

ABIOMED INC
Form 10-Q
November 07, 2011
[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, 2011

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 0-20584

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 31, 2011, there were 38,566,362 shares outstanding of the registrant's Common Stock, \$.01 par value.

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

	Page
<u>PART I - FINANCIAL INFORMATION:</u>	
Item 1. <u>Financial Statements</u>	3
<u>Consolidated Balance Sheets as of September 30, 2011 (unaudited) and March 31, 2011</u>	3
<u>Consolidated Statements of Operations for the three and six months ended September 30, 2011 and 2010 (unaudited)</u>	4
<u>Consolidated Statements of Cash Flows for the six months ended September 30, 2011 and 2010 (unaudited)</u>	5
<u>Notes to Consolidated Financial Statements (unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	16
Item 4. <u>Controls and Procedures</u>	16
<u>PART II - OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	17
Item 1A. <u>Risk Factors</u>	18
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
Item 3. <u>Defaults Upon Senior Securities</u>	18
Item 4. <u>(Removed and Reserved)</u>	18
Item 5. <u>Other Information</u>	18
Item 6. <u>Exhibits</u>	19
<u>SIGNATURES</u>	20

ABIOMED and ABIOCOR 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, 2011 (unaudited)	March 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,338	\$ 5,831
Short-term marketable securities	55,482	54,481
Accounts receivable, net	15,490	15,376
Inventories	9,211	7,505
Prepaid expenses and other current assets	1,407	1,544
Total current assets	86,928	84,737
Property and equipment, net	6,273	6,273
Intangible assets, net	847	1,632
Goodwill	37,562	38,946
Total assets	\$ 131,610	\$ 131,588
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,457	\$ 6,283
Accrued expenses	9,158	14,078
Deferred revenue	1,819	1,982
Total current liabilities	15,434	22,343
Long-term deferred tax liability	4,332	4,010
Other long-term liabilities	445	492
Total liabilities	20,211	26,845
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	386	377
Authorized - 100,000,000 shares; Issued - 38,611,276 shares at September 30, 2011 and 37,756,719 shares at March 31, 2011;		
Outstanding - 38,560,322 shares at September 30, 2011 and 37,705,765 shares at March 31, 2011		
Additional paid-in-capital	391,432	379,218
Accumulated deficit	(278,763)	(274,770)
Treasury stock at cost - 50,954 shares at September 30, 2011 and March 31, 2011	(827)	(827)

Edgar Filing: ABIOMED INC - Form 10-Q

Accumulated other comprehensive (loss) income	(829)	745
Total stockholders' equity	111,399	104,743
Total liabilities and stockholders' equity	\$ 131,610	\$ 131,588

See Accompanying Notes to 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,	
	2011	2010	2011	2010
Revenue:				
Product	\$ 29,151	\$ 23,058	\$ 56,317	\$ 44,819
Funded research and development	327	318	516	559
Total Revenue	29,478	23,376	56,833	45,378
Costs and expenses:				
Cost of product revenue excluding amortization of intangibles	5,551	5,408	11,442	10,692
Research and development	6,459	6,589	13,783	13,242
Selling, general and administrative	16,323	14,054	34,499	29,807
Amortization of intangible assets	379	372	764	739
	28,712	26,423	60,488	54,480
Income (loss) from operations	766	(3,047)	(3,655)	(9,102)
Other income and expense:				
Investment (expense) income, net	(6)	(1)	(2)	(3)
Gain on sale of WorldHeart stock		217		456
Other income (expense), net	66	(128)	(15)	(47)
	60	88	(17)	406
Income (loss) before provision for income taxes	826	(2,959)	(3,672)	(8,696)
Provision for income taxes	225	242	321	485
Net income (loss)	\$ 601	\$ (3,201)	\$ (3,993)	\$ (9,181)
Basic net income (loss) per share	\$ 0.02	\$ (0.09)	\$ (0.10)	\$ (0.25)
Basic weighted average shares outstanding	38,256	37,156	38,081	37,121
Diluted net income (loss) per share	\$ 0.02	\$ (0.09)	\$ (0.10)	\$ (0.25)
Diluted weighted average shares outstanding	39,366	37,156	38,081	37,121

See Accompanying Notes to Consolidated Financial Statements (Unaudited).

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

	Six months ended September 30,	
	2011	2010
Operating activities:		
Net loss	\$ (3,993)	\$ (9,181)
Adjustments required to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	2,125	2,104
Bad debt expense	65	127
Stock-based compensation	4,131	2,746
Write-down of inventory	376	1,364
Loss on disposal of fixed assets	29	5
Deferred tax provision	321	485
Gain on sale of WorldHeart common stock		(456)
Changes in assets and liabilities source (use):		
Accounts receivable	(235)	(1,582)
Inventories	(2,562)	451
Prepaid expenses and other current assets	114	467
Accounts payable	(1,854)	8
Accrued expenses and other long-term liabilities	(4,649)	(1,211)
Deferred revenue	(158)	238
Net cash used in operating activities	(6,290)	(4,435)
Investing activities:		
Purchases of short-term marketable securities	(8,001)	(1,502)
Proceeds from the sale and maturity of short-term marketable securities	7,000	5,000
Proceeds from the sale of WorldHeart common stock		456
Expenditures for property and equipment	(1,137)	(591)
Net cash (used in) provided by investing activities	(2,138)	3,363
Financing activities:		
Proceeds from the exercise of stock options	7,800	343
Proceeds from the issuance of stock under the employee stock purchase plan	197	153
Net cash provided by financing activities	7,997	496
Effect of exchange rate changes on cash	(62)	(61)
Net decrease in cash and cash equivalents	(493)	(637)
Cash and cash equivalents at beginning of period	5,831	4,788
Cash and cash equivalents at end of period	\$ 5,338	\$ 4,151
Supplemental disclosures:		
Fixed asset additions included in accounts payable	\$ 44	\$ 18

See Accompanying Notes to 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 provider of medical devices in circulatory support and offers a continuum of care in heart recovery for acute heart failure patients. The Company's products 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 (cath lab) by interventional cardiologists and/or in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophelactically during high risk angioplasty procedures or who are in pre-shock, shock or profound cardiogenic shock.

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, 2011 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, 2011 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, 2011.

Note 2. New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies, which are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that any recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Note 3. Fair Value Measurements

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 value is 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.

Edgar Filing: ABIOMED INC - Form 10-Q

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

Table of Contents

The Company's marketable securities were invested in the following:

	Level 1	Level 2 (in \$000 s)	Level 3	Total
At September 30, 2011:				
U.S. Treasury securities	\$ 55,482	\$	\$	\$ 55,482
At March 31, 2011:				
U.S. Treasury securities	\$ 54,481	\$	\$	\$ 54,481

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:

	September 30, 2011	March 31, 2011
	(in \$000 s)	
Raw materials and supplies	\$ 3,742	\$ 2,784
Work-in-progress	3,699	3,689
Finished goods	1,770	1,032
	\$ 9,211	\$ 7,505

The Company's inventories relate to its circulatory care product lines, primarily the Impella, AB5000 and BVS 5000. Finished goods and work-in-process inventories consist of direct material, labor and overhead. During the six months ended September 30, 2011 and 2010, the Company recorded \$0.4 million and \$1.4 million, respectively, in write downs of inventory, including excess quantities and obsolete 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 generally amortized over a one to five year life. The Company had \$0.6 million and \$0.7 million in demo inventory at September 30, 2011 and March 31, 2011, respectively. Amortization expense related to demo inventory was \$0.2 million and \$0.3 million for the three months ending September 30, 2011 and 2010, respectively. Amortization expense related to demo inventory was \$0.3 million and \$0.4 million for the six months ended September 30, 2011 and 2010, respectively.

Note 5. Intangible Assets and Goodwill

The carrying amount of goodwill at September 30, 2011 and March 31, 2011 was \$37.6 million and \$38.9 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG, or Impella. The goodwill activity for the six months ended September 30, 2011 is as follows:

	(in \$000 s)
Balance at April 1, 2011	\$ 38,946
Exchange rate impact	(1,384)

Edgar Filing: ABIOMED INC - Form 10-Q

Balance at September 30, 2011 \$ 37,562

The components of intangible assets are as follows:

	September 30, 2011			March 31, 2011		
	Cost	Accumulated Amortization (in \$000 s)	Net Book Value	Cost	Accumulated Amortization (in \$000 s)	Net Book Value
Patents	\$ 6,858	\$ 6,289	\$ 569	\$ 7,099	\$ 6,005	\$ 1,094
Trademarks and tradenames	349	319	30	361	299	62
Distribution agreements	666	610	56	690	584	106
Acquired technology	2,299	2,107	192	2,384	2,014	370
	\$ 10,172	\$ 9,325	\$ 847	\$ 10,534	\$ 8,902	\$ 1,632

Amortization of intangible assets was \$0.4 million for each of the three months ended September 30, 2011 and 2010. Amortization of intangible assets was \$0.8 million and \$0.7 million for the six months ended September 30, 2011 and 2010, respectively. The Company's expected amortization expense will be \$0.7 million for the six months ending March 31, 2012 and \$0.1 million for the year ending March 31, 2013.

Table of Contents**Note 6. Stock-Based Compensation**

Total stock-based compensation recognized in the Company's condensed consolidated statements of operations for the three and six months ended September 30, 2011 and 2010 was as follows:

	Three Months Ended September 30, 2011		Six Months Ended September 30, 2011	
	(in \$000 s)		(in \$000 s)	
Cost of product revenue	\$ 73	\$ 50	\$ 149	\$ 112
Research and development	372	226	872	536
Selling, general and administrative	1,354	1,099	3,110	2,098
	\$ 1,799	\$ 1,375	\$ 4,131	\$ 2,746

The remaining unrecognized stock-based compensation expense for unvested stock option awards at September 30, 2011 was approximately \$3.8 million, net of forfeitures, and the weighted-average time over which this cost will be recognized is 2.2 years.

Stock Option Activity

The following table summarizes the stock option activity for the six months ended September 30, 2011:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at April 1, 2011	5,945	\$ 10.27	6.30	
Granted	44	16.29		
Exercised	(829)	9.41		
Cancelled	(121)	8.86		
Expired	(95)	21.22		
Outstanding at September 30, 2011	4,944	\$ 11.86	6.20	\$ 9,824
Exercisable at September 30, 2011	3,596	\$ 10.57	5.49	\$ 6,024

The total intrinsic value of options exercised was \$6.0 million for the six months ended September 30, 2011. The total fair value of options vested during the six months ended September 30, 2011 was \$11.2 million.

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model. The fair value of options granted during the three and six months ended September 30, 2011 were calculated using the following weighted-average assumptions:

	Three Months Ended September 30, 2011	Six Months Ended September 30, 2011
Risk-free interest rate	0.94%	1.72%
Expected option life (years)	5.21	5.29

Edgar Filing: ABIOMED INC - Form 10-Q

Expected volatility	53.1%	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. The Company estimates the expected term based on historical experience. The expected dividend yield was zero, since the Company does not pay cash dividends and does not expect to pay cash dividends in the future. 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.

The weighted-average grant-date fair value for options granted during the three and six months ended September 30, 2011 was \$5.68 and \$7.72, respectively.

Table of Contents***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:

	Six Months Ended September 30, 2011	
	Number of Shares (in 000 s)	Weighted Average Grant Date Fair Value
Restricted stock awards and restricted stock units at April 1, 2011	407	\$ 9.84
Granted	596	17.70
Vested	(134)	10.88
Forfeited		
Restricted stock awards and restricted stock units at September 30, 2011	869	\$ 15.07

The remaining unrecognized compensation expense for restricted stock awards and restricted stock units, including performance based awards, at September 30, 2011 was approximately \$8.9 million and the weighted-average time over which this cost will be recognized is 2.5 years.

Performance Based Awards

Included in the restricted stock activity discussed above are certain awards granted in fiscal 2011 and 2012 that contain performance based vesting.

During the three months ended June 30, 2010, 311,000 shares of performance based restricted stock and a performance award for the potential issuance of 45,000 shares of common stock were issued to certain executive officers and members of senior management of the Company, all of which could vest upon achievement of prescribed performance milestones. During the year ended March 31, 2011, the Company determined that the prescribed performance targets were met.

During the three months ended June 30, 2011, the Company determined that it should have been using the graded vesting method instead of the straight-line method to expense stock-based compensation for the performance based awards issued in June 2010. This resulted in additional stock based compensation expense of approximately \$0.6 million being recorded during the three months ended June 30, 2011 that should have been recorded during the year ended March 31, 2011. The Company believes that the amount is not material to its March 31, 2011 consolidated financial statements and has therefore recorded the adjustment in the quarter ended June 30, 2011.

During the three months ended June 30, 2011, performance 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, all of which could vest upon achievement of prescribed revenue performance milestones. As of September 30, 2011, the Company believes it is probable that the prescribed performance targets will be met for these awards.

As of September 30, 2011, the Company has recorded \$2.8 million in stock-based compensation for shares in which the prescribed performance milestones have been achieved or are probable of being achieved. The remaining unrecognized compensation expense related to these restricted shares at September 30, 2011 is \$5.0 million based on the Company's current assessment of probability of achieving the performance milestones.

Note 7. 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.

Edgar Filing: ABIOMED INC - Form 10-Q

As of September 30, 2011, the Company has accumulated a net deferred tax liability in the amount of \$4.3 million which is the result of a difference in accounting for the Company's goodwill which is amortized over 15 years for tax purposes, but not amortized 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.

Table of Contents

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 open tax years remain subject to examination by major tax jurisdictions, including the federal government and the Commonwealth of Massachusetts. However, since 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 carry forwards are utilized.

Note 8. 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 shares outstanding any potential dilutive securities outstanding for the period. Potential dilutive securities include stock options, restricted stock, restricted stock units, performance stock and shares to be purchased under the 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 is the same.

	Three Months Ended September 30,		Six Months Ended September 30,	
	2011	2010	2011	2010
Net income (loss)	\$ 601	(3,201)	\$ (3,993)	\$ (9,181)
Weighted average shares used in computing basic net income per share	38,256	37,156	38,081	37,121
Net income (loss) per share basic	\$ 0.02	(0.09)	\$ (0.10)	\$ (0.25)
Net income (loss)	\$ 601	(3,201)	\$ (3,993)	(9,181)
Weighted average shares uses in computing basic net income per share	38,256	37,156	38,081	\$ 37,121
Effect of dilutive securities	1,110			
Weighted average shares uses in computing diluted net income per share	39,366	37,156	38,081	37,121
Net income (loss) per share diluted	\$ 0.02	(0.09)	\$ (0.10)	\$ (0.25)

The calculation of diluted net income per share for the three months ended September 30, 2011 does not include securities totaling 1,656,241 because inclusion would have an antidilutive effect on net income per share. Excluded from the calculation of diluted weighted-average shares outstanding for the three months ending September 30, 2010 are underlying stock options of approximately 6,028,000 and unvested shares of restricted stock of approximately 653,000. Excluded from the calculation of diluted weighted-average shares outstanding for the six months ending September 30, 2011 and 2010 are underlying stock options of approximately 4,944,000 and 6,028,000 shares, respectively, and unvested shares of restricted stock and restricted stock units of approximately 869,000 shares and 653,000 shares, respectively.

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, 2011, the Company did not have any material pending litigation.

Note 10. Accrued Expenses

Accrued expenses consist of the following:

Edgar Filing: ABIOMED INC - Form 10-Q

	September 30, 2011	March 31, 2011
	(in \$000 s)	
Salaries and benefits	\$ 5,839	\$ 7,416
Research and development	1,178	3,991
Professional, accounting and audit fees	404	616
Warranty	660	537
Other	1,077	1,518
	\$ 9,158	\$ 14,078

Note 11. Segment and Enterprise Wide Disclosures

The Company operates in one business segment the research, development and sale of medical devices to assist or replace the pumping function of the failing heart. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results. Approximately 62% and 61% of the Company's total consolidated assets are located within the U.S. as of September 30, 2011 and March 31, 2011, respectively. Remaining assets are located in Europe, primarily related to the Company's Impella production facility, and include goodwill and intangibles of \$38.4 million and \$40.5 million at September 30, 2011 and March 31, 2011, respectively. Total assets in Europe excluding goodwill and intangibles amounted to 9% and 8%, respectively, of total consolidated assets at each of September 30, 2011 and March 31, 2011. For each of the three and six months ended September 30, 2011 and 2010, international sales accounted for 7% of total product revenue.

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, 2011. 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 medical devices in circulatory support and we offer a continuum of care in heart recovery for acute heart failure patients. Our products 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/or in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophylactically during high risk angioplasty procedures or who are in pre-shock, shock or profound cardiogenic shock. We believe heart recovery is the optimal clinical outcome by restoring the quality of life of patients. In addition, we believe heart recovery is the most cost-effective path 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. 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 used in the study. In April 2011, we announced the final results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 21% reduction in major adverse events compared to the intra aortic balloon at 90 days per protocol. We received 510(k) clearance in April 2009 for our Impella 5.0 and Impella LD devices for circulatory support for up to 6 hours. These devices are larger and provide more blood flow than the Impella 2.5.

Revenues from our other heart recovery 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 during fiscal 2012 from our non-Impella business, including BVS and AB5000, will continue to decrease as we continue to focus on our Impella products. In addition, we do not expect that revenues from sales of our replacement heart product, the AbioCor, will be a material portion of our total revenues for the foreseeable future as our primary strategic focus is centered on heart recovery for acute heart failure patients. We have incurred net losses since our inception, including a net loss of \$4.0 million for the six months ended September 30, 2011. Although we recorded net income of \$0.6 million for the three months ended September 30, 2011, we may incur additional losses in the future as we continue to expand our commercial infrastructure and invest in research and development related to our products.

Impella 2.5

The Impella 2.5 catheter is a percutaneous micro heart pump with an integrated motor and sensors. The device is designed primarily for use by interventional cardiologists to support patients in the cath lab who may require assistance to maintain their circulation. The Impella 2.5 device received 510(k) clearance from the U.S. Food and Drug Administration, or 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, deliver it to the arterial system and perfuse the heart muscle. This function is intended to reduce ventricular work, which allows the heart to rest, while providing flow of blood 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 optimal 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 used in the study. In April 2011, we announced final results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 21% reduction in major adverse events compared to the IAB at 90 days per protocol.

In addition to the FDA approved studies for Impella 2.5, we are also conducting USpella, the first U.S. multicenter observational registry collecting clinical data and outcomes for patients supported with Impella 2.5 during elective, urgent and emergent procedures. We have invited 62 hospitals in the U.S. and Canada to participate in the USpella registry.

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 and are approved for use in over 40 countries.

The Impella 5.0 is implanted via a small incision in the femoral artery in the groin and can be quickly inserted via the femoral artery using a guide wire to reach the left ventricle of the heart where it is 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 (resting the heart). The Impella LD is similar to the Impella 5.0 but is implanted directly through an incision in the subclavian vein or through an aortic graft. The Impella 5.0 and Impella LD can pump up to five liters of blood per minute and have been used to treat patients in need of cardiac support resulting from post-cardiotomy cardiogenic shock, myocarditis, low cardiac output after a heart attack, or post-coronary intervention procedures.

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 intended 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 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 IDE to conduct a U.S. patient discharge study at 20 hospitals for 30 patients. In March 2009, we received FDA approval of our PMA supplement for the AB Portable Driver. This clearance allows for commercial shipment of the device to U.S. hospitals for in hospital and transport use. Out-of-hospital use is being studied in the U.S. in a U.S. clinical trial, which, when successfully completed, would allow patients to go home while waiting for recovery.

AbioCor

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 infection. This technology provides patients with mobility and remote diagnostics. The use of AbioCor is limited to normal to larger sized male patients and the product has a life expectancy of 18-24 months.

Edgar Filing: ABIOMED INC - Form 10-Q

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 without the technology. HDE approval allows the AbioCor to be made available to a limited patient population, with no more than 4,000 patients receiving the technology in the U.S. each year under HDE approval limits. Because the AbioCor is only available to a

Table of Contents

limited patient population, we do not expect that demand will meet the 4,000 patient limit under HDE approval. We have no current plans to seek a broader regulatory approval of the AbioCor. We do not expect that revenues from sales of the AbioCor will be a material portion of our total revenues 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, 2011, 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, 2011.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies, which are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Results of Operations

The following table sets forth certain consolidated statements of operations data for the periods indicated as a percentage of total revenues (which includes revenues from products and funded research and development) for the three and six months ended September 30, 2011 and 2010, respectively:

	Three Months Ended September 30,		Six Months Ended September 30,	
	2011	2010	2011	2010
Revenues:				
Product	98.9%	98.6%	99.1%	98.8%
Funded research and development	1.1	1.4	0.9	1.2
	100.0	100.0	100.0	100.0
Costs and expenses:				
Cost of product revenue excluding amortization of intangibles	18.8	23.1	20.1	23.6
Research and development	21.9	28.2	24.3	29.2
Selling, general and administrative	55.4	60.1	60.7	65.7
Amortization of intangible assets	1.3	1.6	1.3	1.6
	97.4	113.0	106.4	120.1
Income (loss) from operations	2.6	(13.0)	(6.4)	(20.1)
Other income and expense:				
Gain on Sale of Worldheart stock		0.9		1.0
Other income (expense), net	0.2	(0.5)	(0.1)	(0.1)
	0.2	0.4	(0.1)	0.9
Income (loss) before provision for income taxes	2.8	(12.6)	(6.5)	(19.2)
Provision for income taxes	0.8	1.0	0.5	1.1
Net income (loss)	2.0%	(13.6)%	(7.0)%	(20.3)%

Edgar Filing: ABIOMED INC - Form 10-Q

Three and six months ended September 30, 2011 compared with the three and six months ended September 30, 2010

Revenues

Our revenues are comprised of the following:

	Three Months Ended September 30, 2011		Six Months Ended September 30, 2011	
	(in \$000 s)		(in \$000 s)	
Impella product revenue	\$ 24,802	\$ 17,679	\$ 46,994	\$ 34,424
Other product revenue	2,511	3,978	5,935	7,857
Service and other revenue	1,838	1,401	3,388	2,538
Total product and service revenues	29,151	23,058	56,317	44,819
Funded research and development	327	318	516	559
Total revenues	\$ 29,478	\$ 23,376	\$ 56,833	\$ 45,378

Table of Contents

Impella product revenue encompasses Impella 2.5, 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, 2011 increased by \$6.1 million, or 26%, to \$29.5 million from \$23.4 million for the three months ended September 30, 2010. The increase in total revenue was primarily due to higher Impella orders due to greater demand in the U.S. Total revenues for the six months ended September 30, 2011 increased by \$11.4 million, or 25%, to \$56.8 million from \$45.4 million for the six months ended September 30, 2010. The increase in total revenue was primarily due to higher Impella orders due to greater demand in the U.S.

Impella product revenues for the three months ended September 30, 2011 increased by \$7.1 million, or 40% to \$24.8 million from \$17.7 million for the three months ended September 30, 2010. Impella revenues for the six months ended September 30, 2011 increased by \$12.6 million, or 37% to \$47.0 million from \$34.4 million for the six months ended September 30, 2010. Most of our Impella revenue was from disposable product sales of Impella in the U.S., as we focus on 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, 2011 decreased by \$1.5 million, or 38%, to \$2.5 million from \$4.0 million for the three months ended September 30, 2010. Other product revenues for the six months ended September 30, 2011 decreased by \$2.0 million, or 25%, to \$5.9 million from \$7.9 million for the six months ended September 30, 2010. 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 2012 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, 2011 increased by \$0.4 million, or 28%, to \$1.8 million from \$1.4 million for the three months ended September 30, 2010. Service revenue for the six months ended September 30, 2011 increased by \$0.9 million, or 36%, to \$3.4 million from \$2.5 million for the six months ended September 30, 2010. The increase in service revenue was primarily due to an increase in service contracts, primarily for Impella consoles.

Cost of Product Revenues

Cost of product revenues for the three months ended September 30, 2011 and 2010, respectively, was \$5.6 million and \$5.4 million. Gross margin was 81% for the three months ended September 30, 2011 compared to 77% for the three months ended September 30, 2010. The increase in gross margin was primarily due to a larger portion of revenues from disposable products, improved manufacturing production and lower writedowns on inventory.

Cost of product revenues for the six months ended September 30, 2011 and 2010, respectively, was \$11.4 million and \$10.7 million. Gross margin was 80% for the six months ended September 30, 2011 compared to 76% for the six months ended September 30, 2010. The increase in gross margin was primarily due to a larger portion of revenues from disposable products, improved manufacturing production and lower writedowns on inventory.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2011 decreased by \$0.1 million, or 2%, to \$6.5 million from \$6.6 million for the three months ended September 30, 2010, primarily due to a decrease in clinical trial expenditures primarily associated with our Impella 2.5 U.S. trials, partially offset by an increase in spending on product development. Research and development expenses for the three months ended September 30, 2011 and 2010 included \$1.2 million and \$2.4 million, respectively, in clinical trial costs primarily associated with our Impella 2.5 U.S. trials.

Research and development expenses for the six months ended September 30, 2011 increased by \$0.6 million, or 5%, to \$13.8 million from \$13.2 million for the six months ended September 30, 2010, primarily due to increased project spending on new product development. Research and development expenses for the six months ended September 30, 2011 and 2010 included \$3.7 million and \$5.0 million, respectively, in clinical trial expenses primarily associated with our Impella 2.5 U.S. trials.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2011 increased by \$2.2 million, or 16%, to \$16.3 million from \$14.1 million for the three months ended September 30, 2010.

Edgar Filing: ABIOMED INC - Form 10-Q

Selling, general and administrative expenses for the six months ended September 30, 2011 increased by \$4.7 million, or 16%, to \$34.5 million from \$29.8 million for the six months ended September 30, 2010. The increase in selling, general and administrative expenses was due to increased field headcount as we concentrate our marketing focus on commercial efforts in the U.S. and an increase in stock-based compensation expense due in part to changes made in assumptions during the first quarter regarding how expense is recognized over the service period for performance-based awards.

Table of Contents

We expect to increase our expenditures on sales and marketing activities in fiscal 2012, 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 \$0.4 million for each of the three months ended September 30, 2011 and 2010, and \$0.8 million and \$0.7 million, respectively, for the six months ending September 30, 2011 and 2010. Amortization expense primarily is related specifically to intangible assets acquired in the Impella acquisition.

Gain on Sale of WorldHeart Stock

During the six months ended September 30, 2010, we sold 188,170 shares of WorldHeart common stock, which resulted in a gain of \$0.5 million. At September 30, 2011, we have no remaining shares of WorldHeart common stock.

Provision for Income Taxes

We recorded an income tax provision of \$0.2 million for each of the three months ended September 30, 2011 and 2010. During the six months ended September 30, 2011 and 2010, we recorded an income tax provision of \$0.3 million and \$0.5 million, respectively. The income tax provision is due to deferred tax related to our goodwill, which is amortizable over 15 years for tax purposes but not amortized for book purposes. The net deferred tax liability cannot be offset against our deferred tax assets since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period.

Net Income (Loss)

During the three months ended September 30, 2011, we recorded net income of \$0.6 million, or \$0.02 per basic and diluted share, compared to a net loss of \$3.2 million, or \$0.09 per basic and diluted share, for the three months ended September 30, 2010. The increase in profitability was due to increased Impella sales due to greater demand in the U.S.

During the six months ended September 30, 2011, we incurred a net loss of \$4.0 million, or \$0.10 per share, compared to a net loss of \$9.2 million, or \$0.25 per basic and diluted share, for the six months ended September 30, 2010. The decrease in net loss was due to increased Impella sales due to greater demand in the U.S.

Liquidity and Capital Resources

At September 30, 2011, our cash, cash equivalents, and short-term marketable securities totaled \$60.8 million, an increase of \$0.5 million compared to \$60.3 million at March 31, 2011. 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.

Marketable securities at September 30, 2011 consist of \$55.5 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.

We will continue to closely monitor our liquidity and the overall health of the credit markets. However, we cannot predict with any certainty the impact on us of any further disruption in the credit environment. Our primary liquidity needs are to fund the expansion of our commercial infrastructure in the U.S., increase our Impella manufacturing capacity, fund new product development and provide for general working capital needs. Through September 30, 2011, we have funded our operations principally from product sales and through the sale of equity securities, including our August 2008 stock offering in which we received proceeds of \$42.0 million. We also generate cash through funded research and development revenue.

Our operating activities during the six months ended September 30, 2011 used cash of \$6.3 million as compared to \$4.4 million during the same period in the prior year. Contributing to our cash used for operations was a \$4.0 million net loss for the six months ended September 30, 2011, a \$2.6 million increase in inventory, a \$0.2 million decrease in deferred revenue, and a \$6.5 million decrease in accounts payable and accrued expenses primarily due to the payment of annual employee bonuses in the first quarter and payments related to the closeout of the Protect II

Edgar Filing: ABIOMED INC - Form 10-Q

study. These decreases in cash were partially offset by non-cash adjustments of \$4.1 million related to stock-based compensation expense and \$2.1 million of depreciation and amortization.

Our investing activities during the six months ended September 30, 2011 used cash of \$2.1 million as compared to a generation of cash of \$3.4 million during the same period in the prior year. Cash used by investment activities for the six months ended September 30, 2011 consisted primarily of \$1.0 million of purchases of short-term marketable securities, net of proceeds, during the period. We also incurred \$1.1 million of cash expenditures for property and equipment primarily for the purchase of manufacturing equipment and computer software.

Table of Contents

Our financing activities during each of the six months ended September 30, 2011 and 2010 provided cash of \$8.0 million and \$0.5 million, respectively. Cash provided by financing activities during the six months ended September 30, 2011 was primarily attributable to the exercise of stock options.

Capital expenditures for fiscal 2012 are estimated to be \$2.5 to \$3.5 million, which relate primarily to our planned manufacturing capacity increases for Impella and software development projects.

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. We have no debt outstanding.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Primary Market Risk Exposures

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. Our cash and marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at September 30, 2011, we believe the decline in fair market value of our investment portfolio would be immaterial. Marketable securities at September 30, 2011 consist of \$55.5 million in five funds that invest in U.S. Treasury securities and related interest.

Currency Exchange Rates

Our foreign subsidiaries' primary functional currency is the Euro. Therefore, our investment in our foreign subsidiaries is sensitive to fluctuations in currency exchange rates. The effect of a change in currency exchange rates on our net investment in international subsidiaries is reflected in the accumulated other comprehensive income component of stockholders' equity. Had a 10% depreciation in foreign currencies occurred relative to the U.S. dollar as of September 30, 2011, the result would have been a reduction of stockholders' equity of approximately \$4.1 million.

Fair Value of Financial Instruments

At September 30, 2011, 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, 2011. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2011, 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

Edgar Filing: ABIOMED INC - Form 10-Q

During the second quarter of our fiscal year ended March 31, 2012, 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.

Table of Contents

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, 2011, which could materially affect our business, financial condition or future results. To the best of our knowledge, as of the date of this report, the only material change to the risk factors described in our Annual Report on Form 10-K is to replace the similarly titled risk factor in the annual report with the risk factor set forth below.

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 have cooperated with the FDA in addressing its concerns and believe that we have resolved the matter without any penalties. Although we believe that this issue has been resolved, if similar matters come up in the future, we may not be able to resolve them without facing significant consequences. Such matters could result in reduced demand for our products and would have a material adverse effect on our operations and prospects.

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

None

Item 3. Defaults Upon Senior Securities

None

Item 4. (Removed and Reserved)

Item 5. Other Information

None

Table of Contents**Item 6. Exhibits**

Exhibit No.	Description	Filed with		Incorporated by Reference	Exhibit No.
		This	Form 10-Q		
			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 8, 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, 2011, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of September 30, 2011 and March 31, 2011; (ii) Consolidated Statements of Operations for the three and six months ended September 30, 2011 and September 30, 2010; (iii) Consolidated Statements of Cash Flows for the six months ended September 30, 2011 and September 30, 2010; and (iv) 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 7, 2011

/s/ ROBERT L. BOWEN

Robert L. Bowen

Vice President and Chief Financial Officer

(Principal Accounting and Financial Officer)