

ABIOMED INC  
Form 10-Q  
November 05, 2012  
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, 2012

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 October 26, 2012, there were 39,670,644 shares outstanding of the registrant's Common Stock, \$.01 par value.

**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 September 30, 2012 (unaudited) and March 31, 2012</u>	3
<u>Consolidated Statements of Operations for the three and six months ended September 30, 2012 and 2011 (unaudited)</u>	4
<u>Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended September 30, 2012 and 2011 (unaudited)</u>	5
<u>Consolidated Statements of Cash Flows for the six months ended September 30, 2012 and 2011 (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>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	20
<b><u>PART II - OTHER INFORMATION:</u></b>	
Item 1. <u>Legal Proceedings</u>	21
Item 1A. <u>Risk Factors</u>	21
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	21
Item 3. <u>Defaults Upon Senior Securities</u>	21
Item 4. <u>Mine Safety Disclosures</u>	21
Item 5. <u>Other Information</u>	21
Item 6. <u>Exhibits</u>	22
<b><u>SIGNATURES</u></b>	<b>23</b>

ABIOMED, ABIOCOR, CP, cVAD and Symphony are trademarks of ABIOMED, Inc., and are registered in the United States and certain foreign countries. BVS is a trademark of ABIOMED, Inc. and is registered in the United States. 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 United States 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)

	September 30, 2012 (unaudited)	March 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,497	\$ 5,990
Short-term marketable securities	84,484	71,233
Accounts receivable, net	18,801	20,458
Inventories	14,461	11,142
Prepaid expenses and other current assets	1,791	1,716
Total current assets	124,034	110,539
Property and equipment, net	6,268	6,378
Intangible assets, net		115
Goodwill	35,512	36,846
Other long-term assets	32	33
Total assets	\$ 165,846	\$ 153,911
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,211	\$ 6,910
Accrued expenses	11,596	12,480
Deferred revenue	2,896	3,025
Total current liabilities	19,703	22,415
Long-term deferred tax liability	5,117	4,799
Other long-term liabilities	354	400
Total liabilities	25,174	27,614
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	397	393
Authorized - 100,000,000 shares; Issued - 39,717,551 shares at September 30, 2012 and 39,323,708 shares at March 31, 2012;		
Outstanding - 39,655,207 shares at September 30, 2012 and 39,272,754 shares at March 31, 2012		
Additional paid in capital	409,519	401,771
Accumulated deficit	(264,687)	(273,275)
	(1,065)	(827)

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

Treasury stock at cost - 62,344 shares at September 30, 2012 and 50,954 shares at March 31, 2012

Accumulated other comprehensive loss	(3,492)	(1,765)
Total stockholders' equity	140,672	126,297
Total liabilities and stockholders' equity	\$ 165,846	\$ 153,911

*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)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
<b>Revenue:</b>				
Product revenue	\$ 37,319	\$ 29,151	\$ 75,966	\$ 56,317
Funded research and development	98	327	234	516
	37,417	29,478	76,200	56,833
<b>Costs and expenses:</b>				
Cost of product revenue	7,194	5,551	14,640	11,442
Research and development	5,854	6,459	12,566	13,783
Selling, general and administrative	18,437	16,323	39,390	34,499
Amortization of intangible assets		379	111	764
	31,485	28,712	66,707	60,488
Income (loss) from operations	5,932	766	9,493	(3,655)
<b>Other (expense) income:</b>				
Investment income (expense), net	1	(6)	(1)	(2)
Other (expense) income, net	(9)	66	(13)	(15)
	(8)	60	(14)	(17)
Income (loss) before income tax provision	5,924	826	9,479	(3,672)
Income tax provision	455	225	891	321
Net income (loss)	\$ 5,469	\$ 601	\$ 8,588	\$ (3,993)
Basic net income (loss) per share	\$ 0.14	\$ 0.02	\$ 0.22	\$ (0.10)
Basic weighted average shares outstanding	39,431	38,256	39,288	38,081
Diluted net income (loss) per share	\$ 0.13	\$ 0.02	\$ 0.21	\$ (0.10)
Diluted weighted average shares outstanding	41,722	39,366	41,645	38,081

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

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

	<b>Three Months Ended September 30,</b>		<b>Six Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
Net income (loss)	\$ 5,469	\$ 601	\$ 8,588	\$ (3,993)
Other comprehensive income (loss)				
Foreign currency translation gains (losses)	850	(2,600)	(1,727)	(1,574)
Total other comprehensive income (loss)	850	(2,600)	(1,727)	(1,574)
Comprehensive income (loss)	\$ 6,319	\$ (1,999)	\$ 6,861	\$ (5,567)

*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>Six Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
<b>Operating activities:</b>		
Net income (loss)	\$ 8,588	\$ (3,993)
Adjustments required to reconcile net income (loss) to net cash provided by (used for) operating activities:		
Depreciation and amortization	1,449	2,125
Bad debt expense	6	65
Stock-based compensation	4,963	4,131
Write-down of inventory	598	376
Loss on disposal of fixed assets		29
Deferred tax provision	317	321
Changes in assets and liabilities:		
Accounts receivable	1,606	(235)
Inventories	(4,208)	(2,562)
Prepaid expenses and other assets	(93)	114
Accounts payable	(1,155)	(1,854)
Accrued expenses and other long-term liabilities	(813)	(4,649)
Deferred revenue	(126)	(158)
<b>Net cash provided by (used for) operating activities</b>	<b>11,132</b>	<b>(6,290)</b>
<b>Investing activities:</b>		
Purchases of short-term marketable securities	(18,750)	(8,001)
Proceeds from the sale and maturity of short-term marketable securities	5,500	7,000
Expenditures for property and equipment	(1,623)	(1,137)
<b>Net cash used for investing activities</b>	<b>(14,873)</b>	<b>(2,138)</b>
<b>Financing activities:</b>		
Proceeds from the exercise of stock options	2,493	7,800
Payments in lieu of issuance of common stock for minimum payroll taxes	(238)	
Proceeds from the issuance of stock under employee stock purchase plan	270	197
<b>Net cash provided by financing activities</b>	<b>2,525</b>	<b>7,997</b>
Effect of exchange rate changes on cash	(277)	(62)
<b>Net decrease in cash and cash equivalents</b>	<b>(1,493)</b>	<b>(493)</b>
Cash and cash equivalents at beginning of period	5,990	5,831
<b>Cash and cash equivalents at end of period</b>	<b>\$ 4,497</b>	<b>\$ 5,338</b>
<b>Supplemental disclosures:</b>		
Fixed asset additions included in accounts payable	\$ 93	\$ 44

*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, 2012 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 and six months ended September 30, 2012 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, 2012 that has been filed with the SEC.

**Recently Adopted Accounting Standards**

During the first quarter of fiscal 2013, the Company adopted Accounting Standards Update, or ASU, No. ASU 2011-05, *Presentation of Comprehensive Income*. ASU 2011-05 requires entities to present net income and other comprehensive income in either a single continuous statement of comprehensive income or in two separate, but consecutive, statements of net income and other comprehensive income. In December 2011, the Financial Accounting Standards Board, or FASB, issued ASU No. 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*. ASU 2011-12 amended ASU 2011-05 by indefinitely deferring the requirement to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement in which net income is presented and the statement in which other comprehensive income is presented. The Company has adopted ASU 2011-05 with retrospective application as required and has included in these condensed consolidated financial statements separate unaudited statements of comprehensive income. The adoption of this standard did not impact the Company's condensed consolidated financial statements other than this change in presentation.

In September 2011, the FASB issued ASU No. 2011-08, *Testing for Goodwill Impairment*. ASU 2011-08 amended current goodwill impairment testing guidance by providing entities with an option to perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The Company adopted ASU 2011-08 during the first quarter of fiscal 2013 and will apply the provisions to its annual impairment assessment to be conducted during the third quarter of fiscal 2013.

**Table of Contents****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 is 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, 2012 and 2011 were as follows (in thousands, except per share data):

	<b>Three Months Ended September 30,</b>		<b>Six Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
<b>Basic Net Income (Loss) Per Share</b>				
Net income (loss)	\$ 5,469	\$ 601	\$ 8,588	\$ (3,993)
Weighted average shares used in computing basic net income (loss) per share	39,431	38,256	39,288	38,081
Net income (loss) per share - basic	\$ 0.14	\$ 0.02	\$ 0.22	\$ (0.10)
<b>Diluted Net Income (Loss) Per Share</b>				
Net income (loss)	\$ 5,469	\$ 601	\$ 8,588	\$ (3,993)
Weighted average shares used in computing basic net income (loss) per share	39,431	38,256	39,288	38,081
Effect of dilutive securities	2,291	1,110	2,357	
Weighted average shares used in computing diluted net income (loss) per share	41,722	39,366	41,645	38,081
Net income (loss) per share - diluted	\$ 0.13	\$ 0.02	\$ 0.21	\$ (0.10)

For the three and six months ended September 30, 2012, approximately 647,000 and 505,000 shares underlying outstanding securities were not included in the computation of diluted earnings per share primarily related to out-of-the-money stock options and performance-based awards where milestones were not met. For the three months ended September 30, 2011, approximately 1,656,000 shares underlying outstanding securities were not included in the computation of diluted earnings per share primarily related to out-of-the-money stock options and performance-based awards where milestones were not met. For the six months ended September 30, 2011, approximately 4,944,000 shares underlying stock options and approximately 869,000 unvested shares of restricted stock 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.

**Note 3. Fair Value Measurements**

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

Fair value is defined as the price that would be received for 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 (in thousands):

	Quoted Prices in Active Markets (Level 1)	Using Significant Other Observable Inputs (Level 2)	Using Significant Unobservable Inputs (Level 3)	Total Carrying Value
<b>At September 30, 2012:</b>				
U.S. Treasury securities	\$ 84,484			\$ 84,484

	Quoted Prices in Active Markets (Level 1)	Using Significant Other Observable Inputs (Level 2)	Using Significant Unobservable Inputs (Level 3)	Total Carrying Value
<b>At March 31, 2012:</b>				
U.S. Treasury securities	\$ 71,233			\$ 71,233

The Company records these marketable securities at fair value and has classified all of its investments as Level 1 since quoted market prices in active markets are readily available.

**Note 4. Inventories**

The components of inventories are as follows (in thousands):

	September 30, 2012	March 31, 2012
Raw materials and supplies	\$ 4,787	\$ 3,586
Work-in-progress	5,433	4,098
Finished goods	4,241	3,458
	\$ 14,461	\$ 11,142

The Company's inventories relate to its circulatory care product lines, primarily the AB5000, BVS 5000 and Impella product platforms. Finished goods and work-in-process inventories consist of direct material, labor and overhead. During the six months ended September 30, 2012 and 2011, the Company recorded \$0.6 million and \$0.4 million, respectively, in write-downs of inventory.

From time to time, the Company loans finished goods inventory on a short-term basis to customers for demonstration purposes and this inventory is amortized over a one to five-year life. The Company had \$0.2 million and \$0.4 million in demo inventory at September 30, 2012 and March 31, 2012, respectively.



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

The carrying amount of goodwill at September 30, 2012 and March 31, 2012 was \$35.5 million and \$36.8 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG, or Impella, in May 2005. The goodwill activity for the six months ended September 30, 2012 is as follows (in thousands):

Balance at March 31, 2012	\$ 36,846
Exchange rate impact	(1,334)
<b>Balance at September 30, 2012</b>	<b>\$ 35,512</b>

**Note 6. Accrued Expenses**

Accrued expenses consist of the following (in thousands):

	September 30, 2012	March 31, 2012
Employee compensation	\$ 7,104	\$ 9,272
Sales and income taxes	1,413	948
Research and development	965	519
Warranty	898	726
Professional, accounting and auditing fees	576	427
Other	640	588
	<b>\$ 11,596</b>	<b>\$ 12,480</b>

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee payroll and benefits at September 30, 2012 and March 31, 2012.

**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 (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
Cost of product revenue	\$ 101	\$ 73	\$ 247	\$ 149
Research and development	435	372	998	872
Selling, general and administrative	1,748	1,354	3,718	3,110
	\$ 2,284	\$ 1,799	\$ 4,963	\$ 4,131

The components of stock-based compensation were as follows (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
Stock options	\$ 582	\$ 602	\$ 1,552	\$ 1,505
Restricted stock	122	304	460	1,460
Restricted stock units	1,542	845	2,865	1,101
Employee stock purchase plan	38	48	86	65
	\$ 2,284	\$ 1,799	\$ 4,963	\$ 4,131

**Stock Options**

The following table summarizes the stock option activity for the six months ended September 30, 2012:

	Shares Underlying Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at April 1, 2012	4,268	\$ 10.42	6.03	
Granted	319	22.43		
Exercised	(289)	8.63		
Cancelled and expired	(56)	9.93		
Outstanding at September 30, 2012	4,242	\$ 11.43	5.78	\$ 41,046
Exercisable at September 30, 2012	3,199	\$ 10.76	5.02	\$ 32,714
Options vested and expected to vest at September 30, 2012	4,001	\$ 11.42	5.66	\$ 38,723

The aggregate intrinsic value of options exercised was \$4.2 million and \$6.0 million for the six months ended September 30, 2012 and 2011, respectively. The total fair value of options vested during the six months ended September 30, 2012 and 2011 was \$2.1 million and \$3.3 million,



respectively.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at September 30, 2012 was approximately \$4.5 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 2.8 years.

**Table of Contents**

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, 2012 and 2011 was \$10.12 per share and \$7.72 per share, respectively.

The fair value of options granted during the three and six months ended September 30, 2012 and 2011 were calculated using the following weighted average assumptions:

	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
Risk-free interest rate	0.68%	0.94%	0.77%	1.72%
Expected option life (years)	4.20	5.21	4.32	5.29
Expected volatility	56.2%	53.1%	56.3%	51.8%

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 adjusted 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 trends and estimates of future exercises of unexercised options.

The calculation of the fair value of the options is net of estimated forfeitures. Forfeitures are estimated based on an analysis of actual option forfeitures, adjusted to the extent historic forfeitures may not be indicative of forfeitures in the future. In addition, an expected dividend yield of zero is used in the option valuation model, because the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable 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, 2012:

	Number of Shares (in 000 s)	Weighted Average Grant Date Fair Value
Outstanding at April 1, 2012	871	\$ 15.76
Granted	397	22.32
Vested	(218)	13.62
Forfeited	(23)	20.32
Outstanding at September 30, 2012	1,027	\$ 18.65

The remaining unrecognized compensation expense for outstanding restricted stock awards and restricted stock units, including performance-based awards, as of September 30, 2012 was \$11.3 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 six months ended September 30, 2012 and 2011 was \$22.32 per share and \$17.70 per share, respectively. The total fair value of restricted stock and restricted stock units vested during the six months ended September 30, 2012 and 2011 was \$3.0 million and \$1.5 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.

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

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, all of which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of September 30, 2012, the Company believes it is probable that the prescribed performance targets will be met for these awards 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

---

**Table of Contents**

which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of September 30, 2012, the Company has met the prescribed targets for 184,000 shares underlying these awards and believes it is probable that the prescribed performance targets will be met for the remaining 100,000 shares, and the compensation expense is being recognized accordingly.

During the three and six months ended September 30, 2012, the Company recorded \$1.0 million and \$1.9 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, 2012 is \$5.7 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 tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates. A valuation reserve is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. The tax benefit associated with the stock option compensation deductions will be credited to equity when realized.

The Company regularly assesses its ability to realize its deferred tax assets. Assessments of the realization of deferred tax assets require that management consider all available evidence, both positive and negative, and make significant judgments about many factors, including the amount and likelihood of future taxable income. Based on the available evidence and uncertainties surrounding the Company's ability to continue to generate future taxable income, the Company has recorded valuation allowances to reduce its deferred tax assets to the amount that is more likely than not to be realizable as of September 30, 2012 and March 31, 2012.

As of September 30, 2012, the Company has accumulated a net deferred tax liability of \$5.1 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*****Litigation***

From time to time, the Company is involved in legal and administrative proceedings and claims of various types. While any litigation contains an element of uncertainty, management presently believes that the outcome of each such proceedings or claims which are pending or known to be threatened, or all of them combined, is not expected to have a material effect on the Company's financial position, and results of operations or cash flows. At September 30, 2012, the Company did not have any material pending litigation.

**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% and 68% of the Company's total consolidated assets are located within the U.S. as of September 30, 2012 and March 31, 2012, respectively. The remaining assets are located in Europe and are primarily related to the Company's Impella production facility in Germany, and include goodwill and intangibles of \$35.5 million and \$37.0 million at September 30, 2012 and March 31, 2012, respectively, associated with the Impella acquisition in May 2005. Total assets in Europe excluding goodwill and intangibles amounted to 8% of total consolidated assets at each of September 30, 2012 and March 31, 2012. International sales (sales outside the U.S. and primarily in Europe) accounted for 6% of total revenue for the three and six months ended September 30, 2012 and 7% of total revenue for the three and six months ended September 30, 2011.

**Note 11. Subsequent Event**

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 Health Insurance Portability and Accounting Act administrative subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5 and the Company understands the investigation focuses primarily on marketing and labeling issues. The Company is in the process of responding to the subpoena and intends to cooperate fully.

---

**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, 2012. 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 most recent revenue growth in our business is the market penetration of our Impella 2.5 product, which received 510(k) clearance in June 2008 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, we announced that the Impella CP received 510(k) clearance from the U.S. Food and Drug Administration, or FDA. The Impella CP (previously marketed outside of the U.S. as Impella cVAD) received CE Marking 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 and expect the Impella CP to be fully commercially available in the U.S. in the fourth quarter of fiscal 2013.

In addition, we are currently conducting initial patient use trials outside of the U.S. of the Impella RP. The Impella RP is a percutaneous catheter-based axial flow pump that is designed to allow greater than four liters of flow and is intended to provide the flow and pressure needed to compensate for right heart failure. This product is not currently available for sale.

Revenues from our other 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 business, including BVS and AB5000, will continue to decrease as we continue to focus on our Impella products.

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 quality of life. The device is designed with the primary goal of stabilizing the progression of heart failure and/or recovering or remodeling the heart. We recently conducted the initial first in man implant of Symphony outside the U.S. and we continue to focus on development initiatives associated with the Symphony product. This product is not currently available for sale.

For the three and six months ended September 30, 2012, we recognized net income of \$5.5 million and \$8.6 million, respectively. With the exception of fiscal 2012, we have incurred annual net losses since our inception. Even though we were profitable in fiscal 2012, 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 and invest in new markets such as Japan.

***Impella 2.5***

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

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.

---

## **Table of Contents**

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 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.

A November 2011 update to the American College of Cardiology Foundation /American Heart Association 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.

We are currently conducting USpella, the first U.S. multicenter observational registry collecting clinical data and outcomes for patients supported with Impella 2.5 and 5.0 during elective, urgent and emergent procedures. Currently, there are 41 hospitals in the U.S. and Canada contributing data to the USpella registry.

### ***Impella CP***

In September 2012, we announced that the Impella CP received 510(k) clearance from the FDA. The Impella CP provides over one liter per minute more than the Impella 2.5 and peak flows of approximately four liters of blood per minute 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 Marking 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 and expect the Impella CP to be fully commercially available in the U.S. in the fourth quarter of fiscal 2013.

### ***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.

### ***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 in the process of transitioning our sales force from the BVS 5000 to the AB5000, the Impella 5.0, and the Impella LD.

We have developed a Portable Circulatory Support Driver for both in-hospital and out-of-hospital patients. The Portable Driver is designed to support our AB5000 VAD. We received CE mark approval for our Portable Driver in March 2008. In May 2008, we received conditional approval for the Portable Driver under an investigational device exemption, or IDE.

### ***AbioCor***



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

Our AbioCor implantable replacement heart is the first completely self-contained artificial heart. Designed to sustain the body's circulation, the AbioCor is intended for end-stage biventricular heart failure patients whose other treatment options have been exhausted. Patients with advanced age, impaired organ function or cancer are generally ineligible for a heart transplant and are potential candidates to receive the AbioCor implantable heart. Once implanted, the AbioCor system does not penetrate the skin, reducing the chance of patient infection. This technology provides patients with mobility and remote diagnostics. AbioCor devices have a life expectancy of 18 to 24 months and can only be implanted in normal to larger sized male patients.

## **Table of Contents**

We received a humanitarian device exemption, or HDE, supplement approval from the FDA for product enhancement of the AbioCor in January 2008. HDE approval signifies that no comparable alternative therapy exists for patients facing imminent death due to end-stage biventricular heart failure and allows the AbioCor to be made available to a limited patient population. We have no current plans to market AbioCor in the foreseeable future or seek a broader regulatory approval of the AbioCor. In September 2012, the FDA agreed to our request to suspend post-approval study on the AbioCor. We have not had any AbioCor sales since fiscal 2009, and we do not expect revenues from sales of the AbioCor for the foreseeable future as our primary strategic focus is centered on heart recovery for acute heart failure patients.

### ***Critical Accounting Policies***

There have been no significant changes in our critical accounting policies during the three and six months ended September 30, 2012, 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, 2012.

### ***Recently Adopted Accounting Standards***

During the first quarter of fiscal 2013, we adopted Accounting Standards Update, or ASU, No. ASU 2011-05, *Presentation of Comprehensive Income*. ASU 2011-05 requires entities to present net income and other comprehensive income in either a single continuous statement of comprehensive income or in two separate, but consecutive, statements of net income and other comprehensive income. In December 2011, the Financial Accounting Standards Board, or FASB, issued ASU No. 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*. ASU 2011-12 amended ASU 2011-05 by indefinitely deferring the requirement to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement in which net income is presented and the statement in which other comprehensive income is presented. We adopted ASU 2011-05 with retrospective application as required and have included in these condensed consolidated financial statements separate unaudited statements of comprehensive income. The adoption of this standard did not impact our condensed consolidated financial statements other than this change in presentation.

In September 2011, the FASB issued ASU No. 2011-08, *Testing for Goodwill Impairment*. ASU 2011-08 amended current goodwill impairment testing guidance by providing entities with an option to perform a qualitative assessment to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. We adopted ASU 2011-08 during the first quarter of fiscal 2013 and will apply the provisions to our annual impairment assessment to be conducted during the third quarter of fiscal 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):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
<b>Revenues:</b>				
Product	99.7%	98.9%	99.7%	99.1%
Funded research and development	0.3	1.1	0.3	0.9
Total revenues	100.0	100.0	100.0	100.0
<b>Costs and expenses:</b>				
Cost of product revenue	19.2	18.8	19.2	20.1
Research and development	15.6	21.9	16.5	24.3
Selling, general and administrative	49.3	55.4	51.7	60.7
Amortization of intangible assets		1.3	0.1	1.3
Total costs and expenses	84.1	97.4	87.5	106.4
Income (loss) from operations	15.9	2.6	12.5	(6.4)
<b>Other (expense) income:</b>				
Other (expense) income, net		0.2		(0.1)
		0.2		(0.1)
Income (loss) before income tax provision	15.9	2.8	12.5	(6.5)
Income tax provision	1.3	0.8	1.2	0.5
Net income (loss)	14.6%	2.0%	11.3%	(7.0)%

*Three and six months ended September 30, 2012 compared with the three and six months ended September 30, 2011*

**Revenues**

Our revenues are comprised of the following (in thousands):

	Three Months Ended September 30,		Six Months Ended September 30,	
	2012	2011	2012	2011
Impella product revenue	\$ 32,843	\$ 24,802	\$ 67,519	\$ 46,994
Other products	2,164	2,511	4,282	5,935
Service and other revenue	2,312	1,838	4,165	3,388
Total product and service revenues	37,319	29,151	75,966	56,317
Funded research and development	98	327	234	516

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

Total revenues	\$ 37,417	\$ 29,478	\$ 76,200	\$ 56,833
----------------	-----------	-----------	-----------	-----------

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 service contracts and maintenance calls.

Total revenues for the three months ended September 30, 2012 increased by \$7.9 million, or 27%, to \$37.4 million from \$29.5 million for the three months ended September 30, 2011. Total revenues for the six months ended September 30, 2012 increased by \$19.4 million, or 34%, to \$76.2 million from \$56.8 million for the six months ended September 30, 2011. The increase in total revenue was primarily due to higher Impella revenue due to greater utilization in the U.S. and the initial launch of Impella CP in fiscal 2013. Following four quarters of sequential growth, Impella revenues were sequentially lower in the second quarter of fiscal 2013, which we believe was primarily due to a general slowdown in cath lab activity during the summer months.

---

**Table of Contents**

Impella product revenues for the three months ended September 30, 2012 increased by \$8.0 million, or 32% to \$32.8 million from \$24.8 million for the three months ended September 30, 2011. Impella revenues for the six months ended September 30, 2012 increased by \$20.5 million, or 44% to \$67.5 million from \$47.0 million for the six months ended September 30, 2011. Most of our Impella revenue was from disposable product sales of Impella 2.5 in the U.S., as we focus on controlled rollouts for new sites and increasing utilization of these products through continued investment in our sales force and physician training.

Other product revenues for the three months ended September 30, 2012 decreased by \$0.3 million, or 12%, to \$2.2 million from \$2.5 million for the three months ended September 30, 2011. Other product revenues for the six months ended September 30, 2012 decreased by \$1.6 million, or 27%, to \$4.3 million from \$5.9 million for the six months ended September 30, 2011. The decrease in other revenue was due to a decline in BVS and AB5000 disposable sales. We expect that BVS and AB5000 revenue will continue to decline in fiscal 2013 as we focus our sales efforts in the surgical suite on Impella 5.0 and LD.

Service and other revenue for the three months ended September 30, 2012 increased by \$0.5 million, or 28%, to \$2.3 million from \$1.8 million for the three months ended September 30, 2011. Service revenue for the six months ended September 30, 2012 increased by \$0.8 million, or 24%, to \$4.2 million from \$3.4 million for the six months ended September 30, 2011. The increase in service revenue was primarily due to an increase in service contracts, primarily for our new Impella consoles.

***Cost of Product Revenues***

Cost of product revenues for the three months ended September 30, 2012 and 2011, respectively, was \$7.2 million and \$5.6 million. Gross margin was 81% for each of the three months ended September 30, 2012 and September 30, 2011. The increase in cost of product revenues was related to higher material purchases and increased headcount to support the higher demand for Impella products.

Cost of product revenues for the six months ended September 30, 2012 and 2011, respectively, was \$14.6 million and \$11.4 million. Gross margin was 81% for the six months ended September 30, 2012 compared to 80% for the six months ended September 30, 2011. The increase in gross margin was primarily due to higher reorders of Impella product disposable pumps and improved manufacturing efficiency with higher production volume.

***Research and Development Expenses***

Research and development expenses for the three months ended September 30, 2012 decreased by \$0.6 million, or 9%, to \$5.9 million from \$6.5 million for the three months ended September 30, 2011. Research and development expenses for the six months ended September 30, 2012 decreased by \$1.2 million, or 9%, to \$12.6 million from \$13.8 million for the six months ended September 30, 2011.

The decrease in research and development expenses was due to a decrease in clinical trial expenditures as we completed our work associated with the Protect II trial for the Impella 2.5, partially offset by an increase in spending on product development initiatives associated with Impella RP and Symphony. We expect research and development expenses to increase slightly in fiscal 2013 as we continue to focus on new product development initiatives associated with Impella RP and Symphony products.

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

Selling, general and administrative expenses for the three months ended September 30, 2012 increased by \$2.1 million, or 13%, to \$18.4 million from \$16.3 million for the three months ended September 30, 2011. Selling, general and administrative expenses for the six months ended September 30, 2012 increased by \$4.9 million, or 14%, to \$39.4 million from \$34.5 million for the six months ended September 30, 2011.

The increase in selling, general and administrative expenses was primarily due to an increased field headcount as we continue to build out our commercial efforts in the U.S. and increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support. We expect to increase our expenditures on sales and marketing activities in fiscal 2013, with particular investments in 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.

***Amortization of Intangibles***

Amortization of intangible assets was \$0 and \$0.4 million for the three months ended September 30, 2012 and 2011, respectively. Amortization of intangible assets was \$0.1 million and \$0.8 million for the six months ended September 30, 2012 and 2011, respectively. Amortization primarily relates to specifically identified assets from the Impella acquisition in May 2005. We fully amortized the remaining net book value of

our intangible assets during the six months ended September 30, 2012.

---

**Table of Contents*****Provision for Income Taxes***

During three months ended September 30, 2012 and 2011, we recorded a provision for income taxes of \$0.5 million and \$0.2 million, respectively. During the six months ended September 30, 2012 and 2011, we recorded an income tax provision of \$0.9 million and \$0.3 million, respectively. The income tax provision for the three and six months ended September 30, 2012 is primarily due to income taxes in Germany that we do not expect will be offset by our net operating loss carryforwards in Germany and therefore we expect to pay in cash. We have also recorded income taxes related to our deferred tax liability on our goodwill and alternative minimum tax in the U.S.

***Net Income (Loss)***

During the three months ended September 30, 2012, we recorded net income of \$5.5 million, or \$0.14 per basic and \$0.13 per diluted share, compared to a net income of \$0.6 million, or \$0.02 per basic and diluted share, for the three months ended September 30, 2011. During the six months ended September 30, 2012, we generated net income of \$8.6 million, or \$0.22 per basic and \$0.21 per diluted share, compared to a net loss of \$4.0 million, or \$0.10 per basic and diluted share, for the six months ended September 30, 2011.

The increase in profitability was due to increased Impella sales from greater demand for our products in the U.S.

***Liquidity and Capital Resources***

At September 30, 2012, our cash, cash equivalents and short-term marketable securities totaled \$89.0 million, which represents an increase of \$11.8 million compared to \$77.2 million in cash, cash equivalents and short-term marketable securities at March 31, 2012. 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 needs 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 and provide for general working capital needs. Through September 30, 2012, we have funded our operations principally from product sales and through the sale of equity securities. Marketable securities at September 30, 2012 consist of \$84.5 million held in funds that invest solely in U.S. Treasury 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. We continue to monitor our cash position closely and currently only invest excess cash in short term U.S. treasury securities.

Cash and cash equivalents held by our foreign subsidiaries totaled \$2.4 million and \$3.0 million at September 30, 2012 and March 31, 2012, 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 may be required to accrue and pay U.S. taxes to repatriate these funds.

During the six months ended September 30, 2012, net cash provided by operating activities was \$11.1 million, compared to net cash used of \$6.3 million during the same period in the prior year. The increase in cash provided by operations was primarily attributable to the net improvement in net income of \$12.6 million reflected in our net income of \$8.6 million for the six months ended September 30, 2012 compared to our net loss of \$4.0 million in fiscal 2012, offset by changes in assets and liabilities used which consist of a \$4.5 million decrease in cash used for accounts payable and accrued expenses primarily related to the closeout of the Protect II study in fiscal 2012, a \$1.8 million increase in cash provided by accounts receivable due to increases in revenue and timing of receivable collections and a \$1.6 million increase in cash used for inventories as we have increased inventory safety stock levels in fiscal 2012 to support continued growing customer demand for Impella. In addition, net cash provided by operating activities was impacted by changes in non-cash adjustments of a \$0.8 million increase in stock-based compensation and a \$0.2 million increase in write-downs of inventory, partially offset by a \$0.7 million decrease in depreciation and amortization expense.

During the six months ended September 30, 2012, net cash used for investing activities was \$14.9 million, compared to \$2.1 million during the same period in the prior year. The increase in cash used for investing activities was primarily attributable to a \$12.3 million increase in net purchases of short-term securities. We also incurred a \$0.5 million increase in capital expenditures in fiscal 2013 due to the buildout costs of a new training facility at our corporate headquarters.

During the six months ended September 30, 2012, net cash provided by financing activities was \$2.5 million, compared to \$8.0 million during the same period in the prior year. The decrease in cash provided by financing activities was primarily attributable to a \$5.3 million decrease in proceeds from the exercise of stock options because fewer stock options were exercised in that period and \$0.2 million for payments in lieu of issuance of common stock for minimum payroll taxes upon vesting of certain equity awards.

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

Capital expenditures for fiscal 2013 are estimated to be \$3.0 to \$4.0 million, which relate primarily to capital expenditures for manufacturing capacity increases for Impella, leasehold improvements and software development projects.



---

## **Table of Contents**

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 continue to review our long-term cash needs on a regular basis. At September 30, 2012, we had no long-term debt outstanding.

### **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 September 30, 2012 consist of \$84.5 million held in funds that invest solely in U.S. Treasury securities. If market interest rates were to increase immediately and uniformly by 10% from levels at September 30, 2012, 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 international 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 foreign currency exchange rates were to have depreciated immediately and uniformly by 10% relative to the U.S. dollar from levels at September 30, 2012, the result would have been a reduction of stockholders' equity of approximately \$3.7 million.

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

At September 30, 2012, our financial instruments consist primarily of cash and cash equivalents, short-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 September 30, 2012. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2012, 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 second quarter of our fiscal year ending March 31, 2013, 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.

As previously disclosed on our Report on Form 8-K dated November 1, 2012, 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 Health Insurance Portability and Accounting Act administrative subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5 and we understand the investigation focuses primarily on marketing and labeling issues. We are in the process of responding to the subpoena and intend to cooperate fully.

**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, 2012, 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, other than the addition of information to the risk factor entitled *If the FDA or another regulatory agency determines that we have promoted off-label use of our products, we may be subject to various penalties, including civil or criminal penalties.* related to the subpoena disclosed in Item 1 and the addition of the risk factor entitled *The FDA continues to consider potential reclassification of our devices under the 515 Program Initiative.*, both of which are detailed below.

**Risks Related to our Business**

*If the FDA or another regulatory agency determines that we have promoted off-label use of our products, we may be subject to various penalties, including civil or criminal penalties.*

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. If the FDA or another regulatory agency determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In June 2011 we received a warning letter from the FDA stating that some of our promotional materials marketed the Impella 2.5 for uses that had not been approved by the FDA. We cooperated with the FDA and made changes to our promotional materials in response to the warning letter. However, in April 2012, we received a follow up letter from the FDA stating that some of our promotional materials continued to market the Impella 2.5 in ways that are not compliant with FDA regulations. We are cooperating with the FDA in addressing its concerns. While we hope to be able to resolve this matter without incurring penalties, we may not be able to resolve it, or any similar matters that may come up in the future without facing significant consequences. Additionally, 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 Health Insurance Portability and Accounting Act administrative subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5 and we understand the investigation focuses primarily on marketing and labeling issues. We are in the process of responding to the subpoena and intend to cooperate fully. Such matters could result in reduced demand for our products and would have a material adverse effect on our operations and prospects.

*The FDA continues to consider potential reclassification of our devices under the 515 Program Initiative.*

In 2009, the FDA implemented the 515 Program Initiative to facilitate the potential reclassification of twenty-six medical devices which are currently classified as Class III devices. Class I and II devices are generally considered to be lower risk than Class III devices and require

clearance through the FDA's 510(k) premarket notification process. Class III devices, however, are typically higher risk and first-of-a-kind and require approval through a premarket approval application, or PMA, which is a much more costly and uncertain process to approval than the 510(k) premarket notification process. Under the 515 Program Initiative, the FDA is reviewing Class III device types to determine whether any of them should be reclassified as Class I or II devices or if they should remain classified as Class III devices and be subject to approval through the PMA process. We have been informed that the FDA plans to hold a 515 Program Initiative Advisory Panel on December 5th and 6th, 2012 to review the classification determination of external counter-pulsating devices and intra-aortic balloon and control systems and nonroller-type cardiopulmonary bypass blood pumps, which includes our Impella products. However, as this Advisory Panel has not been formally announced by the FDA, this estimated timing is subject to change.

We cannot be certain that our devices will be reclassified by the FDA as Class I or Class II devices through the 515 Program Initiative and hence FDA approval of our devices may be uncertain and costly.

**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	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 September 30, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of September 30, 2012 and March 31, 2012; (ii) Consolidated Statements of Operations for the three and six months ended September 30, 2012 and 2011; (iii) Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended September 30, 2012 and 2011; (iv) Consolidated Statements of Cash Flows for the six months ended September 30, 2012 and 2011; 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: November 5, 2012

/s/ ROBERT L. BOWEN

**Robert L. Bowen**

**Vice President and Chief Financial Officer**

**(Principal Accounting and Financial Officer)**