

ABIOMED INC  
Form 10-Q  
August 07, 2013  
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 June 30, 2013

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)

Edgar Filing: ABIOMED INC - Form 10-Q

**DELAWARE**  
(State or other jurisdiction of  
incorporation or organization)

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

**22 CHERRY HILL DRIVE**

**DANVERS, MASSACHUSETTS 01923**

(Address of principal executive offices, including zip code)

**(978) 646-1400**

(Registrant's telephone number, including area code)

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

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

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 July 31, 2013, 39,282,153 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</u>	3
<u>Consolidated Balance Sheets as of June 30, 2013 (unaudited) and March 31, 2013</u>	3
<u>Consolidated Statements of Operations for the three months ended June 30, 2013 and 2012 (unaudited)</u>	4
<u>Consolidated Statements of Comprehensive (Loss) Income for the three months ended June 30, 2013 and 2012 (unaudited)</u>	5
<u>Consolidated Statements of Cash Flows for the three months ended June 30, 2013 and 2012 (unaudited)</u>	6
<u>Notes to Consolidated Financial Statements (unaudited)</u>	7
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	22
<b><u>PART II - OTHER INFORMATION:</u></b>	
Item 1. <u>Legal Proceedings</u>	23
Item 1A. <u>Risk Factors</u>	23
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
Item 3. <u>Defaults Upon Senior Securities</u>	24
Item 4. <u>Mine Safety Disclosures</u>	24
Item 5. <u>Other Information</u>	24
Item 6. <u>Exhibits</u>	25
<b><u>SIGNATURES</u></b>	<b>26</b>

ABIOMED, ABIOCOR, IMPELLA CP, and Symphony are trademarks of ABIOMED, Inc., and are registered in the U.S. and certain foreign countries. The U.S. Trademark Application for IMPELLA CP is pending and additional foreign applications will be filed taking advantage of the U.S. filing date. 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****CONSOLIDATED BALANCE SHEETS****(in thousands, except share and per share data)**

	<b>June 30, 2013</b> <b>(unaudited)</b>	<b>March 31, 2013</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,727	\$ 9,451
Short-term marketable securities	55,725	67,256
Accounts receivable, net	20,983	22,946
Inventories	16,513	14,930
Prepaid expenses and other current assets	1,737	2,022
Total current assets	106,685	116,605
Long-term marketable securities	20,588	11,406
Property and equipment, net	6,479	6,549
Goodwill	35,932	35,410
Other assets	779	29
Total assets	\$ 170,463	\$ 169,999
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,270	\$ 7,696
Accrued expenses	12,829	15,162
Deferred revenue	3,993	4,198
Total current liabilities	23,092	27,056
Long-term deferred tax liability	5,781	5,554
Other long-term liabilities	285	309
Total liabilities	29,158	32,919
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value		
Authorized - 1,000,000 shares; Issued and outstanding - none		
Common stock, \$.01 par value	401	397
Authorized - 100,000,000 shares; Issued - 40,218,485 shares at June 30, 2013 and 39,788,383 shares at March 31, 2013;		
Outstanding - 39,012,118 shares at June 30, 2013 and 38,601,384 shares at March 31, 2013		
Additional paid in capital	420,674	414,810
Accumulated deficit	(259,984)	(258,261)
Treasury stock at cost - 1,206,367 shares at June 30, 2013 and 1,186,999 shares at March 31, 2013	(16,554)	(16,129)
Accumulated other comprehensive loss	(3,232)	(3,737)

Edgar Filing: ABIOMED INC - Form 10-Q

Total stockholders' equity	141,305	137,080
Total liabilities and stockholders' equity	\$ 170,463	\$ 169,999

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

**Table of Contents**

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

(Unaudited)

(in thousands, except per share data)

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Revenue:</b>		
Product revenue	\$ 42,609	\$ 38,647
Funded research and development	61	136
	42,670	38,783
<b>Costs and expenses:</b>		
Cost of product revenue	8,723	7,446
Research and development	7,287	6,712
Selling, general and administrative	27,967	20,953
Amortization of intangible assets		111
	43,977	35,222
(Loss) income from operations	(1,307)	3,561
<b>Other expense:</b>		
Investment income (expense), net	16	(2)
Other expense, net	(21)	(4)
	(5)	(6)
(Loss) income before income tax provision	(1,312)	3,555
Income tax provision	411	436
Net (loss) income	\$ (1,723)	\$ 3,119
Basic net (loss) income per share	\$ (0.04)	\$ 0.08
Basic weighted average shares outstanding	38,678	39,144
Diluted net (loss) income per share	\$ (0.04)	\$ 0.08
Diluted weighted average shares outstanding	38,678	41,549

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

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

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
Net (loss) income	\$ (1,723)	\$ 3,119
Other comprehensive income (loss):		
Foreign currency translation gains (losses)	526	(2,577)
Net unrealized losses on marketable securities	(21)	
Other comprehensive income (loss)	505	(2,577)
Comprehensive (loss) income	\$ (1,218)	\$ 542

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

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

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Operating activities:</b>		
Net (loss) income	\$ (1,723)	\$ 3,119
Adjustments required to reconcile net (loss) income to net cash (used for) provided by operating activities:		
Depreciation and amortization	652	842
Bad debt expense	15	8
Stock-based compensation	3,921	2,679
Write-down of inventory	207	252
Deferred tax provision	226	90
Changes in assets and liabilities:		
Accounts receivable	1,971	2,032
Inventories	(1,689)	(1,982)
Prepaid expenses and other assets	292	(65)
Accounts payable	(1,302)	(300)
Accrued expenses and other long-term liabilities	(2,397)	(2,024)
Deferred revenue	(206)	(333)
Net cash (used for) provided by operating activities	(33)	4,318
<b>Investing activities:</b>		
Purchases of marketable securities	(15,401)	(11,500)
Proceeds from the sale and maturity of marketable securities	17,750	5,500
Purchase of other investment	(750)	
Purchases of property and equipment	(711)	(470)
Net cash provided by (used for) investing activities	888	(6,470)
<b>Financing activities:</b>		
Proceeds from the exercise of stock options	1,931	1,228
Payments in lieu of issuance of common stock for minimum payroll taxes	(426)	(238)
Net cash provided by financing activities	1,505	990
Effect of exchange rate changes on cash	(84)	(839)
Net increase (decrease) in cash and cash equivalents	2,276	(2,001)
Cash and cash equivalents at beginning of period	9,451	5,990
Cash and cash equivalents at end of period	\$ 11,727	\$ 3,989
<b>Supplemental disclosures:</b>		
Fixed asset expenditures incurred, not yet paid	\$ 86	\$ 92

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



**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****NOTES TO 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 in heart recovery 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 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, 2013 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.

There have been no changes in the Company's significant accounting policies for the three months ended June 30, 2013 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, 2013 that has been filed with the SEC.

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

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted average number of common shares outstanding during the period. Diluted net (loss) income per share is computed by dividing net (loss) income by the weighted average number of dilutive common shares outstanding during the period. Diluted shares outstanding are calculated by adding to the weighted average shares outstanding any potential dilutive securities outstanding for the period. Potential dilutive securities include stock options, restricted stock 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 (loss) income per share for the three months ended June 30, 2013 and 2012 were as follows (in thousands, except per share data):

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Basic Net (Loss) Income Per Share</b>		
Net (loss) income	\$ (1,723)	\$ 3,119
<b>Weighted average shares used in computing basic net (loss) income per share</b>		
	38,678	39,144
Net (loss) income per share - basic	\$ (0.04)	\$ 0.08

Edgar Filing: ABIOMED INC - Form 10-Q

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Diluted Net (Loss) Income Per Share</b>		
Net (loss) income	\$ (1,723)	\$ 3,119
Weighted average shares used in computing basic net (loss) income per share	38,678	39,144
Effect of dilutive securities		2,405
Weighted average shares used in computing diluted net (loss) income per share	38,678	41,549
Net (loss) income per share - diluted	\$ (0.04)	\$ 0.08

For the three months ended June 30, 2013, approximately 4,326,000 shares underlying stock options and approximately 1,168,000 restricted shares were excluded from the calculation of diluted weighted average shares outstanding because the Company incurred a loss in the period and to include them would have been anti-dilutive.

**Table of Contents**

For the three months ended June 30, 2012, approximately 490,000 shares of common stock underlying outstanding securities, primarily related to out-of-the-money stock options and performance-based awards where milestones were not met, were not included in the computation of diluted earnings per share because their inclusion would have been anti-dilutive.

**Note 3. 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 June 30, 2013 and March 31, 2013 are invested in the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in \$000 s)			
At June 30, 2013:				
US Treasury securities	\$ 43,116	\$	\$	\$ 43,116
Short-term government-backed securities	12,609	1	(1)	12,609
Long-term government-backed securities	20,607	1	(20)	20,588
	\$ 76,332	\$ 2	\$ (21)	\$ 76,313

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in \$000 s)			
At March 31, 2013:				
US Treasury securities	\$ 59,020	\$	\$	\$ 59,020
Short-term government-backed securities	8,235	1		8,236
Long-term government-backed securities	11,405	3	(2)	11,406
	\$ 78,660	\$ 4	\$ (2)	\$ 78,662

**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.

## Edgar Filing: ABIOMED INC - Form 10-Q

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

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

**Table of Contents**

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	Total
	(in \$000 s)			
At June 30, 2013:				
U.S. Treasury securities	\$	\$ 43,116	\$	\$ 43,116
Short-term government-backed securities		12,609		12,609
Long-term government-backed securities		20,588		20,588
	\$	\$ 76,313	\$	\$ 76,313

	Level 1	Level 2	Level 3	Total
	(in \$000 s)			
At March 31, 2013:				
U.S. Treasury securities	\$	\$ 59,020	\$	\$ 59,020
Short-term government-backed securities		8,236		8,236
Long-term government-backed securities		11,406		11,406
	\$	\$ 78,662	\$	\$ 78,662

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 otherwise at the Company's option. 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 changes in circumstance that may have a significant adverse effect on the fair value of these investments. The aggregate carrying amount of this other investment was \$0.8 million as of June 30, 2013 and is classified within other assets in the unaudited condensed consolidated balance sheets.

**Note 4. Inventories**

The components of inventories are as follows:

	June 30, 2013	March 31, 2013
	(in \$000 s)	
Raw materials and supplies	\$ 7,178	\$ 6,267
Work-in-progress	6,285	5,296
Finished goods	3,050	3,367
	\$ 16,513	\$ 14,930

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 three months ended June 30, 2013 and 2012, the Company recorded \$0.2 million and \$0.3 million, respectively, in write-downs of inventory.

**Table of Contents****Note 5. Goodwill**

The carrying amount of goodwill at June 30, 2013 and March 31, 2013 was \$35.9 million and \$35.4 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG, or Impella, in 2005. The goodwill activity for the three months ended June 30, 2013 is as follows:

	(in \$000 s)
Balance at March 31, 2013	\$ 35,410
Exchange rate impact	522
<b>Balance at June 30, 2013</b>	<b>\$ 35,932</b>

**Note 6. Accrued Expenses**

Accrued expenses consist of the following:

	June 30, 2013	March 31, 2013
	(in \$000 s)	
Employee compensation	\$ 6,955	\$ 9,664
Professional, legal and accounting fees	2,102	1,100
Sales and income taxes	1,609	2,107
Research and development	934	1,025
Warranty	667	708
Other	562	558
	<b>\$ 12,829</b>	<b>\$ 15,162</b>

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at June 30, 2013 and March 31, 2013.

**Table of Contents****Note 7. 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 months ended June 30, 2013 and 2012:

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
	<b>(in \$000 s)</b>	
Cost of product revenue	\$ 208	\$ 146
Research and development	745	563
Selling, general and administrative	2,968	1,970
	<b>\$ 3,921</b>	<b>\$ 2,679</b>

The components of stock-based compensation for the three months ended June 30, 2013 and 2012 were as follows:

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
	<b>(in \$000 s)</b>	
Restricted stock units	\$ 2,644	\$ 1,323
Stock options	925	970
Restricted stock	292	338
Employee stock purchase plan	60	48
	<b>\$ 3,921</b>	<b>\$ 2,679</b>

**Stock Options**

The following table summarizes the stock option activity for the three months ended June 30, 2013:

	<b>Shares Underlying Options (in thousands)</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Outstanding at April 1, 2013	4,228	\$ 11.49	5.37	
Granted	298	23.10		
Exercised	(192)	10.04		
Cancelled and expired	(8)	10.29		
Outstanding at June 30, 2013	4,326	\$ 12.35	5.51	\$ 40,584
Exercisable at June 30, 2013	3,493	\$ 10.78	4.72	\$ 37,729
Options vested and expected to vest at June 30, 2013	4,186	\$ 12.24	5.42	\$ 39,701

The aggregate intrinsic value of options exercised was \$2.3 million for the three months ended June 30, 2013. The total fair value of options vested during the three months ended June 30, 2013 was \$2.2 million.

## Edgar Filing: ABIOMED INC - Form 10-Q

The remaining unrecognized stock-based compensation expense for unvested stock option awards at June 30, 2013 was approximately \$5.7 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 3.1 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 three months ended June 30, 2013 and 2012 was \$9.68 and \$10.13 per share, respectively.



**Table of Contents**

The fair value of options granted during the three months ended June 30, 2013 and 2012 were calculated using the following weighted average assumptions:

	Three Months Ended June 30,	
	2013	2012
Risk-free interest rate	0.85%	0.78%
Expected option life (years)	4.26	4.33
Expected volatility	51.9%	56.3%

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on the historical volatility of the Company's stock and adjustments for factors not reflected in historical volatility that may be more indicative of future volatility. The Company estimates the expected term of options based on historical exercise experience and estimates of future exercises of unexercised options. An expected dividend yield of zero is used in the option valuation model because the Company does not pay cash dividends and does not expect to pay any cash dividends in the foreseeable future. The Company estimates forfeitures based on an analysis of actual historical forfeitures, adjusted to 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 three months ended June 30, 2013:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value (per share)
Outstanding at April 1, 2013	1,022	\$ 18.44
Granted	503	23.15
Vested	(346)	16.61
Forfeited	(11)	21.15
Outstanding at June 30, 2013	1,168	\$ 20.98

The remaining unrecognized compensation expense for outstanding restricted stock awards and restricted stock units, including performance-based awards, as of June 30, 2013 was \$14.7 million and the weighted-average period over which this cost will be recognized is 2.3 years.

The weighted average grant-date fair value for restricted stock and restricted stock units granted during the three months ended June 30, 2013 and 2012 was \$23.15 and \$22.40 per share, respectively. The total fair value of restricted stock and restricted stock units vested during the three months ended June 30, 2013 and 2012 was \$5.7 million and \$2.9 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 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 June 30, 2013, the Company is recognizing compensation expense based on the probable

outcome related to the prescribed performance targets on these awards.

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 June 30, 2013, 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, all of which will vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of June 30, 2013, the Company has met the prescribed milestones for 209,000 shares underlying these awards and believes it is probable that the prescribed performance milestones will be met for the remaining 75,000 shares, and the compensation expense is being recognized accordingly.

---

**Table of Contents**

During the three months ended June 30, 2013, the Company recorded \$1.7 million 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 June 30, 2013 is \$6.8 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 2.3 years.

**Note 8. Income Taxes**

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases 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 net operating losses incurred from the Company's inception to March 31, 2011, expiration of various federal and state tax attributes, the uncertainty relative to the Department of Justice investigation of the Company and the Company's planned PMA application for its Impella products, profits before tax for fiscal 2012 and 2013, current period net loss and forecasted profit before tax for fiscal 2014. Based on its review of all available evidence, the Company determined that the objectively verifiable negative evidence outweighed the positive evidence and continues to record a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realizable as of June 30, 2013 and March 31, 2013.

As of June 30, 2013, the Company has accumulated a net deferred tax liability of \$5.8 million which is the result of the difference in accounting for the Company's goodwill, which is amortizable over 15 years for tax purposes but not amortizable for book purposes. The net 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.

The Company and its subsidiaries are 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. However, 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 9. 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. \$45,000 at June 30, 2013 exchange rates) per month.

***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 United States Attorney's Office for the District of Columbia is conducting an investigation that is 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. The subpoena seeks documents related to the Impella 2.5. The Company is in the process of responding and intends to cooperate fully with the subpoena. Because the investigation is in the early stages, management 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

## Edgar Filing: ABIOMED INC - Form 10-Q

any unfavorable outcome associated with this inquiry. The Company can anticipate, however, that it will incur significant expenses related to this investigation.

## **Table of Contents**

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 by alleged purchasers of its common stock, on behalf of themselves and persons or entities that purchased or acquired securities 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 FDA and the marketing and labeling of the Company's Impella 2.5 product and seek damages in an unspecified amount. The Court has 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.

On February 4, 2013, an alleged stockholder of the Company filed a derivative action on the Company's behalf against each of the Company's directors in the U.S. District Court for the District of Massachusetts. The complaint alleged that the directors breached their fiduciary duties to the Company and its stockholders in connection with disclosures related to the FDA and the marketing and labeling of the Company's Impella 2.5 product and sought damages in an unspecified amount. On March 22, 2013, the Company filed a motion to dismiss the derivative action due to the plaintiff's failure to make a proper demand on the Company's board of directors. On June 21, 2013, the District Court entered an order granting the Company's motion and dismissing the derivative action in its entirety. On July 19, 2013, the plaintiff filed an appeal of the dismissal in the U.S. First Circuit Court of Appeals.

The Company is unable to estimate its potential liability with respect to the DOJ investigation and the purported class action appeal and derivative claims. There are numerous factors that make it difficult to meaningfully estimate possible loss or range of loss at this stage of the investigation and lawsuits, including that: the proceedings are in relatively early stages, there are significant factual and legal issues to be resolved, information obtained or rulings made during any lawsuits or investigations could affect the methodology for calculation. In addition, with respect to claims where 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 10. 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 71% of the Company's total consolidated assets are located within the U.S. as of June 30, 2013 and March 31, 2013. The remaining assets are located in Europe and are primarily related to the Company's Impella production facility in Germany and include goodwill of \$35.9 million and \$35.4 million at June 30, 2013 and March 31, 2013, respectively, associated with the Impella acquisition in May 2005. Total assets in Europe excluding goodwill amounted to 8% of total consolidated assets at each of June 30, 2013 and March 31, 2013. International sales (sales outside the U.S. and primarily in Europe) accounted for 8% and 5% of total product revenue during the three months ended June 30, 2013 and 2012, respectively.

**Table of Contents****ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Forward Looking Statements**

*Abiomed's discussion of financial condition and results of operations may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Our actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, anticipated future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, market acceptance of our new products, technological change, government regulation, future capital needs and uncertainty of additional financing and other risks detailed in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this Report. In particular, we encourage you to review the risks and uncertainties discussed under Item 1A of Part I of our Annual Report on Form 10-K, for the year ended March 31, 2013. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this Report or to reflect the occurrence of unanticipated events.*

**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 and has been placed at 775 sites since initial launch.

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, we announced that our Impella CP product received 510(k) clearance from the FDA for partial circulatory support for up to six hours. The Impella CP received CE Mark approval to market the device in the European Union and Health Canada approval to market the device in Canada. We initially launched the Impella CP at selected top heart hospitals in the U.S. during the second quarter of fiscal 2013. As of June 30, 2013 we have placed Impella CP at approximately 172 U.S. hospitals.

In November 2012, we announced that the Impella RP received Investigational Device Exemption, or IDE, approval from the FDA for use in RECOVER RIGHT, a pivotal clinical study in the U.S. 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 April 2013, we announced the enrollment of the first patient in RECOVER RIGHT and we expect to enroll 30 patients with signs of right side heart failure and are being treated in the cath lab or surgery suite. We are also conducting initial patient use trials of the Impella RP outside of the U.S. This product is not currently available for commercial use.

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. If the FDA accepts the panel's determination and issues a final order classifying these devices in Class III, we will be required to file a Pre-Market Approval, or PMA application for our Impella products. Under the 515 Program Initiative, we will be permitted to continue to market our Impella products pursuant to the 510(k) clearance for a sufficient period of time to allow for the submission and review of PMA applications relating to our Impella products.

We intend to submit a modular PMA submission for Impella 2.5 by the end of fiscal 2014. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. We are working with the FDA to prepare this modular PMA application for our Impella products. In July 2013, we received written notification that FDA has reviewed our proposed PMA shell for modular review of the Impella 2.5 System. The FDA has confirmed that it agrees with our proposed shell and we have begun submitting modules to the FDA.



---

## **Table of Contents**

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. We are currently conducting first-in-human clinical trials of Symphony outside the U.S. This product is not currently approved by the FDA for sale in the U.S.

On October 26, 2012, we were informed that the United States Attorney's Office for the District of Columbia is conducting an investigation that is focused on the Company's marketing and labeling of the Impella 2.5. On October 31, 2012, we accepted service of a subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5. We are in the process of responding and we intend to cooperate fully with the subpoena.

On November 16 and 19, 2012, two purported class action complaints were filed against us and certain of our officers in the U.S. District Court for the District of Massachusetts by alleged purchasers of our common stock, on behalf of themselves and persons or entities that purchased or acquired our securities 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 FDA and the marketing and labeling of our Impella 2.5 product and seek damages in an unspecified amount. The Court has consolidated these complaints and a consolidated amended complaint was filed by the plaintiffs on May 20, 2013. On July 8, 2013, we filed a motion to dismiss the consolidated class action.

On February 4, 2013, an alleged stockholder of the Company filed a derivative action on our behalf against each of our directors in the U.S. District Court for the District of Massachusetts. The complaint alleged that the directors breached their fiduciary duties to us and our stockholders in connection with disclosures related to the FDA and the marketing and labeling of our Impella 2.5 product and sought damages in an unspecified amount. On March 22, 2013, we filed a motion to dismiss the derivative action due to the plaintiff's failure to make a proper demand on our board of directors. On June 21, 2013, the District Court entered an order granting our motion and dismissing the derivative action in its entirety. On July 19, 2013, the plaintiff filed an appeal of the dismissal in the U.S. First Circuit Court of Appeals.

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 recently 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, including BVS and AB5000, will continue to decrease as we continue to focus on our Impella products.

For the three months ended June 30, 2013, we recognized a net loss of \$1.7 million. We may incur additional 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, expand our commercial infrastructure, pay additional excise taxes as a result of the implementation of the medical device tax in the U.S. in January 2013, incur additional legal fees to comply with the subpoena received from the Department of Justice in October 2012, defend ourselves from other legal claims, incur additional costs in preparing our PMA application and invest in new markets such as Japan.

### ***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.

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 intraortic balloon pump, or IAB, at 90 days per protocol (p=0.023), a 52% relative reduction in repeat





## **Table of Contents**

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 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 Impella 2.5, CP, and 5.0 during procedures. Currently, there are 41 hospitals in the U.S. and Canada contributing data to the USpella registry.

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. If the FDA accepts the panel's determination and issues a final order classifying these devices in Class III, we will be required to file a PMA application for our Impella products. Under the 515 Program Initiative, we will be permitted to continue to market our Impella products pursuant to the 510(k) clearance for a sufficient period of time to allow for the submission and review of PMA applications relating to our Impella products.

We intend to submit a modular PMA submission for Impella 2.5 by the end of fiscal 2014. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. We are working with the FDA to prepare this modular PMA application for our Impella products. In July 2013, we received written notification that FDA has reviewed our proposed PMA shell for modular review of the Impella 2.5 System. The FDA has confirmed that the Agency agrees with our proposed shell and we have begun submitting modules.

### ***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 (previously marketed outside of the U.S. as Impella cVAD) received CE Mark approval to market the device in the European Union in April 2012 and Health Canada approval to market the device in Canada in June 2012. We initiated a controlled launch with top heart hospitals in the U.S. during the second quarter of fiscal 2013, which we expect to continue in fiscal 2014.

### ***Impella 5.0 and Impella LD***

The Impella 5.0 catheter 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.

### ***Impella RP***

In November 2012, we announced that the Impella RP received IDE approval from the FDA for use in RECOVER RIGHT, a pivotal clinical study in the U.S. The Impella RP is a percutaneous catheter-based axial flow pump that is designed to allow greater than four liters of flow per

## Edgar Filing: ABIOMED INC - Form 10-Q

minute and is intended to provide the flow and pressure needed to compensate for right heart failure. The study will enroll 30 patients that present with signs of right side heart failure, require hemodynamic support, and are being treated in

## **Table of Contents**

the catheterization lab or cardiac surgery suite. We announced the first enrollment of a patient in RECOVER RIGHT in April 2013 and we estimate the study will take up to 24 months to complete. The study will collect 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. An HDE is similar to a PMA application but is intended for patient populations of 4,000 or less per year in the U.S and the approval relies on the demonstration of safety and probable benefit a lower success criteria than safety and effectiveness requirement of the 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. We are currently conducting initial patient use trials outside of the U.S. of the Impella RP. This product is not currently available for commercial use.

### ***AB5000 and BVS 5000***

We manufacture and sell the AB5000 Circulatory Support System and the BVS 5000 Biventricular 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 and BVS 5000 systems are the only commercially available cardiac assist devices that are approved by the FDA for all indications where heart recovery is the desired outcome, including patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. We are currently only actively selling the BVS 5000 upon request. We have transitioned our sales focus in the surgery market from the BVS 5000 to the AB5000, the Impella 5.0, and the Impella LD.

### ***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. We are currently conducting first-in-human clinical trials of Symphony outside the U.S. This product is not currently approved by the FDA for sale in the U.S.

### **Critical Accounting Policies**

There have been no significant changes in our critical accounting policies during the three months ended June 30, 2013, 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, 2013.

**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 revenues (which includes revenues from products and funded research and development) for the three months ended June 30, 2013 and 2012, respectively:

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Revenues:</b>		
Product	99.9%	99.6%
Funded research and development	0.1	0.4
 Total revenues	 100.0	 100.0
 <b>Costs and expenses:</b>		
Cost of product revenue	20.4	19.2
Research and development	17.1	17.3
Selling, general and administrative	65.5	54.0
Amortization of intangible assets		0.3
 Total costs and expenses	 103.1	 90.8
 (Loss) income from operations	 (3.1)	 9.2
 Income tax provision	 0.9	 1.2
Net (loss) income	(4.0)%	8.0%

**Three months ended June 30, 2013 compared with the three months ended June 30, 2012****Revenues**

Our revenues are comprised of the following:

	<b>Three Months Ended June 30,</b>	
	<b>2013</b>	<b>2012</b>
	<b>(in \$000 s)</b>	
Impella product revenue	\$ 38,654	\$ 34,676
Service and other revenue	2,616	1,849
Other products	1,339	2,122
 Total product revenues	 42,609	 38,647
Funded research and development	61	136
 Total revenues	 \$ 42,670	 \$ 38,783

Impella product revenue encompasses Impella 2.5, Impella CP, Impella 5.0, and Impella LD 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.

## Edgar Filing: ABIOMED INC - Form 10-Q

Total revenues for the three months ended June 30, 2013 increased by \$3.9 million, or 10%, to \$42.7 million from \$38.8 million for the three months ended June 30, 2012. The increase in total revenue was primarily due to higher Impella revenue due to greater utilization in the U.S., which was attributable in part to the introduction of Impella CP in the second half of fiscal 2013.

Impella product revenues for the three months ended June 30, 2013 increased by \$4.0 million, or 12%, to \$38.7 million from \$34.7 million for the three months ended June 30, 2012. Most of our increase in Impella 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. In the second half of fiscal 2013, we began our initial launch of Impella CP in the U.S. We will continue our controlled commercial launch of Impella CP during fiscal 2014 and we expect Impella revenues to increase as we add new customer sites and increase utilization at existing customer sites.

Service and other revenue for the three months ended June 30, 2013 increased by \$0.8 million, or 44%, to \$2.6 million from \$1.8 million for the three months ended June 30, 2012. The increase in service revenue was primarily due to an increase in service contracts, primarily for Impella consoles.

---

**Table of Contents**

Other product revenues for the three months ended June 30, 2013 decreased by \$0.8 million, or 38%, to \$1.3 million from \$2.1 million for the three months ended June 30, 2012. The decrease in other revenue was due to a decline in BVS 5000 and AB5000 disposable sales. We are currently only actively selling the BVS 5000 upon request and expect that AB5000 revenue will continue to decline in fiscal 2014 as we focus our sales efforts in the surgical suite on Impella 5.0 and LD.

***Cost of Product Revenues***

Cost of product revenue for the three months ended June 30, 2013 increased by \$1.3 million, or 18%, to \$8.7 million from \$7.4 million for the three months ended June 30, 2012. Gross margin for the three months ended June 30, 2013 was 80 % compared to 81% for the three months ended June 30, 2012. The increase in cost of product revenues was related to increased Impella demand and higher production volume and costs to support the higher demand for Impella products. The decrease in gross margin was related primarily to increased investment in expanding manufacturing capacity to support future demand for Impella products and increased shipments of AIC consoles.

***Research and Development Expenses***

Research and development expenses for the three months ended June 30, 2013 increased by \$0.6 million, or 9%, to \$7.3 million from \$6.7 million for the three months ended June 30, 2012. The increase in research and development expenses was due primarily to an increase in spending on product development initiatives associated with Impella CP, RP and Symphony, as well as preparation for our PMA application for our existing Impella products. We expect research and development expenses to increase in fiscal 2014 as we continue to focus on new product development initiatives associated with Impella RP, Impella CP and Symphony. We will also have additional research and development costs as we prepare our PMA application for our existing Impella products available for sale in the U.S. and as we continue to pursue regulatory approval for our Impella products in Japan.

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

Selling, general and administrative expenses for the three months ended June 30, 2013 increased by \$7.0 million, or 33%, to \$28.0 million from \$21.0 million for the three months ended June 30, 2012. The increase in selling, general and administrative expenses was primarily due to increased personnel expenses related to increased U.S. field sales and clinical headcount, increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support, higher stock-based compensation expense and increases in legal expenses. During the three months ended June 30, 2013, we incurred legal expenses of approximately \$2.6 million in connection with complying with the subpoena received from the Department of Justice in October 2012 and defense of other legal claims. We also incurred \$0.6 million of expenses in the three months ended June 30, 2013 as a result of the medical device tax, which was implemented in the U.S. in January 2013.

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. In addition, we will continue to incur expenses as a result of the recently implemented medical device tax. We also expect to continue to incur significant legal expenses related to the Department of Justice investigation, our defense of the purported class action, and our defense of the appeal of the dismissal of the derivative action for the foreseeable future.

***Provision for Income Taxes***

During each of the three months ended June 30, 2013 and 2012, we recorded a provision for income taxes of \$0.4 million. The income tax provision for the three months ended June 30, 2013 is primarily due to income taxes related to our deferred tax liability associated with goodwill, income taxes in Germany that we do not expect will be offset by our net operating loss carryforwards in Germany, that we will pay in cash and certain state income taxes that we do not expect to be offset by state net operating loss carryforwards.

***Net (Loss) Income***

During the three months ended June 30, 2013, we incurred net loss of \$1.7 million, or \$0.04 per basic and diluted share, compared to a net income of \$3.1 million, or \$0.08 per basic and diluted share, for the three months ended June 30, 2012. The decrease in net income in for the three months ended June 30, 2013 was due to higher operating expenses from expanding our commercial infrastructure, additional research and development costs, the implementation of the medical device tax in the U.S. in January 2013, and additional legal fees to comply with the subpoena received from the Department of Justice in October 2012 and defend ourselves from other legal claims. We may incur additional 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, prepare our PMA application, expand our commercial infrastructure, pay additional excise taxes, incur additional legal fees and invest

in new markets such as Japan



---

## **Table of Contents**

### ***Liquidity and Capital Resources***

At June 30, 2013, our cash, cash equivalents and short and long-term marketable securities totaled \$88.0 million, compared to \$88.1 million in cash, cash equivalents and short and long-term marketable securities at March 31, 2013. We believe that our revenues 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, pay for legal fees related to the Department of Justice investigation and our defense of legal actions brought against us, and provide for general working capital needs. Through June 30, 2013, we have funded our operations principally from product sales and through the sale of equity securities.

Marketable securities at June 30, 2013 consisted of \$76.3 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 three months ended June 30, 2013, there was no change in net cash used for or provided by operating activities compared to net cash provided by operating activities of \$4.3 million during the same period in the prior year. The increase in cash used for operations was primarily attributable to our net loss of \$1.7 million for the three months ended June 30, 2013 compared to net income of \$3.1 million for the three months ended June 30, 2012 and a \$1.4 million increase in accounts payable and accrued expenses primarily due to higher legal expenses. These amounts were offset by a \$0.3 million decrease in cash used for inventories, a \$0.4 million decrease in prepaid expenses and other assets and a \$1.2 million increase in stock-based compensation.

During the three months ended June 30, 2013, net cash provided by investing activities was \$0.9 million, compared to net cash used for investing activities of \$6.5 million during the same period in the prior year. The increase in cash provided by investing activities was primarily attributable to a \$12.3 million increase in proceeds from the sale and maturity of marketable securities, offset by a \$3.9 million increase in purchases of marketable securities. We also had a \$0.2 million increase in cash used for capital expenditures and we paid \$0.8 million for an investment in a private technology company.

During the three months ended June 30, 2013, net cash provided by financing activities was \$1.5 million, compared to \$1.0 million during the same period in the prior year. The increase in net cash provided by financing activities was primarily attributable to a \$0.7 million increase in proceeds from the exercise of stock options offset by a \$0.2 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 2014 are estimated to range from \$3.0 to \$5.0 million, and are expected to relate primarily to capital expenditures for manufacturing capacity increases for Impella, leasehold improvements and software development projects.

Cash and cash equivalents held by our foreign subsidiaries totaled \$2.6 million and \$2.8 million at June 30, 2013 and March 31, 2013, respectively. Our operating income outside the U.S. is deemed to be permanently reinvested in foreign jurisdictions. We do not intend or currently foresee a need to repatriate cash and cash equivalents held by our foreign subsidiaries. If these funds are needed in the U.S., we would be required to accrue and pay U.S. taxes to repatriate these funds.

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, and collect cash from clients after our products are sold. We also expect to continue to incur legal expenses related to the Department of Justice investigation, our defense of purported class actions for the foreseeable future. We continue to review our long-term cash needs on a regular basis. At June 30, 2013, 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 short-term marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. Marketable securities at June 30, 2013 consist of \$76.3 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 June 30, 2013, 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 June 30, 2013, the result would have been a reduction of stockholders' equity of approximately \$3.8 million.

#### ***Fair Value of Financial Instruments***

At June 30, 2013, our financial instruments consist primarily of cash and cash equivalents, short-term and long-term marketable securities, accounts receivable, and accounts payable. The estimated fair values of the financial instruments have been determined by us using available market information and appropriate valuation techniques. Considerable judgment is required, however, to interpret market data to develop the estimates of fair value. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value amounts.

### **ITEM 4. CONTROLS AND PROCEDURES**

#### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)), as of June 30, 2013. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of June 30, 2013, 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 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 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 first quarter of our fiscal year ending March 31, 2014, 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.

On October 26, 2012, we were informed that the United States Attorney's Office for the District of Columbia is conducting an investigation that is focused on the Company's marketing and labeling of the Impella 2.5. On October 31, 2012, we accepted service of a subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5. We are in the process of responding and we intend to cooperate fully with the subpoena.

On November 16 and 19, 2012, two purported class action complaints were filed against us and certain of our officers in the U.S. District Court for the District of Massachusetts by alleged purchasers of our common stock, on behalf of themselves and persons or entities that purchased or acquired our securities 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 FDA and the marketing and labeling of our Impella 2.5 product and seek damages in an unspecified amount. The Court has 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.

On February 4, 2013, an alleged holder of our common stock filed a derivative action on our behalf against each of our directors in the U.S. District Court for the District of Massachusetts. The complaint alleged that the directors breached their fiduciary duties to us and our stockholders in connection with disclosures related to the FDA and the marketing and labeling of our Impella 2.5 product and sought damages in an unspecified amount. On March 22, 2013, we filed a motion to dismiss the derivative action due to the plaintiff's failure to make a proper demand on our board of directors. On June 21, 2013, the District Court entered an order granting our motion and dismissing the derivative action in its entirety due to the plaintiff's failure to make a proper demand on our board of directors. On July 19, 2013, the plaintiff filed an appeal of the dismissal in the U.S. First Circuit Court of Appeals.

**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, 2013, which could materially affect our business, financial condition or future results. To the best of our knowledge, 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.

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

(a) Not applicable.

(b) Not applicable.

(c) The following table provides information about our repurchases of shares of our common stock during the fiscal quarter ended June 30, 2013. During that period, we did not act in concert with any affiliate or any other person to acquire any of our common stock and, accordingly, we do not believe that purchases by any such affiliate or other person (if any) are reportable in the following table.

<b>Period</b>	<b>Total Number</b>	<b>Average Price Paid</b>	<b>Total Number of Shares Purchased</b>	<b>Maximum Number of</b>
---------------	-------------------------	-------------------------------	---	------------------------------

Edgar Filing: ABIOMED INC - Form 10-Q

	of Shares Purchased	per Share	as Part of Publicly Announced Plans or Programs	Shares that May Yet Be Purchased Under the Plans or Programs
April 1-30, 2013				
May 1-31, 2013	19,368(1)	\$ 21.90		
June 1-30, 2013				

- (1) Represents shares withheld to satisfy minimum tax withholding obligations related to restricted stock units which vested during the indicated period. The shares withheld were recorded as treasury shares.

**Table of Contents**

**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	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	3.4
4.1	Specimen Certificate of common stock.	S-1	June 5, 1987	4.1
11.1	Statement regarding computation of Per Share Earnings (see Note 2, Notes to Consolidated Financial Statements).	X		
31.1	Rule 13a-14(a)/15d-14(a) certification of principal executive officer.	X		
31.2	Rule 13a-14(a)/15d-14(a) certification of principal accounting officer.	X		
32.1	Section 1350 certification.	X		
101	The following financial information from the ABIOMED, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of June 30, 2013 and March 31, 2013; (ii) Consolidated Statements of Operations for the three months ended June 30, 2013 and June 30, 2012; (iii) Consolidated Statements of Comprehensive Income (Loss) for the three months ended June 30, 2013 and June 30, 2012; (iv) Consolidated Statements of Cash Flows for the three months ended June 30, 2013 and June 30, 2012; and (v) Notes to Consolidated Financial Statements.*	X		

\* The information contained in this exhibit shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Act of 1934, whether made before or after the date hereof and regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

**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: August 7, 2013

*/s/* ROBERT L. BOWEN  
**Robert L. Bowen**  
**Vice President and Chief Financial Officer**  
**(Principal Accounting and Financial Officer)**