

ABIOMED INC  
Form 10-Q  
November 10, 2014  
Table of Contents

**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, 2014**

**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)**  
**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)**

**04-2743260**  
**(IRS Employer**  
**Identification No.)**

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

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

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of October 31, 2014, 40,894,675 shares of the registrant's common stock, \$.01 par value, were outstanding.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I - FINANCIAL INFORMATION:</u></b>	
Item 1. <u>Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2014 (unaudited) and March 31, 2014</u>	3
<u>Condensed Consolidated Statements of Operations for the three and six months ended September 30, 2014 and 2013 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Comprehensive (Loss) Income for the three and six months ended September 30, 2014 and 2013 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the six months ended September 30, 2014 and 2013 (unaudited)</u>	6
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	28
Item 4. <u>Controls and Procedures</u>	28
<b><u>PART II - OTHER INFORMATION:</u></b>	
Item 1. <u>Legal Proceedings</u>	29
Item 1A. <u>Risk Factors</u>	29
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
Item 3. <u>Defaults Upon Senior Securities</u>	29
Item 4. <u>Mine Safety Disclosures</u>	29
Item 5. <u>Other Information</u>	29
Item 6. <u>Exhibits</u>	30
<b><u>SIGNATURES</u></b>	<b>31</b>
<b>NOTE REGARDING COMPANY REFERENCES</b>	

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 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. IMPELLA and RECOVER are trademarks of Abiomed Europe GmbH, a subsidiary of ABIOMED, Inc., and are 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, 2014</b>	<b>March 31, 2014</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 17,483	\$ 20,916
Short-term marketable securities	77,981	55,663
Accounts receivable, net	23,072	24,357
Inventories	13,445	13,948
Prepaid expenses and other current assets	3,310	3,082
Total current assets	135,291	117,966
Long-term marketable securities	16,473	41,761
Property and equipment, net	7,351	6,889
Goodwill	36,867	37,990
In-process research and development	17,198	
Long-term deferred tax assets	813	
Other assets	1,551	801
Total assets	\$ 215,544	\$ 205,407
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,616	\$ 7,746
Accrued expenses	13,762	17,899
Deferred revenue	5,756	4,766
Total current liabilities	27,134	30,411
Other long-term liabilities	210	228
Contingent consideration	5,797	
Long-term deferred tax liabilities	6,865	6,415
Total liabilities	40,006	37,054

## 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 417 411

Authorized - 100,000,000 shares; Issued - 41,831,077 shares at

September 30, 2014 and 41,122,695 shares at March 31, 2014;

Outstanding - 40,577,134 shares at September 30, 2014 and

39,916,328 shares at March 31, 2014

Additional paid in capital 447,433 436,136

Accumulated deficit (248,780) (250,910)

Treasury stock at cost - 1,253,943 shares at September 30, 2014 and

1,206,367 shares at March 31, 2014 (17,567) (16,554)

Accumulated other comprehensive loss (5,965) (730)

Total stockholders' equity 175,538 168,353

Total liabilities and stockholders' equity \$ 215,544 \$ 205,407

*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 OPERATIONS**

(Unaudited)

(in thousands, except per share data)

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

*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 (LOSS) INCOME****(Unaudited)****(in thousands, except per share data)**

	<b>Three Months Ended September 30,</b>		<b>Six Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net income (loss)	\$ 3,839	\$ 1,059	\$ 2,130	\$ (664)
Other comprehensive (loss) income:				
Foreign currency translation (losses) gains	(4,804)	1,795	(5,240)	2,321
Net unrealized (losses) gains on marketable securities	(22)	31	5	10
Other comprehensive (loss) income	(4,826)	1,826	(5,235)	2,331
Comprehensive (loss) income	\$ (987)	\$ 2,885	\$ (3,105)	\$ 1,667

*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>Six Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
Operating activities:		
Net income (loss)	\$ 2,130	\$ (664)
Adjustments required to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	1,196	1,322
Bad debt expense	27	15
Stock-based compensation	8,314	6,719
Write-down of inventory	559	537
Deferred tax provision	450	453
Change in fair value of contingent consideration	219	
Changes in assets and liabilities:		
Accounts receivable	1,108	1,912
Inventories	(653)	(876)
Prepaid expenses and other assets	(139)	(762)
Accounts payable	(581)	(1,494)
Accrued expenses and other long-term liabilities	(3,732)	(1,978)
Deferred revenue	1,004	(62)
Net cash provided by operating activities	9,902	5,122
Investing activities:		
Purchases of marketable securities	(44,920)	(33,849)
Proceeds from the sale and maturity of marketable securities	47,890	25,750
Acquisition of ECP and AIS, net of cash assumed	(15,697)	
Purchase of other investment	(750)	(750)
Purchases of property and equipment	(1,496)	(1,236)
Net cash used for investing activities	(14,973)	(10,085)
Financing activities:		
Proceeds from the exercise of stock options	2,560	5,318
Payments in lieu of issuance of common stock for minimum payroll taxes	(1,013)	(426)
Proceeds from the issuance of stock under employee stock purchase plan	397	312
Net cash provided by financing activities	1,944	5,204
Effect of exchange rate changes on cash	(306)	428

Edgar Filing: ABIOMED INC - Form 10-Q

Net (decrease) increase in cash and cash equivalents	(3,433)	669
Cash and cash equivalents at beginning of period	20,916	9,451
Cash and cash equivalents at end of period	\$ 17,483	\$ 10,120

Supplemental disclosure of cash flow information:

Cash paid for income taxes	\$ 299	\$ 870
Supplemental disclosure of non-cash investing and financing activities:		
Contingent consideration related to acquisition of ECP	6,000	
Fixed asset expenditures incurred, not yet paid	577	92

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

**Table of Contents**

**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 or Abiomed), 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, 2014 that has been filed with the Securities and Exchange Commission, or SEC.

In the opinion of management, the accompanying unaudited consolidated financial statements include all adjustments, which are of a normal recurring nature, 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, 2014 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, 2014 that has been filed with the SEC, except for as noted below.

***In-Process Research and Development***

In-process research and development (IPR&D) assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D represents the fair value assigned to technologies that the Company acquires, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs when the Company has regulatory approval and is able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

***Contingent Consideration***

As discussed in Note 3. Acquisitions, on July 1, 2014, the Company acquired all of the issued shares of ECP Entwicklungsgesellschaft GmbH, a German limited liability company, or ECP, 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. These milestone payments may be made, at the Company's option, by a combination of cash or Abiomed common stock.

Contingent consideration is recorded as a liability and measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate commensurate with the risks of the expected cash flows attributable to the various milestones. The material factors that may impact the fair value of the contingent consideration, and therefore this liability, are the probabilities of achieving the related milestones and the discount rate. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The fair value of the contingent consideration, and the associated liability at each reporting date, will be updated by reflecting the changes in fair value reflected in the Company's statement of operations.

### ***Recent Accounting Pronouncements***

In May 2014, the Financial Accounting Standards Board 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

**Table of Contents**

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 2017. Early adoption is not permitted. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

**Note 2. Net Income (Loss) Per Share**

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing net income (loss) 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 awards, 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 (loss) per share for the three and six months ended September 30, 2014 and 2013 were as follows (in thousands, except per share data):

	<b>Three Months Ended September 30,</b>		<b>Six Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
<b>Basic Net Income (Loss) Per Share</b>				
Net income (loss)	\$ 3,839	\$ 1,059	\$ 2,130	\$ (664)
Weighted average shares used in computing basic net income (loss) per share	40,448	39,260	40,256	38,971
Net income (loss) per share - basic	\$ 0.09	\$ 0.03	\$ 0.05	\$ (0.02)
<b>Diluted Net Income (Loss) Per Share</b>				
Net income (loss)	\$ 3,839	\$ 1,059	\$ 2,130	\$ (664)
Weighted average shares used in computing basic net income (loss) per share	40,448	39,260	40,256	38,971
Effect of dilutive securities	1,791	2,077	1,813	

Weighted average shares used in computing diluted net income (loss) per share	42,239	41,337	42,069	38,971
Net income (loss) per share - diluted	\$ 0.09	\$ 0.03	\$ 0.05	\$ (0.02)

For the three months ended September 30, 2014, approximately 47,000 shares underlying stock options primarily related to out-of-the-money stock options and approximately 465,000 restricted shares primarily 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 six months ended September 30, 2014, approximately 44,000 shares underlying stock options primarily related to out-of-the-money stock options and approximately 465,000 restricted shares primarily 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 months ended September 30, 2013, approximately 297,000 shares underlying stock options primarily related to out-of-the-money stock options and approximately 354,000 restricted shares primarily 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 six months ended September 30, 2013, approximately 3,923,000 shares underlying stock options and approximately 1,198,000 restricted shares were excluded from the calculation of diluted weighted average shares outstanding because the Company incurred a loss in the period.

---

**Table of Contents****Note 3. Acquisitions*****Acquisition of ECP Entwicklungsgesellschaft mbH***

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

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

***Preliminary Purchase Price Allocation***



The acquisition 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 purchase price allocation presented herein is preliminary. The final purchase price allocation will be determined after completion of an analysis to determine the fair value of all assets acquired and liabilities assumed, but in no event later than one year following completion of the acquisition. Accordingly, the final acquisition accounting adjustments could differ materially from the preliminary amounts presented herein. Any increase or decrease in the fair value of the assets acquired and liabilities assumed, as compared to the information shown herein, could also change the portion of purchase price allocated to goodwill, and could impact the operating results of the Company following the acquisition due to differences in purchase price allocation, depreciation and amortization related to some of these assets and liabilities.

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

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

**Table of Contents**

The following table summarizes the preliminary 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	874
Other assets acquired	141
<b>Total assets acquired</b>	<b>22,176</b>
Liabilities assumed:	
Accounts payable	295
Accrued liabilities	131
<b>Total liabilities assumed</b>	<b>426</b>
<b>Net assets acquired</b>	<b>\$ 21,750</b>

IPR&D is principally the estimated fair value of the ECP and AIS technology which had not reached commercial technological feasibility nor had alternative future use and therefore 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 is not expected to be deductible for income tax purposes.

All legal, consulting and other costs related to the acquisition, aggregating approximately \$1.1 million, have been expensed as incurred and are included in selling, general and administrative expenses in our consolidated statements of operations. The results of operations for ECP and AIS are included in the Company's condensed consolidated statements of operations for the period from the July 1, 2014 acquisition date to September 30, 2014. The Company recorded no material revenues and incurred \$1.1 million in net losses for the three months ended September 30, 2014 associated with the operations of ECP after the July 1, 2014 acquisition. This also includes a \$0.2 million expense for the change in fair value of the contingent consideration for the three months ended September 30, 2014.

The following unaudited pro forma information presents the combined results of operations for the three and six months ended September 30, 2014 and 2013, as if we had completed the ECP and AIS acquisitions at the beginning of fiscal 2014. The pro forma financial information is provided for comparative purposes only and is not necessarily indicative of what actual results would have been had the acquisition occurred on the date indicated, nor does it give effect to synergies, cost savings, fair market value adjustments, immaterial amortization expense and other changes expected to result from the acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period.

The pro forma consolidated financial information has been calculated after applying the Company's accounting policies and includes adjustments for transaction-related costs, to eliminate revenues earned by AIS from ECP and expenses paid by ECP to AIS associated with a license agreement between the two parties, interest expense incurred by ECP related to bank loans accounted as if the repayment of ECP debt had occurred on April 1, 2013 and was not outstanding during the periods, and income tax provision of AIS due to the elimination of revenue on the license agreement with ECP.

**Table of Contents**

	Three Months Ended		Six Months Ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
	(in \$000 s)		(in \$000 s)	
Revenue	\$ 51,938	\$ 44,359	\$ 100,761	\$ 87,042
Income before income tax provision	4,557	329	2,770	(1,850)
Net income (loss)	4,218	(41)	2,260	(2,631)

**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, 2014 and March 31, 2014 are invested in the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in \$000 s)			
At September 30, 2014:				
US Treasury securities	\$ 19,487	\$	\$	\$ 19,487
Short-term government-backed securities	58,480	17	(3)	58,494
Long-term government-backed securities	16,498	3	(28)	16,473
	\$ 94,465	\$ 20	\$ (31)	\$ 94,454

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in \$000 s)			
At March 31, 2014:				
US Treasury securities	\$ 31,487	\$	\$	\$ 31,487
Short-term government-backed securities	24,174	6	(4)	24,176
Long-term government-backed securities	41,779	8	(26)	41,761
	\$ 97,440	\$ 14	\$ (30)	\$ 97,424

**Fair Value Hierarchy**

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

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

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

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

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

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

**Table of Contents**

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 consolidated balance sheet, classified according to the three categories described above:

	Level 1	Level 2	Level 3	Fair Value
	(in \$000 s)			
<b>At September 30, 2014:</b>				
<b>Assets</b>				
U.S. Treasury securities	\$	\$ 19,487	\$	\$ 19,487
Short-term government-backed securities		58,494		58,494
Long-term government-backed securities		16,473		16,473
<b>Liabilities</b>				
Contingent consideration			5,797	5,797

	Level 1	Level 2	Level 3	Fair Value
	(in \$000 s)			
<b>At March 31, 2014:</b>				
U.S. Treasury securities	\$	\$ 31,487	\$	\$ 31,487
Short-term government-backed securities		24,176		24,176
Long-term government-backed securities		41,761		41,761

The Company has determined that the estimated fair value of its investments in U.S. Treasury securities, short-term government-backed securities and long-term government-backed securities are reported as Level 2 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 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.

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, 2014:

	September 30, 2014
	(in \$000 s)
Beginning balance	\$
Additions	6,000
Payments	

Change in fair value	219
Foreign currency translation impact	(422)
Ending balance	\$ 5,797

The change in fair value of the contingent consideration of \$0.2 million for the six months ended September 30, 2014 was primarily due to an increase in fair value due to the effect of the passage of time on the fair value measurement and the impact of foreign currency exchange rates. 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.

**Table of Contents**

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements classified in Level 3 as of September 30, 2014:

	Fair Value at September 30, 2014 ( in \$000 s)		Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent consideration	\$ 5,797	Probability weighted	Milestone dates	2018 to 2021
		income approach		
			Discount rate	8% to 12%
			Probability of occurrence	0% to 100%

**Other Investment**

In May 2013, the Company invested \$0.8 million in preferred stock of a private technology company. In addition, the Company committed to invest an additional \$0.7 million if the private technology company achieves certain milestones or receives shareholder approval requesting the additional funding. In September 2014, the private technology company requested this additional funding and the Company paid the additional \$0.7 million. There are no additional outstanding funding commitments associated with this investment.

This other investment is accounted for using the cost method and is measured at fair value on a nonrecurring basis only if there are identified events or change in circumstances that may have a significant adverse effect on the fair value of these investments. The aggregate carrying amount of this other investment was \$1.5 million and \$0.8 million at September 30, 2014 and March 31, 2014, respectively, and is classified within other assets in the unaudited condensed consolidated balance sheets.

**Note 5. Inventories**

The components of inventories are as follows:

	September 30, 2014	March 31, 2014
	(in \$000 s)	
Raw materials and supplies	\$ 6,052	\$ 6,414
Work-in-progress	5,718	6,261
Finished goods	1,675	1,273
	\$ 13,445	\$ 13,948

The Company's inventories relate to its circulatory care product lines, primarily the Impella and AB5000 product platforms. Finished goods and work-in-process inventories consist of direct material, labor and overhead. During the six months ended September 30, 2014 and 2013, the Company recorded \$0.6 million and \$0.5 million, respectively, in write-downs of inventory.



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

Goodwill has been recorded in connection with the Company's acquisitions of Impella Cardiosystems AG, or Impella, in 2005 and ECP and AIS in July 2014, as discussed in Note 3. Acquisitions. The carrying value of goodwill and the change in the balance for the six months ended September 30, 2014 is as follows:

	<b>September 30, 2014</b>
	<b>(in \$000 s)</b>
Beginning balance	\$ 37,990
Additions	1,964
Foreign currency translation impact	(3,087)
Ending balance	\$ 36,867

The Company has no accumulated impairment losses on goodwill.

***In-Process Research and Development***

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 the 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 and taking into account the stage of development of the technology at the acquisition date, 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.

**Table of Contents**

The carrying value of the Company's IPR&D assets and the change in the balance for the six months ended September 30, 2014 is as follows:

	<b>September 30, 2014</b>
	<b>(in \$000 s)</b>
Beginning balance	\$
Additions	18,500
Foreign currency translation impact	(1,302)
Ending balance	\$ 17,198

**Note 7. Accrued Expenses**

Accrued expenses consist of the following:

	<b>September 30, 2014</b>	<b>March 31, 2014</b>
	<b>(in \$000 s)</b>	
Employee compensation	\$ 9,083	\$ 11,967
Research and development	1,161	1,587
Professional, legal and accounting fees	1,021	1,304
Sales and income taxes	1,000	1,445
Warranty	775	794
Other	722	802
	<b>\$ 13,762</b>	<b>\$ 17,899</b>

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at September 30, 2014 and March 31, 2014.

**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 consolidated statements of operations for the three and six months ended September 30, 2014 and 2013:

	<b>Three Months Ended</b>		<b>Six Months</b>	
	<b>September 30,</b>		<b>Ended</b>	
	<b>2014</b>	<b>2013</b>	<b>September 30,</b>	<b>2013</b>
	<b>(in \$000 s)</b>		<b>(in \$000 s)</b>	
Cost of product revenue	\$ 148	\$ 139	\$ 357	\$ 347
Research and development	773	540	1,626	1,285
Selling, general and administrative	3,103	2,119	6,331	5,087
	\$ 4,024	\$ 2,798	\$ 8,314	\$ 6,719

The components of stock-based compensation for the three and six months ended September 30, 2014 and 2013 were as follows:

	<b>Three Months Ended</b>		<b>Six Months</b>	
	<b>September 30,</b>		<b>Ended</b>	
	<b>2014</b>	<b>2013</b>	<b>September 30,</b>	<b>2013</b>
	<b>(in \$000 s)</b>		<b>(in \$000 s)</b>	
Restricted stock units and awards	\$ 3,334	\$ 2,162	\$ 6,754	\$ 5,098
Stock options	624	598	1,423	1,523
Employee stock purchase plan	66	38	137	98
	\$ 4,024	\$ 2,798	\$ 8,314	\$ 6,719

**Stock Options**

The following table summarizes the stock option activity for the six months ended September 30, 2014:

	<b>Shares</b>	<b>Weighted</b>	<b>Weighted</b>	<b>Aggregate</b>
	<b>Underlying</b>	<b>Average</b>	<b>Average</b>	<b>Intrinsic</b>
	<b>Options</b>	<b>Exercise</b>	<b>Remaining</b>	<b>Value</b>
	<b>(in thousands)</b>	<b>Price</b>	<b>Contractual</b>	<b>(in thousands)</b>
			<b>Term (years)</b>	
Outstanding at April 1, 2014	3,492	\$ 13.27	4.92	
Granted	313	22.26		
Exercised	(222)	11.49		

Edgar Filing: ABIOMED INC - Form 10-Q

Cancelled and expired	(5)	15.66		
Outstanding at September 30, 2014	3,578	\$ 14.16	5.04	\$ 38,287
Exercisable at September 30, 2014	2,787	\$ 11.94	3.99	\$ 35,928
Options vested and expected to vest at September 30, 2014	3,502	\$ 14.00	4.97	\$ 38,013

The aggregate intrinsic value of options exercised was \$3.0 million for the six months ended September 30, 2014. The total fair value of options vested during the six months ended September 30, 2014 was \$1.7 million.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at September 30, 2014 was approximately \$5.7 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 2.5 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, 2014 and 2013 was \$9.05 and \$9.67 per share, respectively.

**Table of Contents**

The fair value of options granted during the three and six months ended September 30, 2014 and 2013 were calculated using the following weighted average assumptions:

	Three Months Ended		Six Months Ended	
	September 30, 2014	2013	September 30, 2014	2013
Risk-free interest rate	1.75%	1.39%	1.60%	0.85%
Expected option life (years)	4.19	4.23	4.19	4.26
Expected volatility	48.7%	50.6%	49.3%	51.9%

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 reflect that historical forfeitures may not be indicative of forfeitures in the future.

**Restricted Stock and Restricted Stock Units**

In addition to stock option grants, the Company also has the ability to grant restricted stock and restricted stock units. Similar to stock options, these restricted stock and restricted stock unit grants are subject to certain vesting criteria. The following table summarizes the activity for the six months ended September 30, 2014:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value (per share)
Outstanding at April 1, 2014	1,174	\$ 21.37
Granted	664	21.88
Vested	(465)	20.48
Forfeited	(121)	23.10
Outstanding at September 30, 2014	1,252	\$ 21.80

The remaining unrecognized compensation expense for outstanding restricted stock awards and restricted stock units, including performance-based awards, as of September 30, 2014 was \$17.0 million and the weighted-average period over which this cost will be recognized is 2.0 years.

The weighted average grant-date fair value for restricted stock and restricted stock units granted during the six months ended September 30, 2014 and 2013 was \$21.88 and \$23.18 per share, respectively. The total fair value of restricted

stock and restricted stock units vested during the six months ended September 30, 2014 and 2013 was \$9.5 million and \$6.0 million, respectively.

***Performance Based Awards***

Included in the restricted stock and restricted stock units activity discussed above are certain awards that vest subject to certain performance-based criteria.

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. As of September 30, 2014, the Company is recognizing compensation expense based on the probable outcome related to the prescribed performance milestones on the outstanding awards.

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. As of September 30, 2014, the Company has met the prescribed performance milestones for these awards such that 154,991 shares of common stock will vest subject to service requirements for vesting for these employees and the compensation expense is being recognized accordingly.

---

**Table of Contents**

In May 2012, performance-based awards of restricted stock units for the potential issuance of 195,188 shares of common stock were issued to certain executive officers and employees of the Company, all of which will vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of September 30, 2014, the Company has met the prescribed performance milestones for these awards. These awards are still subject to service requirements for vesting for these employees and the compensation expense is being recognized accordingly.

In May 2011 and June 2011, performance-based awards of restricted stock units for the potential issuance of 284,000 shares of common stock were issued to certain executive officers and members of the senior management of the Company, which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of September 30, 2014, the Company has met the prescribed milestones for 234,000 shares underlying these awards and recorded all related stock compensation expense. In March 2014, the Company modified the performance condition on the remaining 50,000 restricted stock units. As of September 30, 2014, the Company believes that it is probable that the prescribed performance milestones will be met on these restricted stock units and the compensation expense is being recognized accordingly.

During the three and six months ended September 30, 2014, the Company has recorded \$2.1 million and \$3.7 million, respectively, in stock-based compensation expense for equity awards in which the prescribed performance milestones have been achieved or are probable of being achieved. The remaining unrecognized compensation expense related to these equity awards at September 30, 2014 is \$8.0 million based on the Company's current assessment of probability of achieving the performance milestones. The weighted-average period over which this cost will be recognized is 1.8 years.

**Note 9. Income Taxes**

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts at each fiscal year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce net deferred tax assets to the amount that is more likely than not to be realized.

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realization of deferred tax assets requires significant management judgment. In determining whether its deferred tax assets are more likely than not realizable, the Company evaluated all available positive and negative evidence, and weighted the evidence based on its objectivity. Evidence the Company considered included its history of net operating losses incurred for most of its existence, expiration of various federal and state attributes, the uncertainty relative to the Marketing and Labelling Investigation and the FCA Investigation (each as defined below in Note 10. Commitments and Contingencies Litigation ) of the Company and the Company's Pre-Market Approval, or PMA, application with the U.S. Food and Drug Administration, or FDA, for its Impella products, the Company's expansion into new markets, such as Japan, the government reimbursement environment for the Company's products, the Company's profitability for recent years and uncertainties around the Company's future profitability. Based on the review of all available evidence, the Company determined that the objectively verifiable negative evidence outweighed the positive evidence and it recorded a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realizable as of September 30, 2014. The Company will continue to assess the level of the valuation allowance required. If sufficient positive evidence exists in future periods to support a release of some or all of the valuation allowance, such a release would likely have a material impact on its results of operations.

As of September 30, 2014, the Company has accumulated a long-term deferred tax liability of \$6.9 million as the result of a difference in accounting for the Company's goodwill associated with its Impella acquisition that was completed in May 2005, which is amortizable over 15 years for tax purposes but not amortizable for book purposes. The net long-term deferred tax liability cannot be offset against the Company's deferred tax assets since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period. As of September 30, 2014, the Company has net long-term deferred tax assets of \$0.8 million relating to differences between the book and tax basis of assets and liabilities associated with the ECP acquisition completed in July 2014.

The Company is subject to U.S. federal income tax, as well as income tax of multiple state and foreign jurisdictions. The Company has accumulated significant losses since its inception in 1981. All tax years remain subject to examination by major tax jurisdictions, including the federal government and the Commonwealth of Massachusetts. 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.

#### **Note 10. Commitments and Contingencies**

##### ***Commitments***

In July 2013, the Company entered into a lease agreement to continue renting its existing space in Aachen, Germany through July 31, 2023. The building serves as the Company's European headquarters and houses most of the manufacturing operations for its Impella product line. The lease payments are approximately 34,500 (euro) (approximately U.S. \$44,000 at September 30, 2014 exchange rates) per month.



## **Table of Contents**

In February 2014, the Company entered into a lease agreement to continue renting its existing space in Danvers, Massachusetts through February 28, 2021. Monthly rent is as follows:

The base rent for March 2014 through April 2014 was \$66,000 per month; and

The base rent for May 2014 through February 2016 is \$74,050 per month; and

The base rent for March 2016 through February 2018 will be \$70,750 per month; and

The base rent for March 2018 through February 2021 will be \$72,750 per month.

## ***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.

## ***Contingent Consideration***

As discussed in Note 3. Acquisitions, in July 2014, the Company acquired ECP using a combination of cash and potential post-acquisition milestone payments. These milestone payments may be payable at some time over the next 20 years, depending on the achievement of certain technical, regulatory and commercial milestones. The maximum amount of the aggregate milestone payments could be \$15.0 million. As of September 30, 2014, the fair value of the contingent consideration was \$5.8 million.

## ***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 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 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 (the Marketing and Labelling 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 related to the Impella 2.5. The Company believes that it has substantially complied with the subpoena and has submitted the requested documents to the United States Attorney's Office. On September 13, 2013, the Company entered into a tolling agreement with the United States Attorney's Office, pursuant to which the Company and the United States Attorney's Office mutually agreed to toll the applicable

statutes of limitations for all criminal, civil and administrative offenses and violations that could be charged or claimed against the Company as of that date until June 2, 2014. On May 27, 2014, the Company executed an extension of the tolling agreement through February 2, 2015. The investigation is ongoing, however, and the Company is unable to predict the ultimate outcome or determine whether a liability has been incurred or make an estimate of the reasonably possible liability, if any, that could result from any unfavorable outcome associated with this investigation. The Company has incurred significant expenses related to this investigation and expects to continue to incur additional expenses in the future.

On November 16 and 19, 2012, two purported class action complaints were filed against the Company and certain of its officers in the U.S. District Court for the District of Massachusetts, or the District Court, by alleged purchasers of its common stock, on behalf of themselves and persons or entities that purchased or acquired common stock of the Company between August 5, 2011 and October 31, 2012. The complaints alleged that the defendants violated the federal securities laws in connection with disclosures related to the Company's marketing and labeling of the Impella 2.5 product and seek damages in an unspecified amount. The District Court consolidated these complaints and a consolidated amended complaint was filed by the plaintiffs on May 20, 2013. On July 8, 2013, the Company filed a motion to dismiss the consolidated class action. Oral arguments on the Company's motion to dismiss were conducted before the District Court on September 18, 2013. On April 10, 2014, the District Court entered an order granting the Company's motion and dismissed the consolidated and amended complaint. On May 9, 2014, the plaintiffs filed a notice of appeal, and subsequently filed their appellate brief with the U.S. Court of Appeals for the First Circuit, or the First Circuit, on July 16, 2014. The appeal process remains ongoing with oral arguments scheduled for January 8, 2015.

On February 4, 2013, an alleged stockholder of the Company filed a derivative action with the District Court on the Company's behalf against each of the Company's directors. The complaint alleged that the directors breached their fiduciary duties to the Company and its stockholders in connection with disclosures related to the Company's marketing and labeling of its Impella 2.5

---

**Table of Contents**

product and sought damages in an unspecified amount. On March 22, 2013, the Company filed a motion to dismiss the derivative action. On June 21, 2013, the District Court granted the Company's motion to dismiss. The plaintiff appealed the dismissal to the First Circuit. The First Circuit affirmed the District Court's Order of Dismissal in a written opinion issued on June 10, 2014.

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") and, together with the Marketing and Labelling Investigation, the "DOJ Investigations"). 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 document production relating to this matter for the time period of January 1, 2012 through December 31, 2013. The Company intends to respond to the CID and cooperate with the U.S. Attorney's Office in connection with the FCA investigation.

The Company is unable to estimate a potential liability with respect to the DOJ Investigations and the appeal of the dismissal of the purported class action claim. There are numerous factors that make it difficult to meaningfully estimate possible loss or range of loss at this stage of these investigations and lawsuits, including that: the proceedings are in relatively early stages, there are significant factual and legal issues to be resolved and information obtained or rulings made during any lawsuits or investigations could affect the methodology for calculation. In addition, with respect to claims for which damages are the requested relief, no amount of loss or damages has been specified. Therefore, the Company is unable at this time to estimate its 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 66% and 74% of the Company's total consolidated assets are located within the U.S. as of September 30, 2014 and March 31, 2014, respectively. The remaining assets are located primarily in Germany and include goodwill and in-process research and development of \$54.1 million and \$35.4 million at September 30, 2014 and March 31, 2014, respectively, associated with the Impella acquisition in May 2005 and ECP acquisition in July 2014. Total assets outside of the U.S. excluding goodwill and in-process research and development amounted to 9% of total consolidated assets as of September 30, 2014 and March 31, 2014. International sales (primarily in Europe) accounted for 11% of total revenue for each of the three and six months ended September 30, 2014 and 7% and 8% of total revenue for the three and six months ended September 30, 2013, respectively.

---

**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 (the Exchange Act). 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 litigation, and expenditures related thereto; plans with respect to clinical trials; our expectations with respect to submissions to and approvals from regulatory bodies, such as the FDA, including, with respect to the PMA submission for the Impella 2.5, our expectation that we no longer need or anticipate the requirement for an FDA panel and expect PMA approval by February or March 2015 and our plans to submit Impella 5.0 and Impella CP as PMA supplements; the development of new and existing products and anticipated costs, including research and development, sales and marketing and training costs associated with product development; expected capital expenditures for the fiscal year ending March 31, 2014; commercial plans for our products, including the launch of Impella CP; demand and expected shipments of our products; anticipated shifts in the revenue mix associated with our products; 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 costs, 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, 2014 and Item 1A of Part II of this Report on Form 10-Q, 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 otherwise 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 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 and/or performing the pumping function of the heart. Our 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. We believe heart recovery is the optimal clinical outcome for patients experiencing heart failure because it 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 Impella family of 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. 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. Our Impella 2.5, Impella 5.0, Impella LD and Impella CP products also have CE Mark approval and Health Canada approval which allow us to market these devices in the European Union, or E.U., and Canada.

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 revenues from our non-Impella products, primarily AB5000, will continue to decrease as we continue to focus on 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 device received 510(k) clearance from the FDA in June 2008 for partial circulatory support for up to six hours, has CE mark approval in Europe for up to five days of use and is approved for use in over 40 countries.

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.

In August 2007, we received approval from the FDA to begin a high-risk percutaneous coronary intervention, or PCI, pivotal clinical trial, known as the Protect II study, for the Impella 2.5. This pivotal study was a superiority study to determine the safety and effectiveness of the Impella 2.5 as compared to medical management with an intra-aortic balloon, or IAB, during high-risk angioplasty procedures. In December 2010, we announced the termination of the Protect II study based on a futility determination at the planned interim analysis regarding the primary end-point, which we view as likely to have resulted from how rotational atherectomy was performed by investigators in the study.

---

**Table of Contents**

In November 2011, we announced additional analysis of the results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 22% relative reduction in major adverse events compared to an IAB at 90 days per protocol ( $p=0.023$ ), a 52% relative reduction in repeat revascularization ( $p=0.024$ ) and a 56% relative reduction in material adverse events post hospital discharge ( $p=0.002$ ). Furthermore, additional data analysis of the clinical data from the Protect II trial revealed that more aggressive revascularization is beneficial for patients with coronary artery disease and reduced left ventricular function.

A November 2011 update to the American College of Cardiology Foundation (ACCF) /American Heart Association (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 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 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 for the first time for patients with multi-organ failure.

We are currently conducting USpella, the first U.S. multicenter observational registry collecting clinical data and outcomes for general use patients supported with the Impella 2.5, CP, and 5.0 during procedures. In December 2012, as part of the FDA's 515 Program Initiative, an FDA panel voted to recommend continuation of Class III status for temporary ventricular support devices within the non-roller type cardiopulmonary bypass blood pumps category, which includes our Impella products. The panel's recommendation of Class III for this category of device is consistent with the current Class III designation for these device types. The FDA accepted the panel's recommendation recently as reflected in its issuance of a Proposed Order reflecting this categorization.

Pursuant to discussions with the FDA, we submitted a modular PMA submission for Impella 2.5. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. In July 2013, we received written notification that the FDA has reviewed our proposed PMA shell for modular review of Impella 2.5. The FDA has confirmed that it agrees with our proposed shell. In March 2014, we submitted all of the modules required by the FDA as part of the planned modular PMA submission. The PMA will be treated as a standard PMA and all modules have now been consolidated for final review by the FDA. In October 2014, we announced that we and the FDA have agreed on the indication for use for high-risk PCI for the Impella 2.5 PMA. Based on the information available to us to date, including multiple discussions with the FDA, we no longer anticipate the requirement for an FDA panel and expect PMA approval for the safety and effectiveness of the Impella 2.5 by February or March 2015.

Following approval of the Impella 2.5, we plan to submit the Impella 4.0 and Impella CP as PMA supplements. Until the PMA supplement approval process is completed, the Impella 5.0 and Impella CP will remain on the market under the existing 510(k) clearances.

***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 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. We began selling Impella CP in the U.S. during the second quarter of fiscal 2013.

***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 quickly implanted via a small incision in the femoral artery in the groin using a guide wire to reach the left ventricle of the heart where it can then be directly deployed to draw blood out of the ventricle, deliver it to the arterial system and perfuse the heart muscle. This function is intended to reduce ventricular work. 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.

## **Table of Contents**

### ***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 will be applied towards the submission of a Humanitarian Device Exemption, or HDE. In May 2014, we received approval for implementation of a Continuous Access Protocol, or CAP, from the FDA for the RECOVER RIGHT trial. The CAP will allow us to enroll up to 22 additional patients at the 15 U.S. investigational sites for a six month period, from the date of the CAP approval. In September 2014, we announced clinical trial results on the RECOVER RIGHT study that showed a survival rate of 73% in the overall patient population that participated in the study.

We expect HDE approval for the Impella RP by February or March 2015. 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. Approval of 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 E.U. and other countries that require a CE Marking approval for sales. This product is not currently available for commercial use outside of Europe.

### ***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.

### ***Symphony***

In November 2011, we announced Symphony, a synchronized minimally invasive implantable cardiac assist device designed to treat chronic patients with moderate heart failure by improving patient hemodynamics and potentially improving their quality of life. The device is designed with the primary goal of stabilizing the progression of heart failure and recovering or remodeling the heart. To date, we have implanted the device in four patients in first-in-human clinical trials of Symphony outside the U.S. We are evaluating the results of these cases and expect to conduct additional Symphony trials outside of the U.S. in the future. Symphony is not currently approved by the FDA for sale in the U.S.

### **Acquisition of ECP**

On July 1, 2014, we acquired all of the issued shares of ECP Entwicklungsgesellschaft GmbH, a German limited liability company, or ECP, 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. 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.

### **Legal Proceedings**

We are the subject of various pending or threatened legal actions and proceedings that arise in the ordinary course of our business. Such matters are subject to many uncertainties and outcomes that are not predictable with assurance and that may not be known for extended periods of time. Any material legal proceedings are discussed in Note 10. Commitments and Contingencies Litigation in the Notes to Condensed Consolidated Financial Statements and are incorporated herein by reference. Since the outcome of such lawsuits or other proceedings cannot be predicted with certainty, the costs associated with such proceedings could have a material adverse effect on our financial condition, results of operations and cash flows.

## **Table of Contents**

### **Summary of Recent Financial Performance**

For the three and six months ended September 30, 2014, we recognized net income of \$3.8 million and \$2.1 million, respectively. We may incur losses in the future as we continue to invest in research and development related to our products, conduct clinical studies and registries on our products, support our PMA submission, expand our commercial infrastructure, incur additional legal fees to comply with the ongoing DOJ Investigations and defend ourselves from other legal claims, pay additional excise taxes, incur additional expenses for activities related to the ECP business that we acquired in July 2014, enter into collaborations with other parties and invest in new markets such as Japan.

### **Critical Accounting Policies**

There have been no changes in our critical accounting policies during the six months ended September 30, 2014, 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, 2014, except for as noted below.

### ***In-Process Research and Development***

In-process research and development ( IPR&D ) assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D represents the fair value assigned to technologies that we acquire, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if we become aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs when we have regulatory approval and are able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, we may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

### ***Contingent Consideration***

Contingent consideration is recorded as a liability and measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate commensurate with the risks of the expected cash flows attributable to the various milestones. The material factors that may impact the fair value of the contingent consideration, and therefore this liability, are the probabilities of achieving the related milestones and the discount rate. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The fair value of the contingent consideration, and the associated liability at each reporting date, will be updated by reflecting the changes in fair value reflected in our statement of operations.

### ***Recent Accounting Pronouncements***

Information regarding recent accounting pronouncements is included in Note 1. Recent Accounting Pronouncements to our Condensed Consolidated Financial Statements in this Report.



**Table of Contents****Results of Operations**

The following table sets forth certain consolidated statements of operations data for the periods indicated as a percentage of total revenue for the three and six months ended September 30, 2014 and 2013, respectively:

	<b>Three Months Ended September 30, 2014</b>		<b>Six Months Ended September 30, 2013</b>	
<b>Revenue:</b>				
Product	99.7%	99.9%	99.7%	99.9%
Funded research and development	0.3	0.1	0.3	0.1
Total revenue	100.0	100.0	100.0	100.0
<b>Costs and expenses:</b>				
Cost of product revenue	18.5	20.3	19.2	20.4
Research and development	16.8	17.4	17.6	17.2
Selling, general and administrative	56.7	59.1	60.6	62.3
Total costs and expenses	92.0	96.8	97.4	99.9
Income from operations	8.0	3.2	2.6	0.1
Other income and income tax provision	0.6	0.8	0.5	0.9
Net income (loss)	7.4%	2.4%	2.1%	(0.8)%

*Three and six months ended September 30, 2014 compared with the three and six months ended September 30, 2013*

**Revenues**

Our revenues are comprised of the following:

	<b>Three Months Ended September 30, 2014</b>		<b>Six Months Ended September 30, 2013</b>	
	<b>(in \$000 s)</b>		<b>(in \$000 s)</b>	
Impella product revenue	\$ 46,910	\$ 40,167	\$ 91,885	\$ 78,821
Service and other revenue	3,297	2,574	6,577	5,190
Other product revenue	1,567	1,547	1,972	2,886
Total product revenue	51,774	44,288	100,434	86,897

Funded research and development	164	57	315	118
Total revenue	\$ 51,938	\$ 44,345	\$ 100,749	\$ 87,015

Impella product revenue encompasses Impella 2.5, Impella CP, Impella 5.0, Impella LD and Impella RP product sales. Other product revenue includes AB5000, BVS5000 and cannulae product sales. Service and other revenue represents revenue earned on preventative maintenance service contracts and maintenance calls.

Total revenues for the three months ended September 30, 2014 increased by \$7.6 million, or 17%, to \$51.9 million from \$44.4 million for the three months ended September 30, 2013. Total revenues for the six months ended September 30, 2014 increased by \$13.7 million, or 16%, to \$100.7 million from \$87.0 million for the six months ended September 30, 2013. The increase in total revenue was primarily due to higher Impella product revenue from increased utilization in the U.S., which was attributable in part to the increased use of Impella CP.

Impella product revenue for the three months ended September 30, 2014 increased by \$6.7 million, or 17% to \$46.9 million from \$40.2 million for the three months ended September 30, 2013. Impella product revenue for the six months ended September 30, 2014 increased by \$13.1 million, or 17% to \$91.9 million from \$78.8 million for the six months ended September 30, 2013. Most of the increase in Impella product revenue was from disposable 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. Impella product revenue outside the U.S., primarily in Europe, also increased during the three and six months ended September 30, 2014. We expect Impella product revenue to continue to increase as we add new customer sites, increase utilization at existing customer sites and continue our commercial launch of Impella CP.

---

**Table of Contents**

Service and other revenue for the three months ended September 30, 2014 increased by \$0.7 million, or 27%, to \$3.3 million from \$2.6 million for the three months ended September 30, 2013. Service and other revenue for the six months ended September 30, 2014 increased by \$1.4 million, or 27%, to \$6.6 million from \$5.2 million for the six months ended September 30, 2013. The increase in service and other revenue was primarily due to an increase in revenue earned under service contracts. The increase in service contract revenue was due to the increased number of Impella consoles at customer sites, many of which have related service contracts for product maintenance.

Other product revenue for the three months ended September 30, 2014 decreased by \$0.1 million, or 7%, to \$1.6 million from \$1.5 million for the three months ended September 30, 2013. Other product revenue for the six months ended September 30, 2014 decreased by \$0.9 million, or 31%, to \$2.0 million from \$2.9 million for the six months ended September 30, 2013. The decrease in other product revenue was due to our discontinuation of sales of our BVS 5000 product and a significant decline in AB5000 disposable sales, particularly in the U.S. We expect that AB5000 revenue will continue to decline as we focus our sales efforts in the surgical suite on Impella 5.0 and LD.

**Costs and Expenses**

Our costs and expenses are comprised of the following:

***Cost of Product Revenue***

Cost of product revenue for the three months ended September 30, 2014 and 2013, respectively, was \$9.6 million and \$9.0 million. Gross margin was 82% for the three months ended September 30, 2014 compared to 80% for the three months ended September 30, 2013. Cost of product revenue for the six months ended September 30, 2014 and 2013, respectively, was \$19.3 million and \$17.8 million. Gross margin was 81% for the six months ended September 30, 2014 compared to 80% for the six months ended September 30, 2013. The increase in cost of product revenue was related to increased Impella product demand and costs to support the higher demand for Impella products. Gross margin for the three and six months ended September 30, 2014 was impacted favorably by lower shipments of consoles and improved efficiencies in manufacturing production. We expect that the shipments of consoles will continue at approximately the current level for the remainder of fiscal 2015.

***Research and Development Expenses***

Research and development expenses for the three months ended September 30, 2014 increased by \$1.0 million, or 13%, to \$8.7 million from \$7.7 million for the three months ended September 30, 2013. Research and development expenses for the six months ended September 30, 2014 increased by \$2.8 million, or 19%, to \$17.8 million from \$15.0 million for the six months ended September 30, 2013.

The increase in research and development expenses for the three months ended September 30, 2014 was primarily due to operating expenses associated with the ECP facility in Berlin that we incurred after the ECP acquisition on July 1, 2014. The increase in research and development expense for the six months September 30, 2014 was due primarily to a \$1.5 million up-front license payment made to Opsens, Inc. in April 2014 and operating expenses associated with the ECP facility in Berlin that we incurred after the ECP acquisition on July 1, 2014. We expect research and development expenses to increase in the remainder of fiscal 2015 as we continue to pursue our PMA application for our existing Impella products available for sale in the U.S., work on other clinical studies and registries and apply for regulatory approval for our Impella products in Japan. In addition, we expect to incur additional costs as we continue to focus on new product development initiatives associated with Impella RP, Impella CP, Symphony and developing recently acquired ECP technology.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses for the three months ended September 30, 2014 increased by \$3.3 million, or 13%, to \$29.5 million from \$26.2 million for the three months ended September 30, 2013. Selling, general and administrative expenses for the six months ended September 30, 2014 increased by \$6.9 million, or 13%, to \$61.1 million from \$54.2 million for the six months ended September 30, 2013.

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 and additional legal and professional expenses related to the ECP acquisition. These amounts were offset by lower legal expenses related to the DOJ Investigations and shareholder suits discussed in Note 10. Commitments and Contingencies Litigation, in the Notes to Condensed Consolidated Financial Statements.

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. We also plan to increase our marketing, service and training investments to support the efforts of the sales and field clinical teams to drive recovery awareness for acute heart failure patients. For the foreseeable future, we

---

**Table of Contents**

also expect to continue to incur significant legal expenses related to the DOJ Investigations and our defense of the purported class action for the foreseeable future, each discussed in Note 10. Commitments and Contingencies Litigation in the Notes to Condensed Consolidated Financial Statements.

***Provision for Income Taxes***

During the three months ended September 30, 2014 and 2013, we recorded a provision for income taxes of \$0.3 million and \$0.4 million, respectively. During the six months ended September 30, 2014 and 2013, we recorded an income tax provision of \$0.6 million and \$0.8 million, respectively. The income tax provision for the three and six months ended September 30, 2014 is 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 (Loss)***

During the three months ended September 30, 2014, we recorded net income of \$3.8 million, or \$0.09 per basic and diluted share, compared to net income of \$1.1 million, or \$0.03 per basic and diluted share, for the three months ended September 30, 2013. During the six months ended September 30, 2014, we recorded net income of \$2.1 million, or \$0.05 per basic and diluted share, compared to net loss of \$0.7 million, or \$0.02 per basic and diluted share, for the six months ended September 30, 2013.

The increase in net income in for the three and six months ended September 30, 2014 was primarily due to higher Impella product revenue due to greater utilization in the U.S. and Europe and lower legal expenses related to the DOJ Investigations and shareholder suits. We may incur losses in the future as we continue to invest in research and development related to our products, conduct clinical studies and registries on our products, support our PMA submission, expand our commercial infrastructure, incur additional legal fees to comply with the ongoing DOJ Investigations and defend ourselves from other legal claims, pay additional excise taxes, incur additional expenses for activities related to the ECP business we acquired in July 2014, enter into collaborations with other parties and invest in new markets, such as Japan.

***Liquidity and Capital Resources***

At September 30, 2014, our cash, cash equivalents, and short and long-term marketable securities totaled \$111.9 million, a decrease of \$6.4 million compared to \$118.3 million in cash, cash equivalents and short-term and long-term marketable securities at March 31, 2014. The decrease in our cash, cash equivalents, and short and long-term marketable securities was due to the ECP and AIS acquisitions discussed above in Overview Acquisition of ECP, and was offset by positive cash flow from operations in fiscal 2015. We paid approximately \$15.7 million in net cash for the initial purchase price of these acquisitions. We also could be required to pay up to an additional \$15.0 million, which may be paid, at our discretion, as cash, shares of our common stock or a combination of both, in connection with the acquisition of ECP, if certain technical, regulatory and commercial milestones are met. We also expect to incur additional expenses with the operation of ECP as we do not expect to have revenues from these businesses in the near future.

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 Impella manufacturing capacity, increase our inventory levels in order to meet increasing customer demand for



Impella in the U.S., fund new product development, prepare for commercial launches of Impella in new markets in the future, such as Japan, pay for legal fees related to the DOJ Investigations, our defense of the appeal relating to the dismissal of purported class actions against us, our response to information requests and to provide for general working capital needs. Through September 30, 2014, we have funded our operations principally from product sales and through the sale of equity securities. We also receive a small amount of funding from government research and development grants.

Marketable securities at September 30, 2014 consisted of \$94.5 million held in funds that invest in U.S. Treasury and government-backed securities. 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.

During the six months ended September 30, 2014, net cash provided by operating activities was \$9.9 million, compared to \$5.1 million during the same period in the prior year. The increase in cash provided by operating activities was primarily attributable to the increase in net income of \$2.8 million reflected in our net income of \$2.1 million for the six months ended September 30, 2014 compared to our net loss of \$0.7 million for the same period in the prior year, partially offset by a \$0.8 million decrease in cash used for accounts receivable due to timing of receivable collections. In addition, net cash provided by operating activities was impacted by changes in non-cash adjustments, including a \$1.6 million increase in stock-based compensation and a \$0.2 million change in fair value of contingent consideration due to the effect of the passage of time on the fair value measurement.

**Table of Contents**

During the six months ended September 30, 2014, net cash used for investing activities was \$15.0 million, compared to \$10.1 million during the same period in the prior year. The increase in net cash used for investing activities was primarily attributable to \$15.7 net cash used for our acquisition of ECP and AIS, an \$11.1 million decrease in marketable securities in the current year due to the redemption of marketable securities to assist in funding the ECP and AIS acquisitions. Our cash used for capital expenditures increased by \$0.3 million during the six months ended September 30, 2014, as compared to the same period in the prior year. We also made an \$0.8 million investment in a private medical technology company during each of the six months ended September 30, 2014 and 2013, respectively.

During the six months ended September 30, 2014, net cash provided by financing activities was \$1.9 million, compared to \$5.2 million during the same period in the prior year. The decrease in net cash provided by financing activities was primarily attributable to a \$2.8 million decrease in proceeds from the exercise of stock options and a \$0.6 million increase in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards.

Capital expenditures for fiscal 2015 are estimated to range from \$3.0 to \$5.0 million, and are expected to be for manufacturing capacity increases for Impella products, leasehold improvements and software development projects.

Cash and cash equivalents held by our foreign subsidiaries totaled \$4.9 million and \$3.3 million at September 30, 2014 and March 31, 2014, respectively. The increase in cash and cash equivalents held by our foreign subsidiaries was due to the transfer of cash to our German subsidiary to fund the operations of ECP and AIS after we acquired these entities on July 1, 2014.

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.

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, invest in collaborative arrangements with other partners and 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 DOJ Investigations, our defense of the appeal of the dismissal of the purported class action and our response to requests for information. We continue to review our long-term cash needs on a regular basis. At September 30, 2014, we had no long-term debt outstanding.

**Table of Contents**

**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. Marketable securities at September 30, 2014 consist of \$94.5 million held in funds that invest in U.S. Treasury and government-backed securities. If market interest rates were to increase immediately and uniformly by 10 percent from levels at September 30, 2014, 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 (loss) income 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, 2014, the result would have been a reduction of stockholders' equity of approximately \$5.3 million.

***Fair Value of Financial Instruments***

At September 30, 2014, our financial instruments consist primarily of cash and cash equivalents, short-term and long-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 Exchange Act of 1934, as of September 30, 2014. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2014, 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, 2015, 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.

---

**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 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 consolidated financial statements. Material legal proceedings are discussed in Note 10. Commitments and Contingencies Litigation in the Notes to 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 1, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended March 31, 2014, 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, 2014, except as noted below:

***We have incurred losses in previous periods and may incur losses in future periods.***

For the years ended March 31, 2014 and 2013, we recognized net income of approximately \$7.4 million and \$15.0 million, respectively. For the year ended March 31, 2012, we were essentially break-even as we recognized a net income of \$1.5 million. Prior to fiscal 2012, we had incurred losses and had no history of profitability. The profitability we achieved in recent years may not be indicative of our ability to sustain profitability and we may incur losses from operations in future periods. We historically have incurred net losses from our operations. Any losses incurred in the future may result primarily from, among other things, the expansion of our global distribution network, investments in new markets such as Japan, ongoing product and clinical development, costs related to new business development initiatives and legal and other expenses related to the DOJ Investigations, including our compliance with the subpoena received from the U.S. Department of Justice in October 2012, the subpoena we received from the Boston regional office of the U.S. Department of Health and Human Services, Office of Inspector General in April 2014 and the CID we received from the United States Attorney's Office for the District of Massachusetts in November 2014 and our defense of other legal claims. Additionally, due to the introduction of the U.S. medical device tax in January 2013 we began incurring a 2.3% excise tax on the sales of certain of our products in the U.S. regardless of whether we are profitable or not. These expenditures may include costs associated with hiring additional personnel, performing clinical trials, continuing our research and development relating to our products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing activities. The amount of these expenditures is difficult to forecast accurately and cost overruns may occur. We also expect that we will make significant expenditures to market and manufacture in commercial quantities our approved circulatory care products, and any other new products for which we may incur additional expense to obtain regulatory approvals or clearances in the future.

***We must comply with healthcare fraud and abuse laws, and we could face substantial penalties for non-compliance and be excluded from government healthcare programs, which would adversely affect our business, financial condition and results of operations.***

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights may be applicable to our business. We may be subject to healthcare fraud and abuse regulation and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

The federal healthcare program Anti-Kickback Statute, which prohibits, among other things, soliciting, receiving or providing remuneration, directly or indirectly, to induce (i) the referral of an individual, for an item or service, or (ii) the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

Federal false claims laws which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us that promote medical devices, provide medical device management services and may provide coding and billing advice to customers;

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

State law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ in significant ways from state to state and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota, requiring reporting to state governments of gifts, compensation and other remuneration to physicians. The Physician Payments Sunshine Act, or PPSA, which was signed into law on March 23, 2010, requires manufacturers of drug, device, biologics, and medical supplies covered under Medicare, Medicaid, or State Children's Health Insurance Program, or SCHIP, to report payments made to physicians on an annual basis to the U.S. Department of Health and Human Services, or HHS. Companies were required to start collecting this data on August 1, 2013 and are required to report this information to HHS in 2014. These laws all provide for penalties for non-compliance. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and reporting requirements, increases the possibility that we may run afoul of one or more laws. On April 25, 2014, we received a subpoena from the Boston regional office of the United States Department of Health and Human Services, Office of Inspector General requesting materials relating to our reimbursement of expenses and remuneration to healthcare providers during the period of July 2012 through December 2012. On November 6, 2014, we received a CID requesting additional document production relating to this matter for the time period of January 1, 2012 through December 31, 2013.

Many of these requirements are new and their application is uncertain, and regulatory guidance is limited. We could face enforcement action, fines and other penalties and could receive adverse publicity, all of which could harm our business, if it is alleged that we have failed to fully comply with such laws and regulations. Similarly, if the physicians or other providers or entities that we do business with are found not to comply with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

***Our operating results may fluctuate unpredictably.***

Historically, our annual and quarterly operating results have fluctuated widely and we expect these fluctuations to continue. Among the factors that may cause our operating results to fluctuate are:

the timing of customer orders and deliveries;

competitive changes, such as price changes or new product introductions that we or our competitors may make;

the timing of regulatory actions, such as product approvals or recalls;

costs we incur developing and testing our Impella heart pumps and other products;

costs we incur in anticipation of future sales, such as inventory purchases, expansion of manufacturing facilities, or establishment of international sales offices;

costs we incur in connection with the class action suits and derivative action that has been filed against us;

costs we incur in connection with the DOJ Investigations;

additional taxes, such as the Medical Device tax;

timing of certain marketing programs and events;

economic conditions in the healthcare industry; and

efforts by governments, insurance companies and others to contain health care costs, including changes to reimbursement policies.

We believe that period-to-period comparisons of our historical results are not necessarily meaningful, and investors should not rely on them as an indication of our future performance. To the extent we experience the factors described above, our future operating results may not meet the expectations of securities analysts or investors from time to time, which may cause the market price of our common stock to decline.

**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	10-K	May 27, 2004 (File No. 001-09585)	3.2
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock.	S-3	September 29, 1997	3.3
3.4	Amendment to the Company's Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000.	8-K	March 21, 2007 (File No. 001-09585)	3.4
4.1	Specimen Certificate of common stock.	S-1	June 5, 1987	4.1
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, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2014 and March 31, 2014; (ii) Condensed Consolidated Statements of Operations for the three and six months	X		

ended September 30, 2014 and September 30, 2013; (iii) Condensed Consolidated Statements of Comprehensive (Loss) Income for the three and six months ended September 30, 2014 and September 30, 2013; (iv) Condensed Consolidated Statements of Cash Flows for the six months ended September 30, 2014 and September 30, 2013; and (v) Notes to Condensed Consolidated Financial Statements.

Table of Contents

**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 10, 2014

/s/ ROBERT L. BOWEN

**Robert L. Bowen**

**Vice President and Chief Financial Officer**

**(Principal Accounting and Financial Officer)**