

ABIOMED INC  
Form 10-Q  
November 04, 2015  
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**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 September 30, 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**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**04-2743260**  
**(IRS Employer**  
**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

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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 October 30, 2015, 42,417,469 shares of the registrant's common stock, \$.01 par value, were outstanding.

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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 is a trademark of ABIOMED, Inc. RECOVER is a trademark of Abiomed Europe

GmbH, a subsidiary of ABIOMED, Inc., and is registered in the U.S. and certain foreign countries.

**Table of Contents****PART 1. FINANCIAL INFORMATION****ITEM 1: FINANCIAL STATEMENTS****ABIOMED, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS****(Unaudited)****(in thousands, except share and per share data)**

	<b>September 30, 2015</b>	<b>March 31, 2015</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 54,421	\$ 22,401
Short-term marketable securities	121,087	109,557
Accounts receivable, net	37,119	31,828
Inventories	23,032	16,774
Prepaid expenses and other current assets	4,030	4,479
Deferred tax assets, net	25,715	35,100
Total current assets	265,404	220,139
Long-term marketable securities		13,996
Property and equipment, net	11,420	9,127
Goodwill	32,676	31,534
In-process research and development	15,243	14,711
Long-term deferred tax assets, net	44,240	45,206
Other assets	4,423	3,654
Total assets	\$ 373,406	\$ 338,367
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 8,788	\$ 10,389
Accrued expenses	18,861	21,894
Deferred revenue	6,803	7,036
Total current liabilities	34,452	39,319
Other long-term liabilities	217	183
Contingent consideration	6,817	6,510
Long-term deferred tax liabilities	824	795
Total liabilities	42,310	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 - 43,756,550 shares at September 30, 2015 and 42,618,717 shares at March 31, 2015;		
Outstanding - 42,417,469 shares at September 30, 2015 and 41,335,773 shares at March 31, 2015		
Additional paid in capital	489,463	465,046
Accumulated deficit	(120,628)	(137,222)
Treasury stock at cost - 1,339,081 shares at September 30, 2015 and 1,282,944 shares at March 31, 2015	(23,157)	(19,347)
Accumulated other comprehensive loss	(15,006)	(17,330)
Total stockholders' equity	331,096	291,560
Total liabilities and stockholders' equity	\$ 373,406	\$ 338,367

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

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**ABIOMED, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

(in thousands, except per share data)

	For the Three Months Ended		For the Six Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
<b>Revenue:</b>				
Product revenue	\$ 76,354	\$ 51,774	\$ 149,780	\$ 100,434
Funded research and development	5	164	11	315
	76,359	51,938	149,791	100,749
<b>Costs and expenses:</b>				
Cost of product revenue	12,144	9,612	23,012	19,301
Research and development	11,569	8,693	21,779	17,755
Selling, general and administrative	39,829	29,455	77,152	61,053
	63,542	47,760	121,943	98,109
Income from operations	12,817	4,178	27,848	2,640
<b>Other income (loss):</b>				
Investment income, net	62	36	125	80
Other income (loss), net	87	(39)	140	(28)
	149	(3)	265	52
Income before income taxes	12,966	4,175	28,113	2,692
Income tax provision	5,231	336	11,519	562
Net income	\$ 7,735	\$ 3,839	\$ 16,594	\$ 2,130
Basic net income per share	\$ 0.18	\$ 0.09	\$ 0.40	\$ 0.05
Basic weighted average shares outstanding	42,228	40,448	41,963	40,256
Diluted net income per share	\$ 0.17	\$ 0.09	\$ 0.37	\$ 0.05
Diluted weighted average shares outstanding	44,922	42,239	44,778	42,069

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





Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)****(Unaudited)****(in thousands)**

	<b>For the Three Months Ended</b>		<b>For the Six Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Net income	\$ 7,735	\$ 3,839	\$ 16,594	\$ 2,130
Other comprehensive income:				
Foreign currency translation gains (losses)	710	(4,804)	2,308	(5,240)
Net unrealized gains (losses) on marketable securities	6	(22)	16	5
Other comprehensive income (loss)	716	(4,826)	2,324	(5,235)
Comprehensive income (loss)	\$ 8,451	\$ (987)	\$ 18,918	\$ (3,105)

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

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(Unaudited)****(in thousands)**

	<b>For the Six Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
Operating activities:		
Net income	\$ 16,594	\$ 2,130
Adjustments required to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,352	1,196
Bad debt (recovery) expense	(18)	27
Stock-based compensation	15,592	8,314
Write-down of inventory	952	559
Excess tax benefit from stock-based awards	(383)	
Deferred tax provision	10,803	450
Change in fair value of contingent consideration	307	219
Changes in assets and liabilities:		
Accounts receivable	(5,214)	1,108
Inventories	(6,855)	(653)
Prepaid expenses and other assets	456	(139)
Accounts payable	(1,817)	(581)
Accrued expenses and other long-term liabilities	(2,674)	(3,732)
Deferred revenue	(239)	1,004
Net cash provided by operating activities	28,856	9,902
Investing activities:		
Purchases of marketable securities	(99,002)	(44,920)
Proceeds from the sale and maturity of marketable securities	101,453	47,890
Acquisition of ECP and AIS, net of cash assumed		(15,697)
Purchase of other investment	(750)	(750)
Purchases of property and equipment	(3,419)	(1,496)
Net cash used for investing activities	(1,718)	(14,973)
Financing activities:		
Proceeds from the exercise of stock options	7,971	2,560
Excess tax benefit from stock-based awards	383	
Taxes paid related to net share settlement of vesting of stock awards	(3,810)	(1,013)
Proceeds from the issuance of stock under employee stock purchase plan	451	397
Net cash provided by financing activities	4,995	1,944
Effect of exchange rate changes on cash	(113)	(306)

Net increase (decrease) in cash and cash equivalents	32,020	(3,433)
Cash and cash equivalents at beginning of period	22,401	20,916
Cash and cash equivalents at end of period	\$ 54,421	\$ 17,483
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ 576	\$ 299
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	396	577
<i>The accompanying notes are an integral part of the condensed consolidated financial statements (unaudited)</i>		

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**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 leading 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 six months ended September 30, 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 is effective for the Company in the first quarter of fiscal 2019 with early adoption permitted for fiscal years beginning on or after December 15, 2016. The Company is currently evaluating the impact of adopting ASU 2014-09 on its condensed consolidated financial statements.

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.

**Table of Contents****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 six months ended September 30, 2015 and 2014 were as follows (in thousands, except per share data):

	For the Three Months Ended		For the Six Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
<b>Basic Net Income Per Share</b>				
Net income	\$ 7,735	\$ 3,839	\$ 16,594	\$ 2,130
Weighted average shares used in computing basic net income per share	42,228	40,448	41,963	40,256
Net income per share - basic	\$ 0.18	\$ 0.09	\$ 0.40	\$ 0.05

	For the Three Months Ended		For the Six Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
<b>Diluted Net Income Per Share</b>				
Net income	\$ 7,735	\$ 3,839	\$ 16,594	\$ 2,130
Weighted average shares used in computing basic net income per share	42,228	40,448	41,963	40,256
Effect of dilutive securities	2,694	1,791	2,815	1,813
Weighted average shares used in computing diluted net income per share	44,922	42,239	44,778	42,069
Net income per share - diluted	\$ 0.17	\$ 0.09	\$ 0.37	\$ 0.05

For the three and six months ended September 30, 2015, approximately 1,000 shares 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 227,000 and 226,000 restricted shares in the three and six months ended September 30, 2015, respectively, 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 six months ended September 30, 2014, approximately 47,000 and 44,000 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 465,000 restricted shares in each of the three and six months ended September 30, 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.



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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**

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

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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
<b>Total assets acquired</b>	<b>23,176</b>
Liabilities assumed:	
Accounts payable	295
Accrued liabilities	131
Long-term deferred tax liabilities	1,000
<b>Total liabilities assumed</b>	<b>1,426</b>
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.

**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 September 30, 2015 and March 31, 2015 are invested in the following:

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Market Value</b>
	(in \$000 s)			
<b>September 30, 2015:</b>				
US Treasury mutual fund securities	\$ 19,487	\$	\$	\$ 19,487
Short-term government-backed securities	101,588	14	(2)	101,600
	\$ 121,075	\$ 14	\$ (2)	\$ 121,087

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Market Value</b>
	(in \$000 s)			
<b>March 31, 2015:</b>				
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

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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
	(in \$000 s)			
<b>September 30, 2015:</b>				
Assets				
U.S. Treasury mutual fund securities	\$	\$ 19,487	\$	\$ 19,487
Short-term government-backed securities		101,600		101,600
Liabilities				
Contingent consideration			6,817	6,817
	Level 1	Level 2	Level 3	Total
	(in \$000 s)			
<b>March 31, 2015:</b>				
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
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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.

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The following table summarizes the change in fair value, as determined by Level 3 inputs, of the contingent consideration for the six months ended September 30, 2015:

	<b>For the Six Months Ended September 30, 2015 (in \$000 s)</b>
Level 3 liabilities, beginning balance	\$ 6,510
Additions	
Payments	
Change in fair value	307
Level 3 liabilities, ending balance	\$ 6,817

The change in fair value of the contingent consideration of \$0.2 million and \$0.3 million for the three and six months ended September 30, 2015, respectively, and \$0.2 million for each of the three and six months ended September 30, 2014, 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. 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 September 30, 2015 classified as Level 3:

<b>Fair Value at September 30,</b>		<b>Weighted Average</b>	
<b>2015 (in \$000 s)</b>	<b>Valuation Methodology</b>	<b>Significant Unobservable Input</b>	<b>(range, if applicable)</b>
Contingent consideration	Probability weighted income approach	Milestone dates Discount rate Probability of occurrence	2018 to 2021 8% to 12% Probability adjusted level of 40% for the base case scenario and 5% to 25% 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 September 30, 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:

	<b>September 30, March 31,</b>	
	<b>2015</b>	<b>2015</b>
	<b>(in \$000 s)</b>	
Raw materials and supplies	\$ 8,479	\$ 7,417
Work-in-progress	9,358	6,466
Finished goods	5,195	2,891
	\$ 23,032	\$ 16,774



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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 six months ended September 30, 2015 and 2014, the Company recorded \$1.0 million and \$0.6 million, respectively, in write-downs of inventory.

**Note 6. Goodwill and In-Process Research and Development*****Goodwill***

The carrying amount of goodwill at September 30, 2015 and March 31, 2015 was \$32.7 million and \$31.5 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG, or 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	1,142
Balance at September 30, 2015	\$ 32,676

The Company evaluates goodwill 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.

As described in Note 3 Acquisitions, in July 2014, the Company acquired ECP and AIS and recorded \$18.5 million of IPR&D. The estimated fair value of IPR&D 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 six months ended September 30, 2015 are as follows:

	(in \$000 s)
Balance at March 31, 2015	\$ 14,711
Foreign currency translation impact	532
Balance at September 30, 2015	\$ 15,243

**Note 7. Accrued Expenses**

Accrued expenses consist of the following:

	<b>September 30, March 31,</b>	
	<b>2015</b>	<b>2015</b>
	<b>(in \$000 s)</b>	
Employee compensation	\$ 11,343	\$ 15,978
Research and development	2,957	1,744
Sales and income taxes	1,249	1,506
Professional, legal and accounting fees	1,112	710
Warranty	697	1,103
Other	1,503	853
	<b>\$ 18,861</b>	<b>\$ 21,894</b>

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at September 30, 2015 and March 31, 2015.

**Table of Contents****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 six months ended September 30, 2015 and 2014:

	For the Three Months Ended		For the Six Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	(in \$000 s)		(in \$000 s)	
Cost of product revenue	\$ 218	\$ 148	\$ 455	\$ 357
Research and development	989	773	1,920	1,626
Selling, general and administrative	9,586	3,103	13,217	6,331
	\$ 10,793	\$ 4,024	\$ 15,592	\$ 8,314

The components of stock-based compensation for the three and six months ended September 30, 2015 and 2014 were as follows:

	For the Three Months Ended		For the Six Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
	(in \$000 s)		(in \$000 s)	
Restricted stock units	\$ 8,446	\$ 3,334	\$ 12,349	\$ 6,754
Stock options	2,227	624	3,046	1,423
Employee stock purchase plan	120	66	197	137
	\$ 10,793	\$ 4,024	\$ 15,592	\$ 8,314

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 three and six months ended September 30, 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 six months ended September 30,

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 three and six months ended September 30, 2015.

**Table of Contents****Stock Options**

The following table summarizes the stock option activity for the six months ended September 30, 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	145	69.50		
Exercised	(703)	11.33		
Cancelled and expired	(1)	14.00		
Outstanding at end of period	2,333	\$ 19.16	5.56	\$ 172,712
Exercisable at end of period	1,696	\$ 13.76	4.50	\$ 134,674
Options vested and expected to vest at end of period	2,277	\$ 18.98	5.50	\$ 169,000

The aggregate intrinsic value of options exercised was \$49.5 million for the six months ended September 30, 2015. The total fair value of options that vested during the six months ended September 30, 2015 was \$2.4 million.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at September 30, 2015 was approximately \$6.4 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 2.3 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 value for options granted during the six months ended September 30, 2015 and 2014 was \$18.08 and \$9.05 per share, respectively.

The fair value of options granted during the three and six months ended September 30, 2015 and 2014 were calculated using the following weighted average assumptions:

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2015	2014	2015	2014
Risk-free interest rate	1.63%	1.75%	1.59%	1.60%
Expected option life (years)	4.13	4.19	4.14	4.19
Expected volatility	48.3%	48.7%	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.

**Table of Contents****Restricted Stock and Restricted Stock Units**

The following table summarizes the activity of restricted stock and restricted stock units for the six months ended September 30, 2015:

	<b>Number of Shares (in thousands)</b>	<b>Weighted Average Grant Date Fair Value (per share)</b>
Restricted stock and restricted stock units at beginning of period	1,160	\$ 21.90
Granted	655	\$ 80.70
Vested	(461)	\$ 22.55
Forfeited	(42)	\$ 13.09
Restricted stock and restricted stock units at end of period	1,312	\$ 51.31

As of September 30, 2015, there are no restricted stock awards outstanding.

The weighted average grant-date fair value for restricted stock units granted, including performance and market-based awards, during the six months ended September 30, 2015 and 2014 was \$80.70 and \$21.88 per share, respectively. This includes 322,980 market based awards which were valued at \$107.10 per share in which a Monte Carlo simulation 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 six months ended September 30, 2015 and 2014 was \$10.2 million and \$9.5 million, respectively. The remaining unrecognized compensation expense for outstanding restricted stock units, including performance and market-based awards, as of September 30, 2015 was \$33.3 million and the weighted-average period over which this cost will be recognized is 2.8 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 September 30, 2015 was \$22.7 million and the weighted-average period over which this cost will be recognized is 3.0 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 September 30, 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 September 30, 2015, 222,563 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 March 2014, the Company modified the performance condition on 50,000 restricted stock units originally granted in June 2011. During the three months ended June 30, 2015, the Company reversed \$1.0 million that had been previously recorded as stock-based compensation expense based on the expectation that it is not probable that certain performance milestones related to this award will be achieved within the time period required by the award.

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 September 30, 2015, 148,995 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.



*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

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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 2018 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)	2.96
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 \$5.2 million and \$11.5 million for the three and six months ended September 30, 2015, respectively. The Company's income tax provision was \$0.3 million and \$0.6 million for the three and six months ended September 30, 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 six months ended September 30, 2015 and 2014 were as follows:

	For the Three Months Ended		For the Six Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Statutory income tax rate	35.0%	34.0%	35.0%	34.0%
Increase (decrease) resulting from:				
Losses not benefited		(26.0)		(15.7)
Credits	(1.2)		(1.4)	
State taxes, net	3.3		3.3	
Permanent differences	3.0		3.5	
Other	0.2		0.6	2.6
Effective tax rate	40.3%	8.0%	41.0%	20.9%

The Company and its subsidiaries are subject to U.S. federal income tax, as well as income taxes in Germany and multiple state jurisdictions. All tax years remain subject to examination by the Internal Revenue Service and state tax authorities, because the Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, 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.

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**Note 10. Commitments and Contingencies**

***Commitments***

In April 2015, the Company entered into an amendment to lease an additional 24,560 square feet of space at its existing headquarters in Danvers, Massachusetts. The Company has certain rights to terminate the lease early, subject to the payment of a specified termination fee based on the timing of the termination, as further outlined in the lease amendment. The amendment also grants the Company a one-time right of first offer to lease new space in the facility and a one-time first right of refusal to buy the facility, subject to certain conditions set forth therein. This facility encompasses most of the Company's U.S. operations, including research and development, manufacturing, sales and marketing and general and administrative departments. The monthly lease payments over the term of the lease are as follows:

The base rent for May 2014 through December 2015 is \$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.

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. \$72,500 at September 30, 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 Agreement***

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 agreed to make additional payments of up to \$4.5 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. 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 heart pump. 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.

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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 ( Percutaneous Heart Pump ) 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 any possible losses and accordingly, 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 77% of the Company s total consolidated assets were located within the U.S. as of September 30, 2015 and March 31, 2015. The remaining assets were located primarily in Germany and included goodwill and IPR&D of \$47.9 million and \$46.2 million at September 30, 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 amounted to 10% of total consolidated assets as of each of September 30, 2015 and March 31, 2015. International sales (primarily in Europe) accounted for 7% of total revenue for each of the three and six months ended September 30, 2015 and 11% of total revenue for each of the three and six months ended September 30, 2014.

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**Table of Contents****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 and the expectation that the PMA supplements will receive regulatory approval by the FDA in the summer of 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. Our Impella 2.5 product received 510(k) clearance in June 2008 from the U.S Food and Drug Administration, or FDA, for partial circulatory support for up to six hours. In March 2015, we received a PMA from the FDA for Impella 2.5 during elective and urgent high-risk percutaneous coronary intervention, or 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 peri- 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. As required by 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 heart pump is supported by clinical guidelines and has been eligible to be reimbursed in the U.S. by the Centers for Medicare & Medicaid Services, or CMS under ICD-9-CM code 37.68 since 2008 for multiple indications, including high-risk PCI. On July 31, 2015, the CMS reconfirmed reimbursement levels for the Impella products and confirmed that the existing MS-DRG mapping for the Impella products remains unchanged in the transition from ICD-9 to ICD-10, which is effective October 1, 2015.



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We received 510(k) clearance in April 2009 for our Impella 5.0 and Impella LD devices for circulatory support for up to six hours. These devices are larger and provide more blood flow to patients than the Impella 2.5. In September 2012, our Impella CP product received 510(k) clearance from the FDA for partial circulatory support for up to six hours.

In August 2015, we submitted the PMA supplement submissions requesting to expand Impella 2.5 PMA approval to 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.

These submissions are proposed as a supplement to the Impella 2.5 PMA approval for high risk PCI received on March 23, 2015, and include analysis on 415 patients from the FDA study RECOVER 1 and the U.S. Impella product registry (the U.S. Impella Registry), and a relevant literature review that references 692 patients in 17 clinical studies. Additionally, over 24,000 patients supported by Impella devices were reviewed in a safety analysis provided using the FDA/Medical Device Reporting (MDR) database. Through its review of the supplemental submission, the FDA will ultimately render a decision concerning the safety and efficacy of the Impella CP, Impella 5.0 and Impella LD in the applied-for patient populations.

We expect the Impella CP, Impella 5.0 and Impella LD to retain their 510(k) clearances until completion of the FDA process.

We received FDA approval for Impella RP under a Humanitarian Device Exemption, or HDE, in January 2015. The Impella RP is the first percutaneous single access heart pump designed for right heart support to receive FDA approval. 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.

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.

In July 2014, we acquired all of the issued shares of ECP Entwicklungsgesellschaft mbH, or 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 GmbH Aachen Innovative Solutions, or 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 revenues are primarily generated from our Impella line of 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.

## **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

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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.

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. The U.S. Impella 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 Impella 2.5 PMA approval 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 Impella 2.5 PMA approval 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

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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 5.0 and Impella LD to retain their 510(k) clearances until completion of the FDA process.

***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 six months ended September 30, 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.

**Table of Contents****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		For the Six Months Ended	
	September 30, 2015	2014	September 30, 2015	2014
<b>Revenues:</b>				
Product	100.0%	99.7%	100.0%	99.7%
Funded research and development		0.3		0.3
Total revenues	100.0	100.0	100.0	100.0
<b>Costs and expenses as a percentage of total revenues:</b>				
Cost of product revenue	15.9	18.5	15.4	19.2
Research and development	15.1	16.8	14.5	17.6
Selling, general and administrative	52.2	56.7	51.5	60.6
Total costs and expenses	83.2	92.0	81.4	97.4
Income from operations	16.8	8.0	18.6	2.6
Other income and income tax provision	6.7	0.6	7.5	0.5
Net income as a percentage of total revenues	10.1%	7.4%	11.1%	2.1%

*Three and six months ended September 30, 2015 compared with the three and six months ended September 30, 2014*

**Revenue**

Our revenues are comprised of the following:

	For the Three Months Ended		For the Six Months Ended	
	September 30, 2015	2014	September 30, 2015	2014
	(in \$000 s)		(in \$000 s)	
Impella product revenue	\$ 71,701	\$ 46,910	\$ 140,506	\$ 91,885
Service and other revenue	3,929	3,297	8,082	6,577
Other products	724	1,567	1,192	1,972
Total product revenues	76,354	51,774	149,780	100,434

Funded research and development	5	164	11	315
Total revenues	\$ 76,359	\$ 51,938	\$ 149,791	\$ 100,749

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 September 30, 2015 increased \$24.5 million, or 47%, to \$76.4 million from \$51.9 million for the three months ended September 30, 2014. Total revenues for the six months ended September 30, 2015 increased by \$49.1 million, or 49%, to \$149.8 million from \$100.7 million for the six months ended September 30, 2014. The increase in total revenue 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 September 30, 2015 increased by \$24.8 million, or 53%, to \$71.7 million from \$46.9 million for the three months ended September 30, 2014. Impella product revenues for the six months ended September 30, 2015 increased by \$48.6 million, or 53%, to \$140.5 million from \$91.9 million for the six months ended September 30, 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 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.



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Service and other revenue for the three months ended September 30, 2015 increased by \$0.6 million, or 18%, to \$3.9 million from \$3.3 million for the three months ended September 30, 2014. Service and other revenue for the six months ended September 30, 2015 increased by \$1.5 million, or 23%, to \$8.1 million from \$6.6 million for the six months ended September 30, 2014. The increase in service revenue was primarily due to an increase in preventative maintenance service contracts, as we expand the use of our Impella AIC consoles to additional sites and place more consoles at existing higher using sites.

Other product revenues for the three months ended September 30, 2015 decreased by \$0.9 million, or 56%, to \$0.7 million from \$1.6 million for the three months ended September 30, 2014. Other product revenues for the six months ended September 30, 2015 decreased by \$0.8 million, or 40%, to \$1.2 million from \$2.0 million for the six months ended September 30, 2014. 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.

**Costs and Expenses*****Cost of Product Revenue***

Cost of product revenue for the three months ended September 30, 2015 increased by \$2.5 million, or 26%, to \$12.1 million from \$9.6 million for the three months ended September 30, 2014. Gross margin was 84% for the three months ended September 30, 2015 and 82% for the three months ended September 30, 2014. Cost of product revenue for the six months ended September 30, 2015 increased by \$3.7 million, or 19%, to \$23.0 million from \$19.3 million for the six months ended September 30, 2014. Gross margin was 85% for the six months ended September 30, 2015 and 81% for the six months ended September 30, 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 September 30, 2015 increased by \$2.9 million, or 33%, to \$11.6 million from \$8.7 million for the three months ended September 30, 2014. Research and development expenses for the six months ended September 30, 2015 increased by \$4.0 million, or 22%, to \$21.8 million from \$17.8 million for the six months ended September 30, 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 U.S. Impella Registry and post approval studies and a renewed focus on quality initiatives for our Impella products.

We expect research and development to increase in fiscal 2016 as we continue to increase clinical spending related to our U.S. Impella 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 September 30, 2015 increased by \$10.3 million, or 35%, to \$39.8 million from \$29.5 million for the three months ended September 30, 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, higher excise taxes associated with the medical device tax in the U.S. and higher professional fees to support the growth of our business. In the three months ended September 30, 2015, we recorded stock compensation expense amounts of \$2.5 million related to the acceleration of vesting of equity awards upon retirement of our former Chief Financial Officer and \$2.0 million related to equity awards granted in August 2015 to retirement eligible non-employee directors which was fully recognized upon grant.

Selling, general and administrative expenses for the six months ended September 30, 2015 increased by \$16.1 million, or 26%, to \$77.2 million from \$61.1 million for the six months ended September 30, 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, higher excise taxes associated with the medical device tax in the U.S. and higher professional fees to support the growth of our business. In the six months ended September 30, 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 for items described above.

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Increases in selling, general and administrative expenses for the three and six months ended September 30, 2015 were partially offset by lower legal expenses related to the Marketing and Labeling Investigation which was closed in June 2015. We expect to continue to incur legal expenses for the foreseeable future related to the FCA Investigation 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 after PMA approval in the U.S. for Impella 2.5.

**Income Tax Provision**

We recorded an income tax provision of \$5.2 million and \$11.5 million for the three and six months ended September 30, 2015, respectively, compared to \$0.3 million and \$0.6 million for the three and six months ended September 30, 2014, respectively. The increase in income tax provision for the three and six months ended September 30, 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 six months ended September 30, 2015 was primarily due to the income generated in the U.S. and Germany in the period. The income tax provision for the three and six months ended September 30, 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 September 30, 2015, we recognized net income of \$7.7 million, or \$0.18 per basic share and \$0.17 per diluted share, compared to \$3.8 million, or \$0.09 per basic and diluted share for the three months ended September 30, 2014. For the six months ended September 30, 2015, we recognized net income of \$16.6 million, or \$0.40 per basic share and \$0.37 per diluted share, compared to a net income of \$2.1 million, or \$0.05 per basic and diluted share for the six months ended September 30, 2014. Our net income for the three and six months ended September 30, 2015 was driven primarily to higher Impella product revenue due to greater utilization of our Impella products in the U.S. and Europe.

**Liquidity and Capital Resources**

At September 30, 2015, our total cash, cash equivalents, and short and long-term marketable securities totaled \$175.5 million, an increase of \$29.5 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 six months ended September 30, 2015 and proceeds from stock option exercises.

Following is a summary of our cash flow activities:

	<b>For the Six Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
Net cash provided by operating activities	\$ 28,856	\$ 9,902
Net cash used for investing activities	(1,718)	(14,973)
Net cash provided by financing activities	4,995	1,944

Effect of exchange rate changes on cash	(113)	(306)
Net increase (decrease) in cash and cash equivalents	\$ 32,020	\$ (3,433)

### *Cash Provided by Operating Activities*

For the six months ended September 30, 2015, cash provided by operating activities consisted of net income of \$16.6 million, adjustments for non-cash items of \$28.6 million and cash used in working capital of \$16.3 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 \$15.6 million of stock-based compensation expense and a \$10.8 million change in deferred tax provision. The decrease in cash from changes in working capital included a \$5.2 million increase in accounts receivable associated with our higher revenues, a \$6.9 million increase in inventory as we build up our inventory safety stock to support growing demand for our Impella products and \$4.5 million decrease in accounts payable and accrued expenses.

For the six months ended September 30, 2014, cash provided by operating activities consisted of net income of \$2.1 million, adjustments for non-cash items of \$10.8 million and cash used in working capital of \$3.0 million. Adjustments for non-cash items primarily consisted of \$8.3 million of stock-based compensation expense and \$1.2 million of depreciation and amortization of long-lived

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assets. The decrease in cash from changes in working capital included a \$1.1 million increase in accounts receivable associated with our higher revenues and a \$4.5 million for changes in accounts payable and accrued expenses. These amounts were partially offset by an increase in deferred revenue of \$1.0 million.

***Cash Used for Investing Activities***

For the six months ended September 30, 2015, net cash provided by investing activities included \$2.5 million in maturities (net of purchases) of marketable securities, partially offset by \$3.4 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 six months ended September 30, 2015.

For the six months ended September 30, 2014, net cash used for investing activities included \$3.0 million in net proceeds from the sale and maturity of marketable securities (net of purchases) and \$1.5 million for the purchase of property and equipment mostly related to expansion of manufacturing capacity in Aachen, Germany. We used \$15.7 million in net cash with our acquisition of ECP and AIS in July 2014. We also made a \$0.8 million investment in a private medical technology company during the six months ended September 30, 2014.

Capital expenditures for fiscal 2016 are estimated to range from \$10.0 to \$30.0 million, and 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 six months ended September 30, 2015, net cash provided by financing activities included \$8.0 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 \$0.4 million in excess tax benefits on stock-based awards. This amount was partially offset by \$3.8 million in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards.

For the six months ended September 30, 2014, net cash provided by financing activities included \$2.6 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. This amount was 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, expand our office space in Danvers, Massachusetts 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 U.S. Impella 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 patent activities 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. We continue to review our long-term cash needs on a regular basis. At September 30, 2015, we had no long-term debt outstanding.

Marketable securities at September 30, 2015 and March 31, 2015 consisted of \$121.1 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 \$7.5 million and \$3.6 million at September 30, 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.

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**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 September 30, 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 September 30, 2015, the result would have been a reduction of stockholders' equity of approximately \$6.3 million.

***Fair Value of Financial Instruments***

At September 30, 2015, our financial instruments consist primarily of cash and cash equivalents, short-term marketable securities, accounts receivable, accounts payable and contingent consideration. 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 September 30, 2015. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 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 second 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.





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**Table of Contents****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.

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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 Company patents relevant to Thoratec s HeartMate PHP ( Percutaneous Heart Pump ) 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.

**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

**Table of Contents****Item 6. Exhibits**

Exhibit No.	Description	Filed with		Exhibit No.	
		This Form 10-Q	Incorporated by Reference		
			Form	Filing Date	
3.1	Restated Certificate of Incorporation.		S-3	September 29, 1997	3.1
3.2	Restated By-Laws, as amended.			May 27, 2004	
			10-K	(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.			March 21, 2007	
			8-K	(File No. 001-09585)	3.4
4.1	Specimen Certificate of common stock.		S-1	June 5, 1987	4.1
10.1	Lease agreement for additional commercial space dated October 19, 2015 for the facility located in Aachen, Germany.	X			
10.2	Supplemental contract no. 1 dated October 19, 2015, to the lease agreement dated July 29, 2013 for the facility located in Aachen, Germany.	X			
10.3	2015 Omnibus Incentive Plan.		Sch. 14A		
			(File No.		
			001-09585)	July 2, 2015	Appendix A
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			

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 September 30, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2015 and March 31, 2015; (ii) Condensed Consolidated Statements of Operations for the three and six months ended September 30, 2015 and 2014; (iii) Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended September 30, 2015 and 2014; (iv) Condensed Consolidated Statements of Cash Flows for the six months ended September 30, 2015 and 2014; and (v) Notes to Condensed Consolidated Financial Statements.	X

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**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: November 4, 2015

/s/ MICHAEL J. TOMSICEK  
**Michael J. Tomsicek**  
**Vice President and Chief Financial Officer**  
**(Principal Accounting and Financial Officer)**