets and liabilities:		
Accounts receivable	(5,084)	(4,320)
Inventories	(10,092)	(3,582)
Prepaid expenses and other assets	343	(180)
Accounts payable	(1,740)	368
Accrued expenses and other liabilities	632	(639)
Deferred revenue	(125)	1,856
Net cash provided by operating activities	54,238	25,027
Investing activities:		
Purchases of marketable securities	(189,595)	(72,411)
Proceeds from the sale and maturity of marketable securities	170,195	57,890
Acquisition of ECP and AIS, net of cash assumed	—	(15,697)
Purchase of other investment	(750)	(1,250)
Purchases of property and equipment	(7,933)	(2,232)
Net cash used for investing activities	(28,083)	(33,700)
Financing activities:		
Proceeds from the exercise of stock options	8,237	8,624
Excess tax benefit from stock-based awards	488	—
Taxes paid related to net share settlement of vesting of stock awards	(3,908)	(1,013)
Proceeds from the issuance of stock under employee stock purchase plan	451	397
Net cash provided by financing activities	5,268	8,008
Effect of exchange rate changes on cash	(598)	(773)
Net increase (decrease) in cash and cash equivalents	30,825	(1,438)
Cash and cash equivalents at beginning of period	22,401	20,916
Cash and cash equivalents at end of period	\$53,226	\$19,478
Supplemental disclosure of cash flow information:		

Cash paid for income taxes	\$724	\$1,090
Supplemental disclosure of non-cash investing and financing activities:		
Contingent consideration related to acquisition of ECP	—	6,000
Property and equipment in accounts payable and accrued expenses	471	501

The accompanying notes are an integral part of the condensed consolidated financial statements (unaudited)

ABIOMED, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

(In thousands, except share data)

Note 1. Nature of Business and Basis of Preparation

Abiomed, Inc. (the “Company”) is a provider of mechanical circulatory support devices and offers a continuum of care to heart failure patients. The Company develops, manufactures and markets proprietary products that are designed to enable the heart to rest, heal and recover by improving blood flow and/or performing the pumping function of the heart. The Company’s products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists and in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophylactically or emergently before, during or after angioplasty or heart surgery procedures.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial reporting and in accordance with Article 10 of Regulation S-X. Accordingly, they do not include all of the information and note disclosures required by GAAP for complete financial statements. These statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended March 31, 2015 that has been filed with the Securities and Exchange Commission (the “SEC”).

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which are of a normal recurring nature and are necessary for a fair presentation of results for the interim periods presented. The results of operations for any interim period may not be indicative of results for the full fiscal year or any other subsequent period.

There have been no changes in the Company’s significant accounting policies for the three and nine months ended December 31, 2015 as compared to the significant accounting policies described in the Company’s Annual Report on Form 10-K for the fiscal year ended March 31, 2015 that has been filed with the SEC.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers to provide updated guidance on revenue recognition. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under today’s guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 will become effective for the Company beginning in fiscal 2019 under either full or modified retrospective adoption, with early adoption permitted as of the original effective date of ASU 2014-09. The Company is currently evaluating the impact of adopting ASU 2014-09 on its net income, financial position, cash flows and disclosures.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory, which applies to inventory that is measured using first-in, first-out or average cost methods. Under the updated guidance, an entity should measure inventory that is within scope at the lower of cost and net realizable value, which

is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Subsequent measurement is unchanged for inventory that is measured using last-in, last-out. This ASU is effective for annual and interim periods beginning after December 15, 2016, and should be applied prospectively with early adoption permitted at the beginning of an interim or annual reporting period. The Company is currently evaluating the impact of adopting ASU 2015-11 on its condensed consolidated financial statements.

In September 2015, the FASB issued ASU 2015-16, Business Combinations (Topic 805)—Simplifying the Accounting for Measurement-Period Adjustments. The amendments in this update require that an acquirer recognizes adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this update require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. For public business entities, the amendments in this update are effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. For all other entities, the amendments in this update are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The Company is in the process of assessing the impact of the adoption of ASU 2015-16 on its financial position.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740)—Balance Sheet Classification of Deferred Taxes. This ASU requires an entity to classify deferred income tax assets and liabilities as noncurrent on the entity's classified statement of financial position. This amendment eliminates the current requirement to classify deferred tax assets and liabilities as either current or noncurrent on the entity's balance sheet. This amendment may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. If applied prospectively, the entity should disclose in the first interim and first annual period of change, the nature of and the reason for the change in accounting principle and a statement that prior periods were not retrospectively adjusted. If applied retrospectively, the entity should disclose in the first interim and first annual period of change, the nature of and reason for the change in accounting principle and quantitative information about the effects of the accounting change on prior periods. This ASU is effective for fiscal years beginning after December 15, 2016, and for interim periods within those fiscal years. Earlier application is permitted as of the beginning of an interim or annual reporting period. The Company is in the process of assessing the impact of the adoption of ASU 2015-17 on its financial position.

The FASB is currently working on amendments to existing accounting standards governing a number of areas including, but not limited to, accounting for leases. In May 2013, the FASB issued an ASU (Revised), Leases (Topic 842) (the "Exposure Draft"), which would replace the existing guidance in ASC 840— Leases ("ASC 840"). Under the Exposure Draft, among other changes in practice, a lessee's rights and obligations under most leases, including existing and new arrangements, would be recognized as assets and liabilities, respectively, on the balance sheet. Other significant provisions of the Exposure Draft include (i) defining the "lease term" to include the noncancellable period together with periods for which there is a significant economic incentive for the lessee to extend or not terminate the lease; (ii) defining the initial lease liability to be recorded on the balance sheet to contemplate only those variable lease payments that depend on an index or that are in substance "fixed"; and (iii) a dual approach for determining whether lease expense is recognized on a straight-line or accelerated basis, depending on whether the lessee is expected to consume more than an insignificant portion of the leased asset's economic benefits. In November 2015, the FASB announced the final lease standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years but the final standard has not yet been issued. This Exposure Draft will likely have an impact on the Company's consolidated financial statements. The Company is currently evaluating the impact of adopting this proposed standard and has not yet determined the impact that this proposed change in accounting standards will have on its consolidated financial statements.

Note 2. Net Income Per Share

Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing net income by the weighted average number of dilutive common shares outstanding during the period. Diluted shares outstanding are calculated by adding to the weighted average shares outstanding any potential dilutive securities outstanding for the period. Potential dilutive securities include stock options, restricted stock units, performance-based stock awards and shares to be purchased under the Company's employee stock purchase plan. In periods when a net loss is reported, all common stock equivalents are excluded from the calculation because they would have an anti-dilutive effect, meaning the loss per share would be reduced. Therefore, in periods when a loss is reported, basic and dilutive loss per share are the same. The Company's basic and diluted net income per share for the three and nine months ended December 31, 2015 and 2014 were as follows (in thousands, except per share data):

Edgar Filing: ABIOMED INC - Form 10-Q

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2015	2014	2015	2014
Basic Net Income Per Share				
Net income	\$ 10,555	\$ 12,684	\$ 27,149	\$ 14,814
Weighted average shares used in computing basic net				
income per share	42,427	40,856	42,118	40,456
Net income per share - basic	\$ 0.25	\$ 0.31	\$ 0.64	\$ 0.37

	For the Three Months Ended December 31, 2015		For the Nine Months Ended December 31, 2015	
	2015	2014	2015	2014
Diluted Net Income Per Share				
Net income	\$ 10,555	\$ 12,684	\$ 27,149	\$ 14,814
Weighted average shares used in computing basic net				
income per share	42,427	40,856	42,118	40,456
Effect of dilutive securities	2,522	2,028	2,687	1,889
Weighted average shares used in computing diluted				
net income per share	44,949	42,884	44,805	42,345
Net income per share - diluted	\$ 0.23	\$ 0.30	\$ 0.61	\$ 0.35

For the three and nine months ended December 31, 2015, approximately 14,000 and 7,000 shares, respectively, underlying out-of-the-money stock options were not included in the computation of diluted earnings per share because their effect would have been anti-dilutive. Also, approximately 226,000 restricted shares in each of the three and nine months ended December 31, 2015, related to performance-based awards for which milestones have not been met, were not included in the computation of diluted earnings per share.

For the three and nine months ended December 31, 2014, approximately 1,000 and 36,000 shares, respectively, underlying out-of-the-money stock options were not included in the computation of diluted earnings per share because their effect would have been anti-dilutive. Also, approximately 460,000 restricted shares in each of the three and nine months ended December 31, 2014 related to performance-based awards for which milestones had not been met, were not included in the computation of diluted earnings per share.

Note 3. Acquisitions

Acquisition of ECP Entwicklungsgesellschaft mbH

On July 1, 2014, the Company entered into a share purchase agreement with its wholly owned German subsidiary, Abiomed Europe GmbH (“Abiomed Europe”) and Syscore GmbH (“Syscore”), a limited liability company located in Berlin, Germany, providing for the Company’s acquisition of all of the share capital of ECP Entwicklungsgesellschaft mbH (“ECP”), a limited liability company incorporated in Germany. ECP is engaged in research, development, prototyping and the production of a percutaneous expandable catheter pump which increases blood circulation from the heart with an external drive shaft. The Company’s acquisition of ECP closed on July 1, 2014.

The Company acquired ECP for \$13.0 million in cash, with additional potential payouts totaling \$15.0 million payable to Syscore based on the achievement of certain technical, regulatory and commercial milestones. These milestone payments may be made, at the Company’s option, by a combination of cash or the Company’s common stock.

With respect to such milestone payments, the share purchase agreement provides:

- that, upon the earlier of (i) the Company's receipt of European CE Marking approval relating to the sale of an expandable device based on certain patent rights acquired from ECP, or (ii) the Company's bringing of a successful claim against a third party competitor (or reaching an economically equivalent settlement) for the infringement of certain patent rights acquired from ECP, it will pay Syscore an additional \$7.0 million (provided that if such claim or settlement does not prohibit the third party competitor's further marketing, production, sale, distribution, lease or use of any violating or infringing products, but only awards monetary damages to the Company or to Abiomed Europe, the amount payable to Syscore shall be limited to the lower of the amount of aggregate damages received and \$7.0 million); and
- that, upon the first to occur of (i) the Company's successful commercialization of one or more rotatable and expandable devices based on certain patent rights acquired from ECP, where such devices achieve aggregate worldwide revenues of \$125.0 million, including the revenues of third-party licensees, or (ii) the Company's sale of (A) ECP, (B) all or substantially all of ECP's assets, or (C) certain of ECP's patent rights, the Company will pay to Syscore the lesser of (x) one-half of the profits earned from such sale described in the foregoing item (ii), after accounting for the costs of acquiring and operating ECP, or (y) \$15.0 million (less any previous milestone payment).

ECP's Acquisition of AIS GmbH Aachen Innovative Solutions

In connection with the Company's acquisition of ECP, ECP acquired all of the share capital of AIS GmbH Aachen Innovative Solutions ("AIS"), a limited liability company incorporated in Germany, pursuant to a share purchase agreement dated as of June 30, 2014, by and among ECP and AIS's four individual shareholders. AIS, based in Aachen, Germany, holds certain intellectual property useful to ECP's business, and, prior to being acquired by ECP, had licensed such intellectual property to ECP.

The purchase price for the acquisition of AIS's share capital was approximately \$2.8 million in cash, which was provided by the Company, and the acquisition closed immediately prior to Abiomed Europe's acquisition of ECP. The share purchase agreement contains representations, warranties and closing conditions customary for transactions of its size and nature.

Purchase Price Allocation

The acquisition of ECP and AIS was accounted for as a business combination. The purchase price for the acquisition has been allocated to the assets acquired and liabilities assumed based on their estimated fair values.

The acquisition-date fair value of the consideration transferred is as follows:

	Total
	Acquisition
	Date Fair
	Value (in
	thousands)
Cash consideration	\$ 15,750
Contingent consideration	6,000
Total consideration transferred	\$ 21,750

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed on July 1, 2014, the date of acquisition (in thousands):

Acquired assets:	
Cash and cash equivalents	\$ 53
Accounts receivable	25
Property and equipment	619
In-process research and development	18,500
Goodwill	1,964
Long-term deferred tax assets	1,874
Other assets acquired	141
Total assets acquired	23,176
Liabilities assumed:	

Edgar Filing: ABIOMED INC - Form 10-Q

Accounts payable	295
Accrued liabilities	131
Long-term deferred tax liabilities	1,000
Total liabilities assumed	1,426
Net assets acquired	\$21,750

In-process research and development (“IPR&D”) is the estimated fair value of the ECP and AIS technology that had either not reached commercial technological feasibility nor had alternative future use at the time of the acquisition. Therefore, the Company considered IPR&D, with assigned values to be allocated among the various IPR&D assets acquired.

Goodwill is calculated as the difference between the acquisition-date fair value of the consideration transferred and the fair values of the assets acquired and liabilities assumed. The goodwill resulting from these acquisitions arises largely from synergies expected from combining the operations of ECP and AIS with the Company’s existing operations. The goodwill is not deductible for income tax purposes.

The following unaudited pro forma information presents the combined results of operations for the three and nine months ended December 31, 2015 and 2014, as if the Company had completed the ECP and AIS acquisitions at the beginning of fiscal 2015. The pro forma financial information is provided for comparative purposes only and is not necessarily indicative of what actual results would have been had the acquisition occurred on the date indicated, nor does it give effect to synergies, cost savings, fair market value adjustments, immaterial amortization expense and other changes expected to result from the acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period. The pro forma consolidated financial information has been calculated after applying the Company's accounting policies and includes adjustments for transaction-related costs, to eliminate revenues earned by AIS from ECP and expenses paid by ECP to AIS associated with a license agreement between the two parties, interest expense incurred by ECP related to bank loans accounted for as if the repayment of ECP debt had occurred and was not outstanding during the periods, and income tax provision of AIS due to the elimination of revenue on the license agreement with ECP.

	For the Three Months Ended December 31, 2015 2014 (in \$000's)		For the Nine Months Ended December 31, 2015 2014 (in \$000's)	
Revenue	\$85,795	\$62,005	\$235,586	\$162,766
Income before income tax provision	17,498	13,665	45,611	16,409
Net income	10,555	12,686	27,149	14,920

The Company has no material revenues and incurred \$2.8 million in net losses from July 1, 2014 through December 31, 2015 associated with the operations of ECP and AIS acquisitions.

Note 4. Marketable Securities and Fair Value Measurements

Marketable Securities

The Company's marketable securities are classified as available-for-sale securities and, accordingly, are recorded at fair value. The difference between amortized cost and fair value is included in stockholders' equity.

The Company's marketable securities at December 31, 2015 and March 31, 2015 are invested in the following:

Amortized Gross	Gross	Fair Market
-----------------	-------	----------------

Edgar Filing: ABIOMED INC - Form 10-Q

	Cost (in \$000's)	Unrealized Gains	Unrealized Losses	Value
December 31, 2015:				
US Treasury mutual fund securities	\$ 19,488	\$ —	\$ —	\$ 19,488
Short-term government-backed securities	123,499	16	(35)	123,480
	\$ 142,987	\$ 16	\$ (35)	\$ 142,968

	Amortized Cost (in \$000's)	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
March 31, 2015:				
US Treasury mutual fund securities	\$ 19,487	\$ —	\$ —	\$ 19,487
Short-term government-backed securities	90,070	9	(9)	90,070
Long-term government-backed securities	13,999	2	(5)	13,996
	\$ 123,556	\$ 11	\$ (14)	\$ 123,553

Fair Value Hierarchy

Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

Level 1 primarily consists of financial instruments whose values are based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, volatility factors, prepayment speeds, default rates, loss severity, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 is comprised of unobservable inputs that are supported by little or no market activity. Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flows, or similar techniques, and at least one significant model assumption or input is unobservable.

The following table presents the Company's financial instruments recorded at fair value in the condensed consolidated balance sheets, classified according to the three categories described above:

	Level 1	Level 2	Level 3	Total
December 31, 2015:	(in \$000's)			
Assets				
U.S. Treasury mutual fund securities	\$—	\$19,488	\$—	\$19,488
Short-term government-backed securities	—	123,480	—	123,480
Liabilities				
Contingent consideration	—	—	7,392	7,392

	Level 1	Level 2	Level 3	Total
March 31, 2015:	(in \$000's)			
Assets				
U.S. Treasury mutual fund securities	\$—	\$19,487	\$—	\$19,487
Short-term government-backed securities	—	90,070	—	90,070
Long-term government-backed securities	—	13,996	—	13,996
Liabilities				
Contingent consideration	—	—	6,510	6,510

The Company's investments in U.S. Treasury mutual fund securities, short-term government-backed securities and long-term government-backed securities are reported as Level 2 financial assets as they are not exchange-traded instruments.

The Company's financial liabilities consisted of contingent consideration potentially payable to former ECP shareholders related to the acquisition of ECP in July 2014. This liability is reported as Level 3 as the estimated fair value of the contingent consideration related to the acquisition of the ECP requires significant management judgment or estimation and is calculated using the income approach, using various revenue and cost assumptions and applying a probability to each outcome.

Edgar Filing: ABIOMED INC - Form 10-Q

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the contingent consideration for the nine months ended December 31, 2015:

	For the Three Months Ended December 31, 2015 2014 (in \$000's)		For the Nine Months Ended December 31, 2015 2014 (in \$000's)	
Level 3 liabilities, beginning balance	\$6,817	\$5,797	\$6,510	\$—
Additions	—	—	—	6,000
Payments	—	—	—	—
Change in fair value	575	568	882	365
Level 3 liabilities, ending balance	\$7,392	\$6,365	\$7,392	\$6,365

The change in fair value of the contingent consideration was due to an increase in fair value caused by the effect of the passage of time on the fair value measurement of milestones related to the ECP acquisition and continued progress on the development of the underlying technology. Adjustments associated with the change in fair value of contingent consideration are included in research and development expenses on the Company's condensed consolidated statements of operations.

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements as of December 31, 2015 classified as Level 3:

	Fair Value at December 31, 2015 (in \$000's)	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent consideration	\$ 7,392	Probability weighted income approach	Milestone dates	2018 to 2021
			Discount rate	8% to 12%
			Probability of occurrence	Probability adjusted level
				of 40% for the base case
				scenario and 5% to 30%
				for various upside and
				downside scenarios

Other Investments

The Company periodically makes investments in private medical device companies that focus on heart failure and heart pump technologies. In July 2015, the Company invested \$0.8 million for its participation in a preferred stock offering of a private medical technology company. The aggregate carrying amount of the Company's other investments was \$4.4 million and \$3.6 million at each of December 31, 2015 and March 31, 2015, respectively, and is classified within other assets in the unaudited condensed consolidated balance sheets. These investments are accounted for using the cost method and are measured at fair value only if there are identified events or changes in circumstances that may have a significant adverse effect on the fair value of these investments.

Note 5. Inventories

The components of inventories are as follows:

	December 31, 2015	March 31, 2015
	(in \$000's)	
Raw materials and supplies	\$8,894	\$7,417
Work-in-progress	10,427	6,466
Finished goods	6,214	2,891
	\$25,535	\$16,774

The Company's inventories relate to its circulatory care product lines, primarily its Impella® heart pump product platforms. Finished goods and work-in-process inventories consist of direct material, labor and overhead. During the three and nine months ended December 31, 2015, the Company recorded \$0.4 million and \$1.4 million, respectively, in write-downs of inventory. During the three and nine months ended December 31, 2014, the Company recorded \$0.6 million and \$1.1 million, respectively, in write-downs of inventory.

Note 6. Goodwill and In-Process Research and Development

Goodwill

The carrying amount of goodwill at December 31, 2015 and March 31, 2015 was \$31.7 million and \$31.5 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG ("Impella Cardiosystems"), in May 2005 and ECP and AIS in July 2014. The goodwill activity is as follows:

	(in \$000's)
Balance at March 31, 2015	\$31,534
Foreign currency translation impact	163
Balance at December 31, 2015	\$31,697

The Company evaluates goodwill and IPR&D assets at least annually at October 31, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. The Company has no accumulated impairment losses on goodwill or IPR&D assets.

As described in Note 3 "Acquisitions," the Company acquired ECP and AIS in July 2014 and recorded \$18.5 million of IPR&D assets. The estimated fair value of IPR&D assets at the acquisition date was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows from the expandable catheter pump technology were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 22.5% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

The carrying value of the Company's IPR&D assets and the change in the balance for the nine months ended December 31, 2015 are as follows:

	(in \$000's)
Balance at March 31, 2015	\$14,711
Foreign currency translation impact	75
Balance at December 31, 2015	\$14,786

Note 7. Accrued Expenses

Accrued expenses consist of the following:

Edgar Filing: ABIOMED INC - Form 10-Q

	December 31, 2015	March 31, 2015
	(in \$000's)	
Employee compensation	\$ 14,484	\$ 15,978
Research and development	2,495	1,744
Sales and income taxes	1,324	1,506
Professional, legal and accounting fees	1,155	710
Warranty	639	1,103
Other	1,824	853
	\$ 21,921	\$ 21,894

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at December 31, 2015 and March 31, 2015.

Note 8. Stock-Based Compensation

The following table summarizes stock-based compensation expense by financial statement line item in the Company's condensed consolidated statements of operations for the three and nine months ended December 31, 2015 and 2014:

	For the Three Months Ended December 31, 2015 2014 (in \$000's)		For the Nine Months Ended December 31, 2015 2014 (in \$000's)	
Cost of product revenue	\$216	\$160	\$671	\$517
Research and development	994	840	2,914	2,466
Selling, general and administrative	4,929	3,382	18,146	9,713
	\$6,139	\$4,382	\$21,731	\$12,696

The components of stock-based compensation for the three and nine months ended December 31, 2015 and 2014 were as follows:

	For the Three Months Ended December 31, 2015 2014 (in \$000's)		For the Nine Months Ended December 31, 2015 2014 (in \$000's)	
Restricted stock units	\$5,133	\$3,640	\$17,482	\$10,394
Stock options	909	666	3,955	2,089
Employee stock purchase plan	97	76	294	213
	\$6,139	\$4,382	\$21,731	\$12,696

The Company's former Chief Financial Officer retired effective July 31, 2015 and currently serves as a consultant to the Company through July 31, 2017. In connection with the former Chief Financial Officer's retirement agreement, his unvested options and restricted stock units were modified such that they will continue to vest and he will be permitted to exercise any vested options until July 31, 2017, including any options that vest after his retirement date, other than such options that expire on the tenth anniversary of the grant date. The Company recorded costs of \$2.5 million in stock compensation expense, which is recorded in selling, general and administrative expenses for the nine months ended December 31, 2015.

In June 2015, the Company's Board of Directors adopted a non-employee director retirement policy that provides for the accelerated vesting of all stock options, restricted stock units and other equity awards held by a non-employee director if he or she permanently ceases his or her service on the Company's Board of Directors by reason of death, disability, or the non-employee director's retirement following at least five years of service and so long as his or her age plus service equals or exceeds 65. This retirement policy accelerated the recognition of stock-based compensation because the outstanding unvested restricted stock units held by retirement eligible non-employee directors are able to vest at their decision to retire. The Company recorded costs of \$1.4 million in accelerated stock compensation expense, which is recorded in selling, general and administrative expenses for the nine months ended December 31, 2015.

In August 2015, the Company approved the annual equity award grant to non-employee directors in the form of restricted stock units covering 3,900 shares of the Company's common stock, which vest on the earlier of: (a) the one year anniversary of the grant date; or (b) the next annual meeting of stockholders. In conjunction with the Company's non-employee director retirement policy, the stock compensation expense for awards to retirement eligible non-employee directors was fully recognized upon grant. The Company recorded costs of \$2.0 million in stock compensation expense, which is recorded in selling, general and administrative expenses for the nine months ended December 31, 2015.

Stock Options

The following table summarizes the stock option activity for the nine months ended December 31, 2015:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at beginning of period	2,892	\$ 14.72	5.18	
Granted	164	71.15		
Exercised	(721)	11.42		
Cancelled and expired	(2)	13.81		
Outstanding at end of period	2,333	\$ 19.71	5.35	\$ 164,775
Exercisable at end of period	1,690	\$ 13.83	4.27	\$ 129,224
Options vested and expected to vest at end of period	2,273	\$ 19.33	5.27	\$ 161,336

The aggregate intrinsic value of options exercised was \$50.7 million for the nine months ended December 31, 2015. The total fair value of options that vested during the nine months ended December 31, 2015 was \$2.5 million.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at December 31, 2015 was approximately \$6.3 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 2.4 years.

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model. The weighted average grant-date fair values and weighted average assumptions used in the calculation of fair value of options granted during the three and nine months ended December 31, 2015 and 2014 was as follows:

	For the Three Months Ended December 31, 2015		For the Nine Months Ended December 31, 2014	
Weighted average grant-date fair value	\$34.05	\$15.36	\$28.91	\$9.18
Valuation assumptions:				
Risk-free interest rate	1.50 %	1.70 %	1.60 %	1.60 %
Expected option life (years)	4.15	4.17	4.14	4.19
Expected volatility	49.6 %	49.7 %	49.7 %	49.3 %

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on the historical volatility of the Company's stock and adjustments for factors not reflected in historical volatility that may be more indicative of future volatility. The Company estimates the expected term of options based on historical exercise experience and

estimates of future exercises of unexercised options. An expected dividend yield of zero is used in the option valuation model because the Company does not pay cash dividends and does not expect to pay any cash dividends in the foreseeable future. The Company estimates forfeitures based on an analysis of actual historical forfeitures, adjusted to the extent historic forfeitures may not be indicative of forfeitures in the future.

Restricted Stock and Restricted Stock Units

The following table summarizes the activity of restricted stock and restricted stock units for the nine months ended December 31, 2015:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value (per share)
Restricted stock and restricted stock units at beginning of period	1,160	\$ 21.90
Granted	679	\$ 87.95
Vested	(465)	) \$ 22.65
Forfeited	(45)	) \$ 15.44
Restricted stock and restricted stock units at end of period	1,329	\$ 55.61

The weighted average grant-date fair value for restricted stock units granted, including performance and market-based awards, during the nine months ended December 31, 2015 and 2014 was \$87.95 and \$22.07 per share, respectively. This includes 322,980 market based awards which were valued at \$107.10 per share based on a Monte Carlo simulation that was used to account for the market condition in valuing the award. See details below in “Market Based Awards”.

The total fair value of restricted stock units that vested during the nine months ended December 31, 2015 and 2014 was \$10.3 million and \$9.5 million, respectively. The remaining unrecognized compensation expense for outstanding restricted stock units, including performance and market-based awards, as of December 31, 2015 was \$33.9 million and the weighted-average period over which this cost will be recognized is 2.4 years.

Performance and Market-Based Awards

Included in the restricted stock units activity are certain awards that vest subject to certain performance and market-based criteria. The remaining unrecognized compensation expense for outstanding performance and market-based restricted stock units as of December 31, 2015 was \$23.2 million and the weighted-average period over which this cost will be recognized is 2.4 years.

Performance-Based Awards

In May 2015, performance-based awards of restricted stock units for the potential issuance of 183,940 shares of common stock were issued to certain executive officers and employees, all of which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of December 31, 2015, the Company is recognizing compensation expense based on the probable outcome related to the prescribed

performance targets on the outstanding awards.

In May 2014, performance-based awards of restricted stock units for the potential issuance of 379,752 shares of common stock were issued to certain executive officers and employees, all of which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. The Company met the prescribed performance milestones in fiscal 2015. As of December 31, 2015, approximately 200,000 shares of common stock underlying restricted stock units remain unvested and such restricted stock units will vest subject to service requirements for vesting for these employees.

In May 2013, performance-based awards of restricted stock units for the potential issuance of 268,988 shares of common stock were issued to certain executive officers and employees, all of which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. The Company met the prescribed performance milestones in fiscal 2014. As of December 31, 2015, approximately 70,000 shares of common stock underlying restricted stock units remain unvested and such restricted stock units will vest subject to service requirements for vesting for these employees.

In June 2011, performance-based awards of restricted stock units for the potential issuance of 100,000 shares of common stock was issued to a certain senior executive officer of the Company that would vest upon achievement of prescribed service milestones by the award recipient and performance milestones by the Company. As of December 31, 2015, the Company has met the prescribed milestones for 50,000 shares of this award. The Company modified the performance condition on the 50,000 remaining restricted stock units that were related to this performance award in March 2014 and December 2015, all of which will vest upon achievement of a prescribed service milestone by the award recipients and a performance milestone by the Company. The Company recorded \$0.5 million in stock compensation expense related to this accounting modification, which is recorded in selling, general and administrative expenses for the three and nine months ended December 31, 2015. The Company believes that it is probable that the prescribed performance milestones will be met and the compensation expense is being recognized accordingly.

Market-Based Awards

In June 2015, the Company awarded certain executive officers a total of up to 322,980 market-based restricted share units. These restricted stock units will vest and result in the issuance of common stock based on continuing employment and the relative ranking of the total shareholder return (“TSR”) of the Company’s common stock in relation to the TSR of the component companies in the S&P Health Care Equipment Select Industry Index over a three-year performance period based on a comparison of average closing stock prices between June 2015 and June 2018. The actual number of market-based restricted stock units that may be earned can range from 0% to 300% of the target number of shares. One-half of the market-based restricted stock units earned will vest in June 2018 and the remaining restricted stock units will vest one year thereafter.

The Company used a Monte Carlo simulation model to estimate that the grant-date fair value of the restricted stock units. The fair value related to the restricted stock units will be recorded as stock compensation expense over the period from date of grant to June 2019 regardless of the actual TSR outcome achieved.

The table below sets forth the assumptions used to value the awards and the estimated grant-date fair value:

Risk-free interest rate	1.10	%
Dividend yield	0	%
Remaining performance period (years)	2.45	
Expected volatility	47.2	%
Estimated grant date fair value (per share)	\$ 107.10	
Target performance (number of shares)	107,660	

Note 9. Income Taxes

The income tax provision represents the Company’s federal and state income tax obligations as well as foreign tax provisions. The Company’s income tax provision was \$6.9 million and \$18.5 million for the three and nine months ended December 31, 2015, respectively. The Company’s income tax provision was \$1.0 million and \$1.6 million for the three and nine months ended December 31, 2014, respectively. The estimated annual effective income tax rate is based upon estimated income before income taxes for the year, the geographical composition of the estimated income before taxes and estimated permanent differences. The estimated annual effective income tax rate can fluctuate and may differ from the actual tax rate recognized in fiscal 2016 for various reasons, including estimates of income before taxes, tax legislation, permanent differences, discrete items, and any adjustments between tax provision calculations and filed tax returns.

The significant differences between the statutory tax rate and effective tax rate for the three and nine months ended December 31, 2015 and 2014 were as follows:

	For the Three Months Ended December 31, 2015		For the Nine Months Ended December 31, 2014	
	2015	2014	2015	2014
Statutory income tax rate	35.0 %	34.0 %	35.0 %	34.0 %

Edgar Filing: ABIOMED INC - Form 10-Q

Increase (decrease) resulting from:

Losses not benefited	—	(26.6)	—	(24.4)
Credits	(1.7)	—	(1.5)	—
State taxes, net	3.2	—	3.4	—
Permanent differences	3.2	—	3.4	—
Other	—	—	0.2	—
Effective tax rate	39.7 %	7.4 %	40.5 %	9.6 %

The Company and its subsidiaries are subject to U.S. federal income tax, as well as income tax in multiple states and Germany. All tax years remain subject to examination by the Internal Revenue Service and state and foreign tax authorities. The Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, and those years may also be subject to review by relevant taxing authorities if the carryforwards are utilized. Fiscal years 2012 through 2015 remain open to examination in Germany.

Note 10. Commitments and Contingencies

Commitments

The Company's headquarters is located at 22 Cherry Hill Drive in Danvers, Massachusetts and consists of approximately 120,500 square feet of space under an operating lease.

The monthly lease payments over the remaining term of the lease are as follows:

- The base rent for May 2014 through December 2015 was \$74,050 per month; and
- The base rent for January 2016 through February 2016 will be \$85,818 per month; and
- The base rent for March 2016 through February 2018 will be \$82,518 per month; and
- The base rent for March 2018 through February 2021 will be \$85,030 per month.

This facility encompasses most of the Company's U.S. operations, including research and development, manufacturing, sales and marketing and general and administrative departments. On December 9, 2015, the Company entered into a purchase and sale agreement (the "P&S Agreement") to acquire its existing corporate headquarters space. Pursuant to the P&S Agreement, the Company will, among other things and subject to closing conditions, acquire the real estate commonly known as 18-22 Cherry Hill Drive, located in Danvers, Massachusetts. Subject to the terms and conditions of the P&S Agreement, the purchase price of the property will be \$16.5 million. On January 19, 2016, the Company entered into an amendment of the P&S Agreement to extend the due diligence period until April 19, 2016. The Company expects to close the transaction in April 2016.

The Company's European headquarters is located in Aachen, Germany and consists of approximately 33,000 square feet of space under an operating lease. In July 2013, the Company entered into a lease agreement to continue renting its existing space in Aachen, Germany through July 31, 2023. In October 2015, the Company entered into an amendment to this lease agreement to lease 9,000 square feet of additional space effective July 1, 2015. The Company also entered into another lease agreement in October 2015 to lease approximately 30,000 square feet of additional space adjacent to its Aachen facility from July 1, 2015 through June 30, 2016. This agreement also provided the Company with options to extend the lease through July 31, 2033. The lease payments under these agreements are approximately 64,500€ (euro) (approximately U.S. \$70,000 at December 31, 2015 exchange rates) per month. The building houses most of the manufacturing operations for the Impella product lines as well as certain research and development functions and the sales, marketing and general and administrative functions for most of its product lines sold in Europe and the Middle East.

License Agreements

In April 2014, the Company entered into an exclusive license agreement with Opsens, Inc. for the rights to certain optical sensor technologies in the field of cardio-circulatory assist devices. The Company made a \$1.5 million upfront payment upon execution of the agreement and could make additional payments of up to \$4.5 million upon the achievement of certain development milestones.

In November 2015, the Company entered into an exclusive license agreement for the rights to certain vascular closure device technologies. The Company made a \$0.5 million upfront payment upon execution of the agreement and a milestone payment of \$0.6 million in December 2015. The Company could make additional payments of up to \$2.8 million upon the achievement of certain development milestones.

Litigation

From time to time, the Company is involved in legal and administrative proceedings and claims of various types. In some actions, the claimants seek damages, as well as other relief, which, if granted, would require significant expenditures. The Company records a liability in its condensed consolidated financial statements for these matters

when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in its condensed consolidated financial statements.

On October 26, 2012, the Company was informed that the Department of Justice, United States Attorney's Office for the District of Columbia was conducting an investigation ("Marketing and Labeling Investigation") focused on the Company's marketing and labeling of the Impella 2.5™ heart pump. On October 31, 2012, the Company accepted service of a subpoena related to this investigation seeking documents and other materials related to the Impella 2.5. The Company cooperated fully with the Marketing and Labeling Investigation, and on June 29, 2015, the Company received confirmation that the Department of Justice had closed the Marketing and Labeling Investigation without taking enforcement action.

On April 25, 2014, the Company received a subpoena from the Boston regional office of the United States Department of Health and Human Services, or HHS, Office of Inspector General requesting materials relevant to the Company's reimbursement of expenses and remuneration to healthcare providers for a six month period from July 2012 through December 2012 in connection with a civil investigation under the False Claims Act (the "FCA Investigation"). The Company submitted the requested documents to HHS and believes that it substantially complied with the subpoena. On November 6, 2014, the Company received notice from the Department of Justice, United States Attorney's Office for the District of Massachusetts in the form of a Civil Investigative Demand ("CID") requesting additional materials relating to this matter for the time period of January 1, 2012 through December 31, 2013. The Company is currently in the process of responding to the additional requests for information contained in the CID, and other informal requests, and intends to continue to cooperate with the U.S. Attorney's Office in connection with the FCA Investigation.

In July and August 2015, Thoratec Corporation ("Thoratec"), acquired by St. Jude Medical, Inc. in October 2015, brought actions in connection with two Company patents relevant to Thoratec's HeartMate PHP medical device ("PHP"). In those proceedings, which are in the United Kingdom and Germany, Thoratec asserts that the two patents are invalid. In September 2015, the Company filed counterclaims in the action in Germany asserting that the PHP product infringes the two patents and a third patent owned by the Company. Both the Germany and United Kingdom proceedings are ongoing.

The Company is unable to estimate a potential liability with respect to the legal matters noted above. There are numerous factors that make it difficult to meaningfully estimate possible loss or range of loss at this stage of the legal proceedings, including that the FCA Investigation and patent dispute with Thoratec remain in relatively early stages, there are significant factual and legal issues to be resolved and information obtained or rulings made during any potential lawsuits or investigations could affect the methodology for calculation. Therefore, the Company is unable at this time to estimate a possible loss or range of possible loss, and no adjustment has been made to the financial statements to reflect the outcome of these uncertainties.

Note 11. Segment and Enterprise Wide Disclosures

The Company operates in one business segment—the research, development and sale of medical devices to assist or replace the pumping function of the failing heart. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results. Approximately 79% and 77% of the Company's total consolidated assets were located within the U.S. as of December 31, 2015 and March 31, 2015, respectively. The remaining assets were located primarily in Germany and included goodwill and IPR&D assets of \$46.5 million and \$46.2 million at December 31, 2015 and March 31, 2015, respectively, associated with the Impella Cardiosystems acquisition in May 2005 and the ECP acquisition in July 2014. Total assets outside of the U.S. excluding goodwill and IPR&D assets amounted to 9% and 10% of total consolidated assets as of December 31, 2015 and March 31, 2015, respectively. International sales (primarily in Europe) accounted for 8% of total revenue for each of the three and nine months ended December 31, 2015, and 9% and 10% of total revenue for the three and nine months ended December 31, 2014, respectively.

ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward Looking Statements

This Report may contain “forward looking” statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. 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 address various matters including, among others, future actions related to ongoing investigations and expenditures related thereto; our expectations with respect to submissions to and approvals from regulatory bodies, such as the FDA, including our expectation that the Impella CP®, Impella 5.0® and Impella LD® devices will retain their 510(k) clearances until completion of the FDA review process of our Pre-Market Approval (“PMA”) supplemental submissions for those devices, the expectation that the PMA supplements will receive regulatory approval by the FDA in the summer of 2016 and the expectation that the application for the Impella 2.5 in Japan will receive regulatory approval during calendar 2016; the development and commercialization of new and existing products and anticipated costs, including research and development, sales and marketing and training costs associated with product development and commercialization; expected capital expenditures for the fiscal year ending March 31, 2016; commercial plans for our products into new markets such as Japan; demand and expected shipments of our products; anticipated shifts in the revenue mix associated with our products; and our ability to increase revenues from our Impella line of products and the sufficiency of revenues to fund future operations. Each forward-looking statement in this Report is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, our inability to predict the outcome of investigations and litigation and associated expenses; possible delays in our research and development programs; our ability to obtain regulatory approvals and market our products, and uncertainties related to regulatory processes; greater government scrutiny and regulation of the medical device industry and our ability to respond to changing laws and regulations affecting our industry, including any reforms to the regulatory approval process administered by the FDA, including the 510(k) process and 515 Program Initiative, and changing enforcement practices related thereto; the inability to manufacture products in commercial quantities at an acceptable cost; the acceptance by physicians and hospitals of our products; the impact of competitive products and pricing; uncertainties associated with future capital needs and the risks identified under Item 1A of Part I of our Annual Report on Form 10-K, for the year ended March 31, 2015, as well as the other information we file with the Securities and Exchange Commission. Readers are cautioned not to place considerable reliance on any forward-looking statements contained in this Report, which speak only as of the date of this Report. We undertake no obligation to update or revise these forward-looking statements whether as a result of new information, future events or otherwise, unless required by law. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

Overview

We are a leading provider of temporary percutaneous mechanical circulatory support devices and we offer a continuum of care to heart failure patients. We develop, manufacture and market proprietary products that are designed to enable the heart to rest, heal and recover by improving blood flow to the coronary arteries and end-organs and/or temporarily performing the pumping function of the heart. Our products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists, the electrophysiology lab, the hybrid lab and in the heart surgery suite by heart surgeons. A physician may use our devices for patients who are in need of hemodynamic support prophylactically or emergently before, during or after angioplasty or heart surgery procedures. We believe heart recovery is the optimal clinical outcome for patients experiencing heart failure because it enables patients to go home with their own native heart and restores their quality of life. In addition, we believe that for the care of such patients, heart recovery is the most cost-effective solution for the healthcare system.

Our strategic focus and the driver of the majority of our revenue growth is the market penetration of our family of Impella products. Revenues from our non-Impella products, largely focused on the heart surgery suite, have been lower over the past several years as we have strategically shifted our sales and marketing efforts towards our Impella products and the cath lab. We expect that most of our product and service revenues in the near future will be from our Impella products.

The Impella product portfolio, which includes the Impella 2.5™, Impella CP®, Impella RP®, Impella LD™ and Impella 5.0™, has supported over 25,000 patients in the U.S. Our Impella 2.5, Impella 5.0, Impella LD, Impella CP and Impella RP products also have CE Mark approval and Health Canada approval which allows us to market these devices in the European Union and Canada. We have submitted an application for the Impella 2.5 in Japan and we are hopeful of receiving regulatory approval in calendar 2016.

In July 2014, we acquired all of the issued shares of ECP, a German limited liability company, for \$13.0 million in cash, with additional potential payments up to a maximum of \$15.0 million based on the achievement of certain technical, regulatory and commercial milestones. ECP, based in Berlin, Germany, is engaged in research, development, prototyping and the pre-serial production of a percutaneous expandable catheter pump which increases blood circulation from the heart with an external drive shaft. In connection with our acquisition of ECP, ECP acquired all of the issued shares of AIS, a German limited liability company, for \$2.8 million in cash which was provided by us. AIS, based in Aachen, Germany, holds certain intellectual property useful to ECP's business, and, prior to being acquired by ECP, had licensed such intellectual property to ECP.

Our Products

Impella 2.5™

The Impella 2.5 catheter is a percutaneous micro heart pump with an integrated motor and sensors. The device is designed primarily for use by interventional cardiologists to support patients in the cath lab who may require assistance to maintain their circulation. The Impella 2.5 catheter can be quickly inserted via the femoral artery to reach the left ventricle of the heart where it is directly deployed to draw blood out of the ventricle and deliver it to the circulatory system. This function is intended to reduce ventricular work and provide flow to vital organs. The Impella 2.5 is introduced with normal interventional cardiology procedures and can pump up to 2.5 liters of blood per minute.

The Impella 2.5 product received 510(k) clearance in June 2008 from the FDA for partial circulatory support for up to six hours. In March 2015, we received PMA from the FDA for Impella 2.5 during elective and urgent high-risk PCI procedures. Impella 2.5 is the first hemodynamic support device to receive a PMA indication for use during high-risk PCI procedures, demonstrating its safety and effectiveness for this complex patient population. With this approval, the Impella 2.5 is a temporary (up to six hours) ventricular support device indicated for use during high-risk PCI performed in elective or urgent hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 in these patients may prevent hemodynamic instability that may occur during planned temporary coronary occlusions and may reduce periprocedural and post-procedural adverse events. The product labeling allows for the clinical decision to leave Impella 2.5 in place beyond the intended duration of up to six hours due to unforeseen circumstances. Per our PMA approval, we will conduct a single-arm, post-approval study on the Impella 2.5, collecting data on high-risk PCI patients. The study will be a prospective, multi-center study comprised of 369 patients from 70 sites supported with the Impella 2.5 system. The Impella 2.5 device has CE mark approval in Europe for up to five days of use and is approved for use in over 40 countries.

In August 2015, we submitted the PMA supplement submissions requesting to expand our current Impella 2.5 PMA approval for additional indications for Impella 2.5 and for most of our other Impella devices (Impella CP, Impella 5.0 and Impella LD). The submissions are for a set of indications related to the use of the Impella devices in patients suffering cardiogenic shock following acute myocardial infarction or cardiac surgery and for a longer duration of support. We anticipate receiving regulatory approval on the PMA supplements from the FDA in the summer of 2016.

A November 2011 update to the American College of Cardiology Foundation, or ACCF, / American Heart Association, or AHA, Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions Guidelines for Percutaneous Coronary Intervention, for the first time, included Impella devices in both the emergent and prophylactic hemodynamic support settings. In addition, a December 2012 update to the AHA's Recommendations for the Use of Mechanical Circulatory Support: Device Strategies and Patient Selection recommended Impella devices for use in mechanical circulatory support; a December 2012 update to the ACCF/AHA Guidelines for the Management of ST-Elevation Myocardial Infarction (STEMI) included Impella 2.5 for use in patients requiring urgent coronary artery bypass grafting with STEMI and in treatment of patients with cardiogenic shock complications after STEMI; and a January 2013 update to the International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support included Impella devices for the first time for patients with multi-organ failure. In addition, Impella devices were included in a January 2013 update to the ACCF /AHA Task Force on Practice Guidelines for the Management of ST-Elevation Myocardial Infarction and a September 2014 AHA /the American College of Cardiology (ACC) Task Force on Practice Guidelines for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes.

In addition to the U.S. clinical trial data, the Impella 2.5 PMA submission included clinical and scientific supporting evidence from more than 215 publications, covering 1,638 Impella 2.5 patients and incorporated a medical device reporting (MDR) analysis from 13,981 Impella 2.5 patients. In addition to PROTECT I and PROTECT II, further data was provided in the submission from 637 high-risk patients enrolled in the U.S. Impella Registry or cVAD

Registry™. The cVAD Registry™ is an ongoing multicenter, observational retrospective registry that includes 49 centers that collect data on the Impella 2.5, Impella 5.0 and Impella CP. The data collection from the registry includes Institutional Review Board, or IRB, approval, complete data monitoring and Clinical Events Committee adjudication. Additionally, the PMA analysis included hemodynamic science described in the literature and validated with a series of pre-clinical and clinical studies.

Impella CP®

In September 2012, we announced that the Impella CP received 510(k) clearance from the FDA. The Impella CP provides blood flow of approximately one liter more per minute than the Impella 2.5 and is primarily used by either interventional cardiologists to support patients in the cath lab or by surgeons in the heart surgery suite. The Impella CP is indicated for up to six hours of partial circulatory support using an extracorporeal bypass control unit. It is also intended to be used to provide partial circulatory support, for up to six hours, during procedures not requiring cardiopulmonary bypass. The Impella CP received CE Mark approval to be marketed in the European Union in April 2012 and Health Canada approval to be marketed in Canada in June 2012.

In August 2015, we submitted the PMA supplement submissions requesting to expand our current Impella 2.5 PMA approval for additional indications for Impella 2.5 and for most of our other Impella devices (Impella CP, Impella 5.0 and Impella LD). The submissions are for a set of indications related to the use of the Impella devices in patients suffering cardiogenic shock following acute myocardial infarction or cardiac surgery and for a longer duration of support. We anticipate receiving regulatory approval on the PMA supplements from the FDA in the summer of 2016.

We expect the Impella CP to retain its 510(k) clearance until completion of the FDA process.

Impella 5.0™ and Impella LD™

The Impella 5.0 and Impella LD are percutaneous micro heart pumps with integrated motors and sensors for use primarily in the heart surgery suite. These devices are designed to support patients who require higher levels of circulatory support as compared to the Impella 2.5. The Impella 5.0 and Impella LD devices received 510(k) clearance in April 2009, for circulatory support for up to six hours and have CE Mark approval in Europe for up to ten days' duration and are approved for use in over 40 countries.

The Impella 5.0 can be inserted into the left ventricle via femoral cut down or through the axillary artery. The Impella 5.0 pump goes through the ascending aorta, across the valve and into the left ventricle. The Impella LD is similar to the Impella 5.0 but is implanted directly through an aortic graft. The Impella 5.0 and Impella LD can pump up to five liters of blood per minute, providing full circulatory support.

In August 2015, we submitted the PMA supplement submissions requesting to expand our current Impella 2.5 PMA approval for additional indications for Impella 2.5 and for most of our other Impella devices (Impella CP, Impella 5.0 and Impella LD). The submissions are for a set of indications related to the use of the Impella devices in patients suffering cardiogenic shock following acute myocardial infarction or cardiac surgery and for a longer duration of support. We anticipate receiving regulatory approval on the PMA supplements from the FDA in the summer of 2016.

Impella RP®

The Impella RP is a percutaneous catheter-based axial flow pump that is designed to allow greater than four liters of flow per minute and is intended to provide the flow and pressure needed to compensate for right side heart failure.

In November 2012, we announced that the Impella RP received U.S. investigational device exemption, or IDE, approval from the FDA for use in RECOVER RIGHT, a pivotal clinical study in the U.S. In March 2014, we completed enrollment of 30 patients at sites that present with signs of right side heart failure, require hemodynamic support, and are being treated in the catheterization lab or cardiac surgery suite. The study collected safety and effectiveness data on the percutaneous use of the Impella RP and was submitted to the FDA in connection with the HDE application towards the submission of an HDE. In January 2015, we received FDA approval for Impella RP under an HDE. As part of the HDE approval, we are required to conduct two post approval studies (PAS) for Impella RP. One includes an adult patient population of 30 patients and the other, a pediatric patient population for a maximum of 15 patients. These studies will be conducted to monitor the post-market safety and probable benefit of the Impella RP device. Both studies will be single-arm multicenter studies that will follow the respective patients at 30 and 180 days post device explant.

Impella RP is the first percutaneous single access heart pump designed for right heart support to receive FDA approval. An HDE is similar to a PMA application but is intended for patient populations of 4,000 or less per year in the U.S. and is subject to certain profit and use restrictions. The Impella RP is a percutaneous device approved to provide support of the right heart during times of acute failure for certain patients who have received a left ventricle assist device or have suffered heart failure due to acute myocardial infarction, or AMI, or a failed heart transplant. An HDE requires demonstration of the safety and probable benefit of the product, which is a lower standard than is applied to a PMA. In order to receive an HDE, there must be no comparable devices approved under PMA that are

available to treat the targeted population. An approved HDE authorizes sales of the device to any hospital after Institutional Review Board review and approval by the hospital. In April 2014, the Impella RP received CE Marking approval which allows for commercial sales of Impella RP in the EU and other countries that require a CE Marking approval for sales.

AB5000™

We manufacture and sell the AB5000 Circulatory Support System for the temporary support of acute heart failure patients in profound shock, including patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock, or myocarditis. We believe the AB5000 is the only commercially available cardiac assist device that is approved by the FDA for all indications where heart recovery is the desired outcome, including patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. We expect revenues from the AB5000 to be a smaller part of our business in the future as we focus our efforts on the Impella family of products.

Critical Accounting Policies and Estimates

There have been no significant changes in our critical accounting policies during the three and nine months ended December 31, 2015, as compared to the critical accounting policies disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2015.

Recent Accounting Pronouncements

Information regarding recent accounting pronouncements is included in "Note 1. Nature of Business and Basis of Preparation" to our condensed consolidated financial statements and are incorporated herein by reference.

Results of Operations

The following table sets forth certain condensed consolidated statements of operations data for the periods indicated as a percentage of total revenues:

	For the Three Months Ended December 31, 2015				For the Nine Months Ended December 31, 2015			
	2014		2014		2014		2014	
Revenues:								
Product revenue	100.0	%	99.9	%	100.0	%	99.8	%
Funded research and development	-		0.1		-		0.2	
Total revenues	100.0		100.0		100.0		100.0	
Costs and expenses as a percentage of total revenues:								
Cost of product revenue	14.9		15.9		15.2		17.9	
Research and development	16.0		13.5		15.1		16.1	
Selling, general and administrative	48.8		48.6		50.5		56.0	
Total costs and expenses	79.7		78.0		80.8		90.0	
Income from operations	20.3		22.0		19.2		10.0	
Other income and income tax provision	8.0		1.5		7.7		0.9	
Net income as a percentage of total revenues	12.3	%	20.5	%	11.5	%	9.1	%

Three and nine months ended December 31, 2015 compared with the three and nine months ended December 31, 2014

Revenue

Our revenues are comprised of the following:

For the Three Months Ended December 31, 2015		For the Nine Months Ended December 31, 2015	
2014		2014	
(in \$000's)		(in \$000's)	

Edgar Filing: ABIOMED INC - Form 10-Q

Impella product revenue	\$81,022	\$57,424	\$221,528	\$149,309
Service and other revenue	4,025	3,447	12,107	10,024
Other products	742	1,095	1,934	3,067
Total product revenues	85,789	61,966	235,569	162,400
Funded research and development	6	39	17	354
Total revenues	\$85,795	\$62,005	\$235,586	\$162,754

Impella product revenue encompasses Impella 2.5™, Impella CP®, Impella 5.0™, Impella LD™ and Impella RP® product sales. Other product revenue includes AB5000™ and product accessory revenue. Service and other revenue represents revenue earned on service maintenance contracts and preventive maintenance calls.

Total revenues for the three months ended December 31, 2015 increased \$23.8 million, or 38%, to \$85.8 million from \$62.0 million for the three months ended December 31, 2014. Total revenues for the nine months ended December 31, 2015 increased by \$72.8 million, or 45%, to \$235.6 million from \$162.8 million for the nine months ended December 31, 2014. The increase in total revenues was primarily due to higher Impella product revenue from increased utilization in the U.S., which was attributable to increased use of Impella 2.5 as a result of PMA approval in March 2015 and higher utilization of Impella CP for those interventional cardiologists who prefer higher blood flow.

Impella product revenues for the three months ended December 31, 2015 increased by \$23.6 million, or 41%, to \$81.0 million from \$57.4 million for the three months ended December 31, 2014. Impella product revenues for the nine months ended December 31, 2015 increased by \$72.2 million, or 48%, to \$221.5 million from \$149.3 million for the nine months ended December 31, 2014. Most of the increase in Impella product revenue was from Impella CP and Impella 2.5 catheter sales in the U.S., as we focus on increasing utilization of our disposable catheter products through continued investment in our field organization and physician training programs. We also experienced an increase in Impella RP revenue after receiving HDE approval in the U.S. in January 2015. We expect Impella product revenues to continue to increase with our recent PMA approval in the U.S. as we increase utilization at existing customer sites, add new customer sites, continue our commercial launch of Impella CP, begin our controlled launch of Impella RP in the U.S. and expand our efforts in Europe.

Service and other revenue for the three months ended December 31, 2015 increased by \$0.6 million, or 18%, to \$4.0 million from \$3.4 million for the three months ended December 31, 2014. Service and other revenue for the nine months ended December 31, 2015 increased by \$2.1 million, or 21%, to \$12.1 million from \$10.0 million for the nine months ended December 31, 2014. The increase in service revenue was primarily due to an increase in preventative maintenance service contracts. We have expanded the use of our Impella AIC consoles to additional sites and placed more consoles at existing higher using sites. Many customers are entering into maintenance service contracts as these AIC consoles are being delivered.

Other product revenues for the three months ended December 31, 2015 decreased by \$0.4 million, or 36%, to \$0.7 million from \$1.1 million for the three months ended December 31, 2014. Other product revenues for the nine months ended December 31, 2015 decreased by \$1.2 million, or 39%, to \$1.9 million from \$3.1 million for the nine months ended December 31, 2014. Most of the decrease was due to lower AB sales in the U.S. We expect that AB5000 revenue will continue to decline in fiscal 2016 as we focus our sales efforts in the surgical suite on Impella 5.0 and Impella LD and we focus more of our attention on the cath lab.

Costs and Expenses

Cost of Product Revenue

Cost of product revenue for the three months ended December 31, 2015 increased by \$2.9 million, or 30%, to \$12.7 million from \$9.8 million for the three months ended December 31, 2014. Gross margin was 85% for the three months ended December 31, 2015 and 84% for the three months ended December 31, 2014. Cost of product revenue for the nine months ended December 31, 2015 increased by \$6.7 million, or 23%, to \$35.8 million from \$29.1 million for the nine months ended December 31, 2014. Gross margin was 85% for the nine months ended December 31, 2015 and 82% for the nine months ended December 31, 2014. The increase in cost of product revenues was related to increased demand for Impella products and higher production volume and costs to support growing demand for our Impella products. Gross margin has been impacted favorably in fiscal 2016 by higher manufacturing production volume, fewer shipments of Impella AIC consoles and improved efficiencies in manufacturing production.

Research and Development Expenses

Research and development expenses for the three months ended December 31, 2015 increased by \$5.4 million, or 64%, to \$13.8 million from \$8.4 million for the three months ended December 31, 2014. Research and development expenses for the nine months ended December 31, 2015 increased by \$9.4 million, or 36%, to \$35.5 million from \$26.1 million for the nine months ended December 31, 2014. The increase in research and development expenses was primarily due to product development initiatives on our existing products and new technologies, increased clinical spending primarily related to our cVAD Registry™ and post approval studies and a focus on quality initiatives for our Impella products.

We expect research and development to increase for the remainder of fiscal 2016 as we continue to increase clinical spending related to our cVAD Registry™, apply for regulatory approval for our Impella products in Japan and support the PMA supplements for Impella CP, Impella 5.0 and Impella LD which were submitted in August 2015. In addition, we expect to incur additional costs as we continue to focus on engineering initiatives to improve our existing products and develop new technologies.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended December 31, 2015 increased by \$11.8 million, or 39%, to \$41.9 million from \$30.1 million for the three months ended December 31, 2014. The increase in selling, general and administrative expenses was primarily due to the hiring of additional U.S. field sales and clinical personnel, increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support after receiving PMA approval for Impella 2.5, higher legal expenses on patent related activities, higher stock-based compensation expense and higher professional fees to support the growth of our business.

Selling, general and administrative expenses for the nine months ended December 31, 2015 increased by \$27.8 million, or 30%, to \$119.0 million from \$91.2 million for the nine months ended December 31, 2014. The increase in selling, general and administrative expenses was primarily due to the hiring of additional U.S. field sales and clinical personnel, increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support after receiving PMA approval for

Impella 2.5, higher stock-based compensation expense and higher professional fees to support the growth of our business. In the nine months ended December 31, 2015, we recorded stock compensation expense amounts totaling \$5.9 million which consist of \$1.4 million recorded in the three months ended June 30, 2015 due to the non-employee director retirement policy that was adopted in June 2015, which upon occurrence of certain specified events, provides for the accelerated vesting of outstanding unvested restricted stock units held by retirement eligible non-employee directors and \$4.5 million in expense recorded in the three months ended September 30, 2015 related to the acceleration of vesting of equity awards upon retirement of our former Chief Financial Officer and related to equity awards granted in August 2015 to retirement eligible non-employee directors which was fully recognized upon grant.

We expect to continue to incur legal expenses for the foreseeable future related to the FCA Investigation and patent related matters discussed in “Note 10. Commitments and Contingencies—Litigation,” to our condensed consolidated financial statements. Additionally, we expect to continue to increase our expenditures on sales and marketing activities, with particular investments in field sales and clinical personnel with cath lab expertise to drive recovery awareness for acute heart failure patients. We also plan to increase our marketing, service and training investments as a result of PMA approval in the U.S. for Impella 2.5™ and as we expand to new markets outside of the U.S., such as Japan. We expect that this increase in selling, general and administrative expense will be offset somewhat by the moratorium of the medical device tax in the U.S. for the next two calendar years beginning in January 2016.

Income Tax Provision

We recorded an income tax provision of \$6.9 million and \$18.5 million for the three and nine months ended December 31, 2015, respectively, compared to \$1.0 million and \$1.6 million for the three and nine months ended December 31, 2014, respectively. The increase in income tax provision for the three and nine months ended December 31, 2015 was due to the fact that we had a full valuation allowance on most of our federal, state and certain foreign deferred tax assets prior to March 31, 2015, at which time most of the valuation allowance was reversed. The income tax provision for the three and nine months ended December 31, 2015 was primarily due to the income generated in the U.S. and Germany. The income tax provision for the three and nine months ended December 31, 2014 was primarily due to income taxes related to our deferred tax liability associated with tax deductible goodwill that is not amortized for U.S. GAAP purposes.

Net Income

For the three months ended December 31, 2015, we recognized net income of \$10.6 million, or \$0.25 per basic share and \$0.23 per diluted share, compared to \$12.7 million, or \$0.31 per basic share and \$0.30 per diluted share for the three months ended December 31, 2014. For the nine months ended December 31, 2015, we recognized net income of \$27.1 million, or \$0.64 per basic share and \$0.61 per diluted share, compared to a net income of \$14.8 million, or \$0.37 per basic share and \$0.35 diluted share for the nine months ended December 31, 2014. Our net income for the three and nine months ended December 31, 2015 was driven primarily to higher Impella product revenue due to greater utilization of our Impella products in the U.S. and Europe, partially offset by the increase in income tax provision for the three and nine months ended December 31, 2015 due to the fact that we had a full valuation allowance on most of our federal, state and certain foreign deferred tax assets prior to March 31, 2015, at which time most of the valuation allowance was reversed.

Liquidity and Capital Resources

At December 31, 2015, our total cash, cash equivalents, and short and long-term marketable securities totaled \$196.2 million, an increase of \$50.2 million compared to \$146.0 million at March 31, 2015. The increase in our cash, cash equivalents, and short and long-term marketable securities was due primarily to positive cash flows from operations in the nine months ended December 31, 2015 and proceeds from stock option exercises.

Following is a summary of our cash flow activities:

	For the Nine Months Ended December 31,	
	2015	2014
Net cash provided by operating activities	\$54,238	\$25,027
Net cash used for investing activities	(28,083)	(33,700)
Net cash provided by financing activities	5,268	8,008
Effect of exchange rate changes on cash	(598)	(773)
Net increase (decrease) in cash and cash equivalents	\$30,825	\$(1,438)

Cash Provided by Operating Activities

For the nine months ended December 31, 2015, cash provided by operating activities consisted of net income of \$27.1 million, adjustments for non-cash items of \$43.2 million and cash used in working capital of \$16.1 million. The increase in net income was primarily due to higher Impella product revenues from increased utilization of our Impella products. Adjustments for non-cash items consisted primarily of \$21.7 million of stock-based compensation expense, a \$17.4 million change in deferred tax provision and \$2.2 million of depreciation and amortization of property, plant and equipment. The decrease in cash from changes in working capital included a \$5.1 million increase in accounts receivable associated with our higher revenues, a \$10.1 million increase in inventory as we build up our inventory safety stock to support growing demand for our Impella products and \$1.1 million decrease in accounts payable and accrued expenses.

For the nine months ended December 31, 2014, cash provided by operating activities consisted of net income of \$14.8 million, adjustments for non-cash items of \$16.7 million and cash used in working capital of \$6.5 million. Adjustments for non-cash items primarily consisted of \$12.7 million of stock-based compensation expense and \$1.8 million of depreciation and amortization of property, plant and equipment. The decrease in cash from changes in working capital included a \$4.3 million increase in accounts receivable associated with our higher revenues, a \$3.6 million increase in inventory to support growing demand for our Impella products and a \$1.1 million for changes in accounts payable and accrued expenses. These amounts were partially offset by an increase in deferred revenue of \$1.9 million.

Cash Used for Investing Activities

For the nine months ended December 31, 2015, net cash provided by investing activities included \$19.4 million in purchases (net of maturities) of marketable securities and \$7.9 million for the purchase of property and equipment mostly related to expansion of manufacturing capacity and office space in Danvers, Massachusetts and Aachen, Germany. We also made a \$0.8 million investment in a private medical technology company during the nine months ended December 31, 2015.

For the nine months ended December 31, 2014, net cash used for investing activities included \$14.5 million in purchases (net of maturities) of marketable securities, \$15.7 million for our acquisition of ECP and AIS, \$2.2 million for the purchase of property and equipment mostly related to expansion of manufacturing capacity in Aachen, Germany and \$1.3 million of investments in private medical technology companies.

Capital expenditures for fiscal 2016 are estimated to range from \$10.0 to \$15.0 million, assuming that we do not complete the purchase of our Danvers facility on or before March 31, 2016. The purchase price of the property is expected to be \$16.5 million. These expenditures are expected to be for manufacturing capacity expansions in both our Danvers, Massachusetts and Aachen, Germany facilities, leasehold improvements associated with build-out of additional rental office space and software development projects.

Cash Provided by Financing Activities

For the nine months ended December 31, 2015, net cash provided by financing activities included \$8.2 million in proceeds from the exercise of stock options, \$0.5 million in proceeds from the issuance of stock under the employee stock purchase plan and \$0.5 million in excess tax benefits on stock-based awards. These amounts were partially offset by \$3.9 million in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards.

For the nine months ended December 31, 2014, net cash provided by financing activities included \$8.6 million in proceeds from the exercise of stock options and \$0.4 million in proceeds from the issuance of stock under the employee stock purchase plan. These amounts were partially offset by \$1.0 million in payments in lieu of issuance of

common stock for payroll withholding taxes upon vesting of certain equity awards.

Operating Capital and Liquidity Requirements

We believe that our revenue from product sales together with existing resources will be sufficient to fund our operations for at least the next twelve months, exclusive of activities involving any future acquisitions of products or companies that complement or augment our existing line of products.

Our primary liquidity requirements are to fund the expansion of our commercial infrastructure in the U.S., increase our manufacturing capacity, incur additional capital expenditures as we expand our office space in Danvers and Aachen, Germany, increase our inventory levels in order to meet growing customer demand for our Impella products, fund new product development initiatives, prepare for commercial launches of Impella products in new markets in the future, such as Japan, increased clinical spending associated with our cVAD Registry™, as well as post approval study on Impella 2.5 related to our PMA approval and the Impella RP post approval study, costs of legal fees related to the FCA Investigation and ongoing patent litigation and to provide for general working capital needs. To date, we have primarily funded our operations principally from product sales and through the sale of equity securities.

Our liquidity is influenced by our ability to sell our products in a competitive industry and our customers' ability to pay for our products. Factors that may affect liquidity include our ability to penetrate the market for our products, maintain or reduce the length of the selling cycle for our products, capital expenditure requirements, investments in collaborative arrangements with other partners, and our ability to collect cash from customers after our products are sold. We also expect to continue to incur legal expenses for the foreseeable future related to the FCA Investigation and our response to requests for information, as well as ongoing patent litigation. We continue to review our short-term and long-term cash needs on a regular basis. At December 31, 2015 we had no long-term debt outstanding.

Marketable securities at December 31, 2015 and March 31, 2015 consisted of \$143.0 million and \$123.6 million held in funds that invest in U.S. Treasury and government-backed securities, respectively. We are not a party to any interest rate swaps, currency hedges or derivative contracts of any type and have no exposure to commercial paper or auction rate securities markets.

Cash and cash equivalents held by our foreign subsidiaries totaled \$5.7 million and \$3.6 million at December 31, 2015 and March 31, 2015, respectively. Our operating income outside the U.S. is deemed to be permanently reinvested in foreign jurisdictions. We do not intend or currently foresee a need to repatriate cash and cash equivalents held by our foreign subsidiaries. If these funds are needed in the U.S., we believe that the potential U.S. tax impact to repatriate these funds would be immaterial.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Primary Market Risk Exposures

Our cash, cash equivalents and marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at December 31, 2015, we believe the decline in fair market value of our investment portfolio would be immaterial.

Currency Exchange Rates

We have foreign currency exposure to exchange rate fluctuations and particularly with respect to the euro, British pound sterling and Japanese yen. Therefore, our investment in our subsidiaries is sensitive to fluctuations in currency exchange rates. The effect of a change in currency exchange rates on our net investment in international subsidiaries is reflected in the accumulated other comprehensive income (loss) component of stockholders' equity. If rates of exchange for the euro, British pound and Japanese yen were to have depreciated immediately and uniformly by 10% relative to the U.S. dollar from levels at December 31, 2015, the result would have been a reduction of stockholders' equity of approximately \$5.8 million.

Fair Value of Financial Instruments

At December 31, 2015, our financial instruments consist primarily of cash and cash equivalents, short-term marketable securities, accounts receivable, accounts payable and contingent consideration. The carrying amounts of accounts receivable and accounts payable are considered reasonable estimates of their fair value, due to the short maturity of these instruments. The estimated fair values of the financial instruments have been determined by us using available market information and appropriate valuation techniques. Considerable judgment is required, however, to interpret market data to develop the estimates of fair value. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value amounts.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), as of December 31, 2015. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2015, these disclosure controls and procedures are effective to provide reasonable

assurance that material information required to be disclosed by us, including our consolidated subsidiaries, in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Evaluation of Changes in Internal Control over Financial Reporting

During the third quarter of our fiscal year ending March 31, 2016, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

We are from time to time involved in various legal actions, the outcomes of which are not within our complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages, as well as other relief, which, if granted, would require significant expenditures. We record a liability in our condensed consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. We review these estimates each accounting period as additional information is known and adjust the loss provision when appropriate. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in the condensed consolidated financial statements. Material legal proceedings are discussed in “Note 10. Commitments and Contingencies—Litigation” to our condensed consolidated financial statements and are incorporated herein by reference.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this Report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended March 31, 2015, which could materially affect our business, financial condition or future results. As of the date of this Report there has been no material change in any of the risk factors described in our Annual Report on Form 10-K for the fiscal year ended March 31, 2015, except as noted below:

We own patents, trademarks, trade secrets, copyrights and other intellectual property and know-how that we believe gives us a competitive advantage. If we cannot protect our intellectual property and develop or otherwise acquire additional intellectual property, competition could force us to lower our prices, which could hurt our profitability.

Our intellectual property rights are and will continue to be a critical component of our success. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, copyright, trade secret and domain name protection laws, as well as confidentiality agreements with our employees and others, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from using our proprietary technologies or from marketing products that are very similar or identical to ours.

A substantial portion of our intellectual property rights relating to the Impella® products and other products under development is in the form of trade secrets, rather than patents. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge, that we will have adequate remedies for any such breach, or that our

trade secrets will not become known to or be independently developed by our competitors. The loss of trade secret protection for technologies or know-how relating to our product portfolio and products under development could adversely affect our business and our prospects.

Our business position also depends in part on our ability to maintain and defend our existing patents and obtain, maintain, and defend additional patents and other intellectual property rights. We intend to seek additional patents, but our pending and future patent applications may not result in issued patents or be granted on a timely basis. In addition, issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. The scope of our patent claims also may vary between countries, as individual countries have distinctive patent laws. We may be subject to challenges by third parties regarding our intellectual property, including, among others, claims regarding validity, enforceability, scope and effective term. Patent prosecution, related proceedings, and litigation in the U.S. and in other countries may be expensive, time consuming and ultimately unsuccessful. In addition, patents issued by foreign countries may afford less protection than is available under U.S. patent law and may not adequately protect our proprietary information. Our competitors may independently develop proprietary technologies and processes that are the same as or substantially equivalent to ours or design around our patents. Our competition may also hold or obtain intellectual property rights that would threaten our ability to develop or commercialize our product offerings. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect our business and our prospects.

Companies in the medical device industry typically obtain patents and frequently engage in substantial intellectual property litigation. Our products and technologies could infringe on the rights of others. If a third-party successfully asserts a claim for infringement against us, we may be liable for substantial damages, be unable to sell products using that technology, or have to seek a license or redesign the related product. These alternatives may be uneconomical or impossible. Intellectual property litigation could be costly, result in product development delays and divert the efforts and attention of management from our business.

In July and August 2015, Thoratec Corporation (“Thoratec”), acquired by St. Jude Medical, Inc. in October 2015, brought actions in connection with two of our patents relevant to Thoratec’s HeartMate PHP medical device (“PHP”). In those proceedings, which are in the United Kingdom and Germany, Thoratec asserts that the two patents are invalid. In September 2015, we filed counterclaims in the action in Germany asserting that the PHP product infringes the two patents and a third patent owned by us. Both the Germany and United Kingdom proceedings are ongoing.

In December 2015, we received a letter from Maquet Cardiovascular LLC, a subsidiary of the Getinge Group (“Maquet”) and maker of the intra-aortic balloon pump, requesting that we discuss the option for a license for two patents and one pending patent application in the United States and elsewhere, which they believe read on certain features of our Impella products. After comprehensive review, in January 2016, we sent Maquet a response letter informing them that we believe that Maquet’s listed patents are not infringed by our Impella products and that the cited claims are invalid. We, accordingly, declined the offer to take a license from Maquet to such patents.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Not applicable.

(b) Not applicable.

(c) Not applicable.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None

Item 6. Exhibits

Exhibit No.	Description	Filed with This Form 10-Q	Incorporated by Reference	
			Form	Filing Date Exhibit No.
2.1	Agreement on the Sale and Transfer of all shares in ECP Entwicklungsgesellschaft mbH			July 7, 2014 (File No. 8-K 001-09585) 2.1
2.2	Agreement on the Sale and Transfer of all shares in AIS GmbH Aachen Innovation Solutions			July 7, 2014 (File No. 8-K 001-09585) 2.2
3.1	Restated Certificate of Incorporation.		S-3	September 29, 1997 3.1
3.2	Restated By-Laws, as amended.		10-K	May 27, 2004 (File No. 001-09585) 3.2
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock.		S-3	September 29, 1997 3.3
3.4	Amendment to the Company's Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000.		8-K	March 21, 2007 (File No. 001-09585) 3.4
4.1	Specimen Certificate of common stock.		S-1	June 5, 1987 4.1
10.1	Purchase and Sale Agreement dated as of December 9, 2015 between Abiomed, Inc. and Thibeault Nominee Trust.	X		
10.2	First Amendment to Purchase and Sale Agreement dated as of January 19, 2016 between Abiomed, Inc. and Thibeault Nominee Trust	X		
10.3	Form of Employee Time-Based RSU Agreement under the 2015 Omnibus Incentive Plan	X		
10.4	Form of Non-Employee Director Time-Based RSU Agreement under the 2015 Omnibus Incentive Plan	X		
10.5	Form of Performance-Based RSU Agreement under the 2015 Omnibus Incentive Plan	X		

Edgar Filing: ABIOMED INC - Form 10-Q

10.6	Form of Employee Time-Based Option Agreement under the 2015 Omnibus Incentive Plan	X
10.7	Form of Non-Employee Director Time-Based Option Agreement	X
31.1	Principal Executive Officer Certification pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
31.2	Principal Financial Officer Certification pursuant to Securities Exchange Act Rule 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X

Edgar Filing: ABIOMED INC - Form 10-Q

Exhibit No.	Description	Filed with This Form 10-Q Incorporated by Reference Form Filing Date Exhibit No.
32.1	Principal Executive Officer and Principal Financial Officer Certifications pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101	The following financial information from the ABIOMED, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of December 31, 2015 and March 31, 2015; (ii) Condensed Consolidated Statements of Operations for the three and nine months ended December 31, 2015 and 2014; (iii) Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended December 31, 2015 and 2014; (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended December 31, 2015 and 2014; and (v) Notes to Condensed Consolidated Financial Statements.	X

ABIOMED, INC. AND SUBSIDIARIES

PART II. OTHER INFORMATION

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.

Date: February 5, 2016 /s/ MICHAEL J. TOMSICEK
Michael J. Tomsicek
Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)