ABIOMED INC Form 10-Q February 06, 2014 Table of Contents

#### **UNITED STATES**

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended December 31, 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)

**DELAWARE** (State or other jurisdiction of

04-2743260 (IRS Employer

incorporation or organization)

**Identification No.)** 

#### 22 CHERRY HILL DRIVE

#### DANVERS, MASSACHUSETTS 01923

(Address of principal executive offices, including zip code)

(978) 646-1400

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 x

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 x

As of January 31, 2014, 39,818,029 shares of the registrant s common stock, \$.01 par value, were outstanding.

# ABIOMED, INC. AND SUBSIDIARIES

#### TABLE OF CONTENTS

PART I -	FINANCIAL INFORMATION:	Page
Item 1.	Financial Statements	3
	Consolidated Balance Sheets as of December 31, 2013 (unaudited) and March 31, 2013	3
	Consolidated Statements of Operations for the three and nine months ended December 31, 2013 and 2012 (unaudited)	4
	Consolidated Statements of Comprehensive Income for the three and nine months ended December 31, 2013 and 2012 (unaudited)	5
	Consolidated Statements of Cash Flows for the nine months ended December 31, 2013 and 2012 (unaudited)	6
	Notes to Consolidated Financial Statements (unaudited)	7
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	17
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	25
Item 4.	Controls and Procedures	25
PART II -	OTHER INFORMATION:	
Item 1.	<u>Legal Proceedings</u>	26
Item 1A.	Risk Factors	26
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	27
Item 3.	Defaults Upon Senior Securities	27
Item 4.	Mine Safety Disclosures	27
Item 5.	Other Information	27
Item 6.	<u>Exhibits</u>	28
SIGNATI	JRES	29

ABIOMED, ABIOCOR, IMPELLA, 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. RECOVER is a trademark of Abiomed Europe GmbH, a subsidiary of ABIOMED, Inc., and is registered in the U.S. and certain foreign countries.

# PART 1. FINANCIAL INFORMATION

# **ITEM 1: FINANCIAL STATEMENTS**

# ABIOMED, INC. AND SUBSIDIARIES

# CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2013 (unaudited)		ch 31, 2013
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 22,632	\$	9,451
Short-term marketable securities	56,944		67,256
Accounts receivable, net	22,958		22,946
Inventories	14,819		14,930
Prepaid expenses and other current assets	2,376		2,022
Total current assets	119,729		116,605
Long-term marketable securities	27,784		11,406
Property and equipment, net	7,022		6,549
Goodwill	38,029		35,410
Other assets	801		29
Total assets	\$ 193,365	\$	169,999
LIABILITIES AND STOCKHOLDERS EQUITY			
Current liabilities:			
Accounts payable	\$ 6,066	\$	7,696
Accrued expenses	16,015		15,162
Deferred revenue	4,354		4,198
Total current liabilities	26,435		27,056
Long-term deferred tax liability	6,234		5,554
Other long-term liabilities	239		309
Total liabilities	32,908		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	409		397
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Authorized - 100,000,000 shares; Issued - 40,972,146 shares at December 31, 2013 and 39,788,383 shares at March 31, 2013;

December 31, 2013 and 39,700,303 shares at Waren 31, 2013,		
Outstanding - 39,765,779 shares at December 31, 2013 and 38,601,384		
shares at March 31, 2013		
Additional paid in capital	431,754	414,810
Accumulated deficit	(254,532)	(258,261)
Treasury stock at cost - 1,206,367 shares at December 31, 2013 and		
1,186,999 shares at March 31, 2013	(16,554)	(16,129)
Accumulated other comprehensive loss	(620)	(3,737)
Total stockholders equity	160,457	137,080
Total liabilities and stockholders equity	\$ 193,365	\$ 169,999

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

# ABIOMED, INC. AND SUBSIDIARIES

# CONSOLIDATED STATEMENTS OF OPERATIONS

# (Unaudited)

# (in thousands, except per share data)

		on the Ended ber 31, 2012	Nine Mont Decemb 2013	
Revenue:				
Product revenue	\$ 46,141	\$ 38,112	\$ 133,038	\$ 114,078
Funded research and development	54	138	172	372
	46,195	38,250	133,210	114,450
Costs and expenses:				
Cost of product revenue	9,458	8,130	27,208	22,770
Research and development	7,779	6,259	22,787	18,825
Selling, general and administrative	24,364	20,943	78,530	60,333
Amortization of intangible assets				111
	41,601	35,332	128,525	102,039
Income from operations	4,594	2,918	4,685	12,411
Other income:				
Investment income, net	37	1	78	
Other income, net	20	324	5	311
	57	325	83	311
Income before income tax provision	4,651	3,243	4,768	12,722
Income tax provision	258	559	1,039	1,450
Net income	\$ 4,393	\$ 2,684	\$ 3,729	\$ 11,272
Basic net income per share	\$ 0.11	\$ 0.07	\$ 0.10	\$ 0.29
Basic weighted average shares outstanding	39,592	39,417	39,179	39,331
Diluted net income per share	\$ 0.11	\$ 0.07	\$ 0.09	\$ 0.27
Diluted weighted average shares outstanding	41,726	40,865	41,315	41,418

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

4

# ABIOMED, INC. AND SUBSIDIARIES

# CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(in thousands, except per share data)

	Three Mor Decem		Nine Months Ende December 31,		
	2013	2012	2013	2012	
Net income	\$ 4,393	\$ 2,684	\$ 3,729	\$ 11,272	
Other comprehensive income (loss):					
Foreign currency translation gains (losses)	807	1,147	3,128	(580)	
Net unrealized losses on marketable securities	(21)		(11)		
Other comprehensive income (loss)	786	1,147	3,117	(580)	
Comprehensive income	\$ 5,179	\$ 3,831	\$ 6,846	\$ 10,692	

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

# ABIOMED, INC. AND SUBSIDIARIES

# CONSOLIDATED STATEMENTS OF CASH FLOWS

# (Unaudited)

# (in thousands)

		line Mon Decem 2013	ths Ended ber 31, 2012
Operating activities:			
Net income	\$	3,729	\$ 11,272
Adjustments required to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization		1,863	2,086
Bad debt expense		11	42
Stock-based compensation		8,367	6,899
Write-down of inventory		641	891
Deferred tax provision		679	545
Changes in assets and liabilities:			
Accounts receivable		123	489
Inventories		(69)	(4,898)
Prepaid expenses and other assets		(345)	359
Accounts payable		(1,679)	(286)
Accrued expenses and other long-term liabilities		104	1,366
Deferred revenue		147	76
Net cash provided by operating activities		13,571	18,841
Investing activities:			
Purchases of marketable securities	(	(58,330)	(24,252)
Proceeds from the sale and maturity of marketable securities		52,264	20,500
Purchase of other investment		(750)	
Purchases of property and equipment		(2,301)	(2,072)
Net cash used for investing activities		(9,117)	(5,824)
Financing activities:			
Proceeds from the exercise of stock options		8,227	2,739
Repurchase of common stock			(10,654)
Payments in lieu of issuance of common stock for minimum payroll taxes		(426)	(238)
Proceeds from the issuance of stock under employee stock purchase plan		312	270
Net cash provided by (used for) financing activities		8,113	(7,883)
Effect of exchange rate changes on cash		614	(367)
Net increase in cash and cash equivalents		13,181	4,767
Cash and cash equivalents at beginning of period		9,451	5,990
			-

Cash and cash equivalents at end of period

\$ 22,632 \$ 10,757

Supplemental disclosures:		
Cash paid for income taxes	\$ 1,106	\$ 75
Fixed asset expenditures incurred, not yet paid	92	105

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

#### 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 and nine months ended December 31, 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.

7

#### **Note 2. Net Income Per Share**

Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing net income by the weighted average number of dilutive common shares outstanding during the period. Diluted shares outstanding are calculated by adding to the weighted average shares outstanding any potential dilutive securities outstanding for the period. Potential dilutive securities include stock options, restricted stock 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 per share for the three and nine months ended December 31, 2013 and 2012 were as follows (in thousands, except per share data):

		nths Ended lber 31, 2012		oths Ended aber 31, 2012	
Basic Net Income Per Share					
Net income	\$ 4,393	\$ 2,684	\$ 3,729	\$ 11,272	
Weighted average shares used in computing basic net					
income per share	39,592	39,417	39,179	39,331	
Net income per share - basic	\$ 0.11	\$ 0.07	\$ 0.10	\$ 0.29	
		nths Ended lber 31, 2012		ths Ended ber 31, 2012	
Diluted Net Income Per Share	Decem	ber 31,	Decem	ber 31,	
Diluted Net Income Per Share Net income	Decem	ber 31,	Decem	ber 31,	
	Decem 2013	ber 31, 2012	Decem 2013	ber 31, 2012	
Net income	Decem 2013	ber 31, 2012	Decem 2013	ber 31, 2012	
Net income  Weighted average shares used in computing basic net	<b>Decem 2013</b> \$ 4,393	s 2,684	Decem 2013 \$ 3,729	ber 31, 2012 \$11,272	
Net income  Weighted average shares used in computing basic net income per share	Decem 2013 \$ 4,393	\$ 2,684	Decem 2013 \$ 3,729 \$ 39,179	ber 31, 2012 \$11,272	
Net income  Weighted average shares used in computing basic net income per share  Effect of dilutive securities	Decem 2013 \$ 4,393	\$ 2,684	Decem 2013 \$ 3,729 \$ 39,179	ber 31, 2012 \$11,272	

For the three and nine months ended December 31, 2013, approximately 3,000 and 252,000 shares underlying out-of-the-money stock options were not included in the computation of diluted earnings per share because their inclusion would have been anti-dilutive. In addition, for each of the three and nine months ended December 31, 2013, approximately 85,000 restricted shares that related to performance-based awards where milestones were not met were

not included in the computation of diluted earnings per share because their inclusion would also have been anti-dilutive.

For the three and nine months ended December 31, 2012, approximately 575,000 and 268,000 shares underlying out-of-the-money stock options and approximately 333,000 and 294,000 restricted shares, respectively, 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.

8

The Company s marketable securities at December 31, 2013 and March 31, 2013 are invested in the following:

	Amortized Cost	Gross Unrealized Gains (in	Unre	ross ealized esses s)	r Market Value
At December 31, 2013:					
US Treasury securities	\$ 33,987	\$	\$		\$ 33,987
Short-term government-backed securities	22,952	5			22,957
Long-term government-backed securities	27,798	3		(17)	27,784
	\$84,737	\$ 8	\$	(17)	\$ 84,728

	Amortized Cost	Gross Unrealized Gains (in	Gross Unrealized Losses \$000 s)	r Market Value
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.

Table of Contents 15

9

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

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

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

		Level			
	Level 1	Level 2	3	Total	
		(in	\$000 s)		
At December 31, 2013:					
U.S. Treasury securities	\$	\$33,987	\$	\$33,987	
Short-term government-backed securities		22,957		22,957	
Long-term government-backed securities		27,784		27,784	
	\$	\$84,728	\$	\$84,728	

	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 this 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 December 31, 2013 and is classified within other assets in the unaudited condensed consolidated balance sheets.

#### **Note 4. Inventories**

The components of inventories are as follows:

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	December 31, 2013	March 31, 2013
	(in \$0	000 s)
Raw materials and supplies	\$ 6,704	\$ 6,267
Work-in-progress	5,896	5,296
Finished goods	2,219	3,367
	\$ 14,819	\$ 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 nine months ended December 31, 2013 and 2012, the Company recorded \$0.6 million and \$0.9 million, respectively, in write-downs of inventory.

# Note 5. Goodwill

The carrying amount of goodwill at December 31, 2013 and March 31, 2013 was \$38.0 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 nine months ended December 31, 2013 is as follows:

	(in \$000 s)
Balance at March 31, 2013	\$ 35,410
Exchange rate impact	2,619
Balance at December 31, 2013	\$ 38,029

#### **Note 6. Accrued Expenses**

Accrued expenses consist of the following:

	December 31, 2013		arch 31, 2013
	(in \$0	)00	$\mathbf{s})$
Employee compensation	\$ 10,665	\$	9,664
Sales and income taxes	1,672		2,107
Research and development	1,588		1,025
Professional, legal and accounting fees	740		1,100
Warranty	732		708
Other	618		558
	\$ 16,015	\$	15,162

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

# **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 and nine months ended December 31, 2013 and 2012:

	Three Months Ended December 31,		Nine Months Ended December 31,					
		2013 2012		2	013	2	012	
		(in \$	000	s)		(in \$	000	s)
Cost of product revenue	\$	130	\$	83	\$	476	\$	330
Research and development		527		333		1,813		1,331
Selling, general and administrative		991		1,520	(	5,078		5,238
	\$	1,648	\$	1,936	\$ 3	8,367	\$	6,899

The components of stock-based compensation for the three and nine months ended December 31, 2013 and 2012 were as follows:

		Three Months Ended December 31,			ths Ended ber 31,		
	201	13	2012	2013	2012		
		(in \$000 s)			(in \$000 s)		
Restricted stock units	\$ 1,	013 \$	1,220	\$ 5,808	\$ 4,085		
Stock options		571	583	2,094	2,135		
Restricted stock		7	81	310	541		
Employee stock purchase plan		57	52	155	138		
	\$ 1,	648 \$	1,936	\$ 8,367	\$ 6,899		

# Stock Options

The following table summarizes the stock option activity for the nine months ended December 31, 2013:

	Shares Underlying Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at April 1, 2013	4,228	\$ 11.49	5.37	
Granted	333	23.53		
Exercised	(907)	9.18		
Cancelled and expired	(37)	18.74		

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Outstanding at December 31, 2013	3,617	\$ 13.10	5.13	\$ 49,330
Exercisable at December 31, 2013	2,798	\$ 11.25	4.18	\$ 43,350
Options vested and expected to vest at December 31, 2013	3,521	\$ 13.00	5.06	\$ 48,397

The aggregate intrinsic value of options exercised was \$13.8 million for the nine months ended December 31, 2013. The total fair value of options vested during the nine months ended December 31, 2013 was \$2.3 million.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at December 31, 2013 was approximately \$4.9 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 2.8 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 nine months ended December 31, 2013 and 2012 was \$9.84 and \$10.07 per share, respectively.

12

The fair value of options granted during the three and nine months ended December 31, 2013 and 2012 were calculated using the following weighted average assumptions:

		Three Months Ended December 31,		hs Ended er 31,
	2013	2012	2013	2012
Risk-free interest rate	1.71%	0.63%	0.94%	0.77%
Expected option life (years)	4.18	4.23	4.25	4.32
Expected volatility	50.2%	58.1%	51.8%	56.4%

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.

13

#### 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 nine months ended December 31, 2013:

	Number of Shares (in thousands)	Gra Fai	ted Average ant Date ir Value r share)
Outstanding at April 1, 2013	1,022	\$	18.44
Granted	553		23.18
Vested	(364)		16.58
Forfeited	(52)		18.86
Outstanding at December 31, 2013	1,159	\$	21.27

The remaining unrecognized compensation expense for outstanding restricted stock awards and restricted stock units, including performance-based awards, as of December 31, 2013 was \$10.5 million and the weighted-average period over which this cost will be recognized is 1.9 years.

The weighted average grant-date fair value for restricted stock and restricted stock units granted during the nine months ended December 31, 2013 and 2012 was \$23.18 and \$22.32 per share, respectively. The total fair value of restricted stock and restricted stock units vested during the nine months ended December 31, 2013 and 2012 was \$6.0 million and \$3.0 million, respectively.

#### Performance Based Awards

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

In May 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 December 31, 2013, the Company is recognizing compensation expense based on the probable outcome related to the prescribed performance targets on the outstanding 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 December 31, 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 December 31, 2013, the Company has met the prescribed milestones for 234,000 shares underlying these awards and believes that it is not probable that the prescribed performance milestones will be met for the remaining 50,000 shares. The compensation expense on these performance-based awards is being recognized accordingly.

During the three months ended December 31, 2013, the Company incurred \$3,000 in stock-based compensation expense on performance-based awards as it reversed \$0.8 million that had been previously recorded as stock-based compensation expense based on it no longer being probable that certain performance milestones will be achieved. During the nine months ended December 31, 2013, the Company recorded \$2.8 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 December 31, 2013 is \$4.0 million based on the Company s current assessment of the probability that certain performance milestones will be achieved. The weighted-average period over which this cost will be recognized is 1.9 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 Pre-Market Approval, or PMA, application with the FDA for its Impella products, net income before tax for fiscal 2012 and fiscal 2013, year to date and forecasted results for fiscal 2014 and future years. 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 December 31, 2013 and March 31, 2013. The Company will continue to assess the level of the valuation allowance required. If sufficient positive evidence exists in future periods to support a release of some or all of the valuation allowance, such a release would likely have a material impact on our results of operations.

As of December 31, 2013, the Company has accumulated a net deferred tax liability of \$6.2 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 December 31, 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 is cooperating fully with the subpoena. The Company expects to substantially complete the requested document production by the end of fiscal 2014. On September 13, 2013, the Company entered into a tolling agreement with the United States Attorney s Office, pursuant to which the Company and the United States Attorney s Office mutually agreed to toll the applicable statutes of limitations for all criminal, civil and administrative offenses and violations that could be charged or claimed against the Company as of that date until June 2, 2014. 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 any unfavorable outcome associated with this inquiry. The Company can anticipate, however, that it will incur significant expenses related to this investigation.

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 U.S. Food and Drug Administration 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 complaint. Oral argument on the Company s motion to dismiss was conducted before the presiding district court judge on September 18, 2013.

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 United States Court of Appeals for the First Circuit. Oral argument was conducted before the appellate court on February 5, 2014.

The Company is unable to estimate its potential liability with respect to the Department of Justice investigation, the purported class action claim and the appeal of the dismissal of the 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 72% and 71% of the Company s total consolidated assets are located within the U.S. as of December 31, 2013 and March 31, 2013, respectively. The remaining assets are located primarily in Germany and include goodwill of \$38.0 million and \$35.4 million at December 31, 2013 and March 31, 2013, respectively, associated with the Impella acquisition in May 2005. Total assets outside of the U.S. excluding goodwill amounted to 8% of total consolidated assets as of each of December 31, 2013 and March 31, 2013. International sales (sales outside the U.S. and primarily in Europe) accounted for 10% and 8% of total revenue for the three and nine months ended December 31, 2012, respectively.

# 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, including the potential for future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, litigation matters, future capital needs and uncertainty of additional financing and other risks and challenges 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 836 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, our Impella CP product received 510(k) clearance from the FDA for partial circulatory support for up to six hours. The Impella CP also has CE Mark approval and Health Canada approval which allow us to market the device in the European Union and Canada. As of December 31, 2013 we have placed Impella CP at 312 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 up to 30 patients with signs of right side heart failure who require hemodynamic support and are being treated in the cath lab or surgery suite. In November

2013, we announced that the Impella RP RECOVER RIGHT study has enrolled more than 50% of the required patients in this clinical study. 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, and the FDA recently issued a proposed order reflecting this categorization. The proposed order is open for public comment until April 7, 2014. If the FDA 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 within 90 days of the issuance of the final order. 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 the 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 submitted 4 of the 5 modules required by the FDA as part of the planned modular PMA submission. If the submitted modules are not closed by the filing of the Final Module they will be integrated into the final module timeline.

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 are cooperating fully with the subpoena. We expect to substantially complete the requested document production by the end of fiscal 2014. On September 13, 2013, we entered into a tolling agreement with the United States Attorney s Office, pursuant to which we and the United States Attorney s Office mutually agreed to toll the applicable statutes of limitations for all criminal, civil and administrative offenses and violations that could be charged or claimed against us as of that date until June 2, 2014. 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 any unfavorable outcome associated with this inquiry. We can anticipate, however, that we will incur significant expenses related to this investigation.

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. Oral argument on our motion to dismiss was conducted before the presiding district court judge on September 18, 2013.

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 United States Court of Appeals for the First Circuit. Oral argument was conducted before the appellate court on February 5, 2014.

Our revenues are primarily generated from our Impella line of products. Revenues from our non-Impella products, largely focused on the heart surgery suite, have been lower over the past several years as we have strategically shifted our sales and marketing efforts towards our Impella products and the cath lab. We expect revenues from our

non-Impella products, primarily AB5000, will continue to decrease as we continue to focus on our Impella products.

For the three and nine months ended December 31, 2013, we recognized a net income of \$4.4 million and \$3.7 million, respectively. Even though we have been profitable in fiscal 2014 through December 31, 2013, 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, enter into collaborations with other parties 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.

18

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 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. 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.

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.

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 and the FDA recently issued a proposed order reflecting this categorization. The proposed order is open for public comment until April 7, 2014. If the FDA issues a final order classifying these devices in Class III, we will be required to file a PMA application for our Impella products within 90 days of the issuance of the final order. 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 the 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 submitted 4 of the 5 modules

required by the FDA as part of the planned modular PMA submission.

#### Impella CP

In September 2012, we announced that the Impella CP received 510(k) clearance from the FDA. The Impella CP provides blood flow of approximately one liter more per minute than the Impella 2.5 and is indicated for up to six hours of partial circulatory support using an extracorporeal bypass control unit. It is also intended to be used to provide partial circulatory support, for up to six hours, during procedures not requiring cardiopulmonary bypass. The Impella CP received CE Mark approval to 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.

19

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 minute and is intended to provide the flow and pressure needed to compensate for right heart failure. The study will enroll up to 30 patients at 15 sites that present with signs of right side heart failure, require hemodynamic support, and are being treated in the catheterization lab or cardiac surgery suite. We announced the first enrollment of a patient in RECOVER RIGHT in April 2013. 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. To date, the Impella RP RECOVER RIGHT study has enrolled 24 of the required patients and we expect to complete enrollment in the first half of calendar 2014. Based on this schedule we forecast that the HDE will be approved in the first quarter of calendar 2015. An HDE is similar to a PMA application but is intended for patient populations of 4,000 or less per year in the U.S and the approval relies on the demonstration of safety and probable benefit, which is a lower success criteria than the safety and effectiveness requirement of a PMA. In order to receive an HDE, there must be no comparable devices approved under PMA that are available to treat the targeted population. An approved HDE authorizes sales of the device to any hospital after Institutional Review Board review. We are currently conducting initial patient use trials aimed at CE Mark approval 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. In January 2014, the AB5000 was approved for use in Japan. We do not expect a significant market for the AB5000 to develop in Japan, as we intend to continue to focus our efforts on achieving approval in Japan for our Impella products.

#### 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 nine months ended December 31, 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.

20

# **Results of Operations**

The following table sets forth certain consolidated statements of operations data for the periods indicated as a percentage of total revenues for the three and nine months ended December 31, 2013 and 2012, respectively:

	Three Mont		Nine Months Ended December 31,		
	2013	2012	2013	2012	
Revenues:					
Product	99.9%	99.6%	99.9%	99.7%	
Funded research and development	0.1	0.4	0.1	0.3	
Total revenues	100.0	100.0	100.0	100.0	
Costs and expenses:					
Cost of product revenue	20.5	21.3	20.4	19.9	
Research and development	16.9	16.4	17.1	16.5	
Selling, general and administrative	52.7	54.7	59.0	52.7	
Amortization of intangible assets				0.1	
Total costs and expenses	90.1	92.4	96.5	89.2	
Income from operations	9.9	7.6	3.5	10.8	
Other income and income tax provision	0.4	0.6	0.7	1.0	
Net income	9.5%	7.0%	2.8%	9.8%	

Three and nine months ended December 31, 2013 compared with the three and nine months ended December 31, 2012

#### Revenues

Our revenues are comprised of the following:

	Three 1	Months				
	En	Ended				
	Decem	ber 31,	Decem	December 31,		
	2013	2012	2013	2012		
	(in \$	000 s)	(in \$000 s)			
Impella product revenue	\$42,012	\$ 33,519	\$120,833	\$ 101,038		
Service and other revenue	2,727	2,372	7,917	6,533		
Other products	1,402	2,221	4,288	6,507		

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Total product revenues	46,141	38,112	133,038	114,078
Funded research and development	54	138	172	372
Total revenues	\$ 46,195	\$38,250	\$ 133,210	\$ 114,450

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.

Total revenues for the three months ended December 31, 2013 increased by \$7.9 million, or 21%, to \$46.2 million from \$38.3 million for the three months ended December 31, 2012. Total revenues for the nine months ended December 31, 2013 increased by \$18.7 million, or 16%, to \$133.2 million from \$114.5 million for the nine months ended December 31, 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 December 31, 2013 increased by \$8.5 million, or 25% to \$42.0 million from \$33.5 million for the three months ended December 31, 2012. Impella revenues for the nine months ended December 31, 2013 increased by \$19.8 million, or 20% to \$120.8 million from \$101.0 million for the nine months ended December 31, 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. Also, contributing to the sales increase is the introduction of Impella CP to 312 sites in the U.S. since regulatory approval in September 2012. Impella product

revenues in Europe, primarily Germany, also increased during the three months ended December 31, 2013. We expect Impella revenues to continue to increase as we add new customer sites, increase utilization at existing customer sites and continue our commercial launch of Impella CP.

Service and other revenue for the three months ended December 31, 2013 increased by \$0.3 million, or 13%, to \$2.7 million from \$2.4 million for the three months ended December 30, 2012. Service revenue for the nine months ended December 31, 2013 increased by \$1.4 million, or 22%, to \$7.9 million from \$6.5 million for the nine months ended December 31, 2012. The increase in service revenue was primarily due to an increase in service contracts, primarily for Impella consoles.

Other product revenues for the three months ended December 31, 2013 decreased by \$0.8 million, or 36%, to \$1.4 million from \$2.2 million for the three months ended December 31, 2012. Other product revenues for the nine months ended December 31, 2013 decreased by \$2.2 million, or 34%, to \$4.3 million from \$6.5 million for the nine months ended December 31, 2012. The decrease in other product 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 had virtually no revenue from BVS 5000 during the three months ended December 31, 2013. We also expect that AB5000 revenue will continue to decline during the remainder of 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 revenues for the three months ended December 31, 2013 and 2012, respectively, was \$9.5 million and \$8.1 million. Gross margin was 80% for the three months ended December 31, 2013 compared to 79% for the three months ended December 31, 2012. Cost of product revenues for the nine months ended December 31, 2013 and 2012, respectively, was \$27.2 million and \$22.8 million. Gross margin was 80% for each of the nine months ended December 31, 2013 and 2012. The increase in cost of product revenues was related to increased Impella demand and costs to support the higher demand for Impella products. The increase in gross margin for the three months ended December 31, 2013 was primarily a result of increased production volume and improved manufacturing efficiency for our Impella products, partially offset by increased shipments of AIC consoles. We expect that shipments of AIC consoles will continue at approximately the current level for the remainder of fiscal 2014.

#### Research and Development Expenses

Research and development expenses for the three months ended December 31, 2013 increased by \$1.5 million, or 24%, to \$7.8 million from \$6.3 million for the three months ended December 31, 2012. Research and development expenses for the nine months ended December 31, 2013 increased by \$4.0 million, or 21%, to \$22.8 million from \$18.8 million for the nine months ended December 31, 2012.

The increase in research and development expenses was due primarily to an increase in spending associated with our PMA application for our existing Impella products, clinical spending on our Impella RP IDE study and product development initiatives associated with Impella RP, Impella CP and Symphony. We expect research and development expenses to increase in the remainder of fiscal 2014 as we continue to pursue our PMA application for our existing Impella products available for sale in the U.S., work on other clinical studies, such as Impella RP IDE and apply for regulatory approval for our Impella products in Japan. In addition, we expect to incur additional research and development costs as we continue to focus on new product development initiatives associated with Impella RP, Impella CP and Symphony.

## Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended December 31, 2013 increased by \$3.5 million, or 17%, to \$24.4 million from \$20.9 million for the three months ended December 31, 2012. Selling, general and administrative expenses for the nine months ended December 31, 2013 increased by \$18.2 million, or 30%, to \$78.5 million from \$60.3 million for the nine months ended December 31, 2012.

The increase in selling, general and administrative expenses was primarily due to the hiring of additional U.S. field sales and clinical personnel, increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support, implementation of the medical device tax and higher legal expenses related to the Department of Justice investigation and shareholder suits. During the three and nine months ended December 31, 2013, we incurred legal expenses of approximately \$0.7 million and \$4.9 million, respectively, 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 \$0.7 million and \$2.0 million of expenses in the three and nine months ended December 30, 2013, respectively, 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 the three months ended December 31, 2013 and 2012, we recorded a provision for income taxes of \$0.3 million and \$0.6 million, respectively. During the nine months ended December 31, 2013 and 2012, we recorded an income tax provision of \$1.0 million and \$1.5 million, respectively. The income tax provision for the three and nine months ended December 31, 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, and certain state income taxes that we do not expect to be offset by state net operating loss carryforwards. For the three and nine months ended December 31, 2013 differences between the expected tax at the US statutory tax rate and actual tax relate primarily to the use of the valuation allowance and the reversal of a prior tax accrual for federal taxes.

#### Net Income

During the three months ended December 31, 2013, we recorded net income of \$4.4 million, or \$0.11 per basic and diluted share, compared to net income of \$2.7 million, or \$0.07 per basic share and diluted share, for the three months ended December 31, 2012. During the nine months ended December 31, 2013, we incurred net income of \$3.7 million, or \$0.10 per basic share and \$0.09 per diluted share, compared to a net income of \$11.3 million, or \$0.29 per basic share and \$0.27 per diluted share, for the nine months ended December 31, 2012.

The increase in net income for the three months ended December 31, 2013 was due to increased Impella sales from greater demand for our products in the U.S, partially offset by 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.

The decrease in net income in for the nine months ended December 31, 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, partially offset by increased Impella sales from greater demand for our products in the U.S.

Even though we have been profitable in fiscal 2014 through December 31, 2013, 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, enter into future collaborations with other parties and invest in new markets such as Japan.

#### Liquidity and Capital Resources

At December 31, 2013, our cash, cash equivalents and short and long-term marketable securities totaled \$107.4 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, manage 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, pay the U.S. medical device tax and provide for general working capital needs. Through December 31, 2013, we have funded our operations principally from product sales and through the sale of equity securities.

Marketable securities at December 31, 2013 consisted of \$84.7 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.

23

During the nine months ended December 31, 2013, net cash provided by operating activities was \$13.6 million, compared to \$18.8 million during the same period in the prior year. The decrease in cash provided by operations was primarily attributable to the decrease in net income of \$7.6 million reflected in our net income of \$3.7 million for the nine months ended December 31, 2013 compared to our net income of \$11.3 million for the same period in fiscal 2013, an aggregate \$2.7 million increase in cash used for accounts payable and accrued expenses and other long-term liabilities, a \$0.7 million increase in cash used for prepaid expenses and other assets and a \$0.4 million decrease in cash provided by accounts receivable due to timing of receivable collections which were partially offset by a \$4.8 million decrease in cash used for inventories attributable to our completion of building up of inventory safety stock levels in fiscal year 2013. In addition, net cash provided by operating activities was impacted by changes in non-cash adjustments, including a \$1.5 million increase in stock-based compensation, partially offset by a \$0.3 million decrease in write-downs of inventory and a \$0.2 million decrease in depreciation and amortization expense.

During the nine months ended December 31, 2013, net cash used for investing activities was \$9.1 million, compared to \$5.8 million during the same period in the prior year. The increase in cash used for investing activities was primarily attributable to a \$34.1 million increase in purchases of marketable securities, partially offset by a \$31.8 million increase in proceeds from the sale and maturity of marketable securities. We also paid \$0.8 million for an investment in a private medical technology company and had a \$0.2 million increase in cash used for capital expenditures due to an increase in amounts spent in leasehold improvements in fiscal 2014.

During the nine months ended December 31, 2013, net cash provided by financing activities was \$8.1 million, compared to net cash used for financing activities of \$7.9 million during the same period in the prior year. The increase in net cash provided by financing activities was primarily attributable to a \$10.7 million decrease in cash used for the repurchase of common stock under our share repurchase program in fiscal 2013 and a \$5.5 million increase in proceeds from the exercise of stock options, partially 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 \$2.8 million at December 31, 2013 and March 31, 2013. 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. Our foreign operations are primarily treated as disregarded entities from a U.S. tax perspective. Any repatriation from our foreign operations would not result any material taxes.

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 existing and new markets 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 additional legal expenses related to the Department of Justice investigation, and to defend ourselves from other legal claims. We continue to review our cash needs on a regular basis. At December 31, 2013, 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 marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. Marketable securities at December 31, 2013 consist of \$84.7 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 December 31, 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 December 31, 2013, the result would have been a reduction of stockholders equity of approximately \$4.0 million.

#### Fair Value of Financial Instruments

At December 31, 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 December 31, 2013. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 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 third 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.

#### 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 are cooperating fully with the subpoena. We expect to substantially complete the requested document production by the end of fiscal 2014. On September 13, 2013, we entered into a tolling agreement with the United States Attorney s Office for the District of Columbia, pursuant to which we agreed to toll the applicable statutes of limitations for all criminal, civil and administrative offenses and violations that could be charged or claimed against us as of that date until June 2, 2014.

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. Oral argument on our motion to dismiss was conducted before the presiding district court judge on September 18, 2013.

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 United States Court of Appeals for the First Circuit. Oral argument was conducted before the appellate court on February 5, 2014.

#### 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, other than the addition of information to the risk factor entitled *Changes in health care reimbursement systems in the U.S. and abroad could reduce our revenues and profitability*, detailed below.

#### Changes in health care reimbursement systems in the U.S. and abroad could reduce our revenues and profitability.

In March 2010, the federal government enacted healthcare reform legislation. The legislation has changed the manner in which healthcare services are provided and paid for in the U.S. These changes may impact reimbursement for health care services, including reimbursement to hospitals and physicians. States may also enact further legislation that impacts Medicaid payments to hospitals and physicians. In addition, the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering the Medicare program, has established new payment levels for hospitals and physicians in line with the new legislation, which can increase or decrease payment to such entities.

The healthcare reform legislation and any future legislative, regulatory and reimbursement initiatives or changes to the reimbursement for our products could adversely affect demand for our products and have a material adverse impact on our revenues. Our business and results of operations could therefore be adversely affected by the current healthcare reform legislation as well as future healthcare reform or regulatory actions.

26

CMS uses International Classification of Diseases (ICD) codes to determine hospital reimbursement, which are aggregated into groups called Diagnosis Related Groups (DRGs) according to procedure and patient types, as well as other factors. On October 1, 2014, CMS will transition from the use of ICD-9 codes to the use of ICD-10 codes. ICD-9 codes have 4 numerical digits whereas ICD-10 codes have 7 alpha-numeric characters, each of which signifies a specific usage or characteristic. Of note, CMS intent for ICD-10 is to be more descriptive, not to change DRG mapping or payment. On October 30, 2013, an update was posted by CMS with a proposed code for the Impella family of devices to be mapped to DRGs 216, 217, 218, 219, 220, and 221, consistent with the most common current DRG mapping for the Impella pump.

Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers—spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we succeed in bringing our new products to market, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at profitable prices.

# **Item 2.** Unregistered Sales of Equity Securities and Use of Proceeds None

# **Item 3. Defaults Upon Senior Securities** None

# **Item 4. Mine Safety Disclosures** Not applicable.

# **Item 5. Other Information None**

27

## Item 6. Exhibits

# Filed with

Exhibit		This			
No.	Description	Form 10-Q		Incorporated by Referen	ce Exhibit
			Form	Filing Date	No.
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 December 31, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2013 and March 31, 2013; (ii) Consolidated Statements of Operations for the three and nine months ended December 31, 2013 and December 31, 2012; (iii) Consolidated Statements of Comprehensive Income for the three and nine months ended December 31, 2013 and	X			

Table of Contents 47

December 31, 2012; (iv) Consolidated Statements of Cash Flows for the nine

months ended December 31, 2013 and December 31, 2012; and (v) Notes to Consolidated Financial Statements.

28

## ABIOMED, INC. AND SUBSIDIARIES

#### PART II. OTHER INFORMATION

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Abiomed, Inc.

Date: February 6, 2014

/s/ ROBERT L. BOWEN
Robert L. Bowen
Vice President and Chief Financial Officer

(Principal Accounting and Financial Officer)

29