

ABIOMED INC  
Form 10-Q  
November 08, 2007  
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, 2007

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)

---

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

22 CHERRY HILL DRIVE

DANVERS, MASSACHUSETTS 01923

**04-2743260**  
(IRS Employer

Identification No.)

Edgar Filing: ABIOMED INC - Form 10-Q

(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) or 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 is, a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated Filer  Non-accelerated filer

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 November 7, 2007, there were 32,523,761 shares outstanding of the registrant's Common Stock, \$.01 par value.

---

**Table of Contents**

ABIOMED, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

	<b>Page</b>
<b><u>PART I - FINANCIAL INFORMATION:</u></b>	
Item 1. <u>Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2007 (unaudited) and March 31, 2007</u>	3
<u>Condensed Consolidated Statements of Operations for the three and six months ended September 30, 2007 and 2006 (unaudited)</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the six months ended September 30, 2007 and 2006 (unaudited)</u>	5
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	23
Item 4. <u>Controls and Procedures.</u>	24
 <b><u>PART II - OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings.</u>	25
Item 1A. <u>Risk Factors.</u>	25
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds.</u>	26
Item 3. <u>Defaults Upon Senior Securities.</u>	26
Item 4. <u>Submission of Matters to a Vote of Security Holders.</u>	26
Item 5. <u>Other Information.</u>	26
Item 6. <u>Exhibits.</u>	26
<b><u>SIGNATURES</u></b>	27

ABIOMED and ABIOCOR are trademarks of ABIOMED, Inc., and are registered in the U.S.A. and certain foreign countries. BVS is a trademark of ABIOMED, Inc. and is registered in the U.S.A. AB5000 is a trademark of ABIOMED, Inc. IMPELLA and RECOVER are trademarks of Abiomed Europe GmbH, a subsidiary of ABIOMED, Inc., and are registered in the U.S.A. and certain foreign countries.

**Table of Contents****PART 1. FINANCIAL INFORMATION****ITEM 1: FINANCIAL STATEMENTS****ABIOMED, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except share data)

	September 30, 2007 (Unaudited)	March 31, 2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 59,518	\$ 69,646
Short-term marketable securities		5,479
Accounts receivable, net	8,615	10,932
Inventories	14,600	8,567
Prepaid expenses and other current assets	1,661	1,758
Total current assets	84,394	96,382
Property and equipment, net	7,033	5,764
Intangible assets, net	6,989	7,329
Goodwill	28,396	26,708
Total assets	\$ 126,812	\$ 136,183
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,312	\$ 5,185
Accrued expenses	6,582	7,017
Deferred revenue	774	695
Total current liabilities	12,668	12,897
Long-term deferred tax liability	2,458	1,191
Other long-term liabilities	275	
Total liabilities	15,401	14,088
Commitments and contingencies		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value		
Authorized 1,000,000 shares; Issued and outstanding none		
Common stock, \$.01 par value	325	323
Authorized 100,000,000 shares;		
Issued 32,524,030 shares at September 30, 2007 and 32,254,577 shares at March 31, 2007;		
Outstanding 32,513,011 shares at September 30, 2007 and 32,243,558 shares at March 31, 2007		
Additional paid-in-capital	298,248	292,467
Accumulated deficit	(189,121)	(171,189)
Treasury stock at cost 11,019 shares at September 30, 2007 and at March 31, 2007	(116)	(116)
Accumulated other comprehensive income	2,075	610
Total stockholders' equity	111,411	122,095

Edgar Filing: ABIOMED INC - Form 10-Q

Total liabilities and stockholders' equity	\$	126,812	\$	136,183
--	----	---------	----	---------

See Accompanying Notes to Condensed Consolidated Financial Statements (Unaudited).

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

(in thousands, except per share data)

	<b>Three Months Ended September 30,</b>		<b>Six Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>Revenue:</b>				
Products	\$ 11,272	\$ 10,867	\$ 25,173	\$ 23,875
Funded research and development	83	19	246	19
	11,355	10,886	25,419	23,894
<b>Costs and expenses:</b>				
Cost of product revenue excluding amortization of intangibles	2,877	2,925	6,409	6,408
Research and development	5,832	5,285	11,348	10,704
Selling, general and administrative	12,257	11,046	24,699	20,438
Arbitration decision	(26)		1,206	
Expensed in-process research and development				800
Amortization of intangible assets	386	504	766	870
	21,326	19,760	44,428	39,220
Loss from operations	(9,971)	(8,874)	(19,009)	(15,326)
<b>Other income:</b>				
Investment income	802	286	1,709	601
Other income, net	(68)	15	(67)	159
	734	301	1,642	760
Net loss before provision for income taxes	(9,237)	(8,573)	(17,367)	(14,566)
Provision for income taxes	145	103	290	241
Net loss	\$ (9,382)	\$ (8,676)	\$ (17,657)	\$ (14,807)
Basic and diluted net loss per share	\$ (0.29)	\$ (0.33)	\$ (0.55)	\$ (0.56)
Weighted average shares outstanding	32,422	26,611	32,379	26,553

See Accompanying Notes to Condensed Consolidated Financial Statements (Unaudited).

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW**

(Unaudited)

(in thousands)

	<b>Six months ended September 30, 2007</b>	
	<b>2007</b>	<b>2006</b>
<b>Operating activities:</b>		
Net loss	\$ (17,657)	\$ (14,807)
Adjustments required to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	2,191	1,930
Bad debt expense	101	45
Stock-based compensation	2,934	3,251
Write-down of inventory	243	159
Loss on disposal of fixed assets	7	
Impairment of intangibles		134
Deferred tax provision	290	241
Arbitration decision	728	
Expensed in-process research and development		800
Changes in assets and liabilities:		
Accounts receivable	2,301	605
Inventories	(6,362)	(1,050)
Prepaid expenses and other current assets	131	(174)
Accounts payable	111	389
Accrued expenses	(433)	(207)
Deferred revenue	76	175
<b>Net cash used for operating activities</b>	<b>(15,339)</b>	<b>(8,509)</b>
<b>Investing activities:</b>		
Proceeds from the sale and maturity of short-term securities	5,479	18,872
Purchases of short-term securities		(10,799)
Expenditures for intangible assets	(15)	(829)
Expenditures for property and equipment	(2,323)	(1,550)
<b>Net cash provided by investing activities</b>	<b>3,141</b>	<b>5,694</b>
<b>Financing activities:</b>		
Issuance of common stock	874	
Proceeds from the exercise of stock options	1,044	1,599
Proceeds from employee stock purchase plan	128	159
<b>Net cash provided by financing activities</b>	<b>2,046</b>	<b>1,758</b>
Effect of exchange rate changes on cash	24	277
<b>Net decrease in cash and cash equivalents</b>	<b>(10,128)</b>	<b>(780)</b>
Cash and cash equivalents at beginning of period	69,646	7,832
<b>Cash and cash equivalents at end of period</b>	<b>\$ 59,518</b>	<b>\$ 7,052</b>

See Accompanying Notes to Condensed Consolidated Financial Statements (Unaudited).



---

**Table of Contents**

**ABIOMED, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

**(In thousands, except share data)**

***1. Nature of Business and Basis of Preparation***

Abiomed, Inc. (the Company or Abiomed) is a leading provider of medical devices in circulatory support that offers a continuum of care in heart recovery to acute heart failure patients. The Company's strategy is focused on establishing heart recovery as the goal for all acute cardiac attacks. 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 products can be used in a broad range of clinical settings, including by cardiologists for patients who are in pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab, and by heart surgeons for patients in profound shock. Abiomed is focused on increasing awareness of heart recovery and establishing it as the goal for all acute patients experiencing cardiac attacks (heart attacks) with failing but potentially recoverable hearts. The Company expects that recovery awareness and utilization of its products will significantly increase the number of patients able to return home from the hospital with their own hearts.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (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, 2007 that has been filed with the SEC.

In the opinion of management, the accompanying unaudited condensed 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.

***2. Significant Accounting Policies***

***Principles of Consolidation***

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, inventories, impairment of intangible assets and goodwill, income taxes including the valuation allowance for deferred tax assets, stock-based compensation, valuation of long-lived assets and investments, contingencies and litigation. Abiomed bases its estimates on historical experiences and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimated or assumed.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued****(In thousands, except share data)****Note 3. Restricted Cash**

The Company had restricted cash of \$0 million at September 30, 2007 and approximately \$0.3 million included in prepaid expenses and other current assets at March 31, 2007. This cash represents security deposits that were held in the Company's European banks for a certain facility lease.

**Note 4. Marketable Securities**

The amortized cost, including interest receivable, approximates market value of held-to-maturity short-term marketable securities and was \$0 million at September 30, 2007 and \$5.5 million at March 31, 2007. There were no available-for-sale securities at September 30, 2007 and at March 31, 2007.

**Note 5. Accounts Receivable**

The components of accounts receivable are as follows:

	September 30, 2007	March 31, 2007
Trade receivables	\$ 8,924	\$ 11,135
Allowance for doubtful accounts	(309)	(203)
<b>Total</b>	<b>\$ 8,615</b>	<b>\$ 10,932</b>

**Note 6. Inventories**

The components of inventory are as follows:

	September 30, 2007	March 31, 2007
Raw materials and supplies	\$ 6,913	\$ 3,755
Work-in-progress	2,455	1,771
Finished goods	5,232	3,041
<b>Total</b>	<b>\$ 14,600</b>	<b>\$ 8,567</b>

All of the Company's inventories relate to circulatory care product lines that include the iPulse, AB5000, BVS 5000, AbioCor and Impella product platforms. Finished goods and work-in-process inventories consist of direct material, labor and overhead. The Company's Impella and iPulse products are CE-marked and available for sale outside the U.S. but are not approved by the FDA. The Company's AbioCor product line is approved by the FDA under a Humanitarian Device Exemption (HDE).

From time to time, the Company loans finished goods inventory on a short-term basis to customers for demonstration purposes or clinical trial purposes and this inventory is amortized over a three-year life. This cost of demo inventory and the net carrying value are reflected in the table below:

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

	<b>September 30, 2007</b>	<b>March 31, 2007</b>
Cost of inventory used for demo purposes	\$ 3,157	\$ 2,082
Accumulated amortization	(1,261)	(904)
<b>Total</b>	<b>\$ 1,896</b>	<b>\$ 1,178</b>

Amortization expense related to demo inventory was \$0.2 million and \$0.1 million for the three months ended September 30, 2007 and 2006, respectively. Amortization expense related to demo inventory was \$0.3 million and \$0.2 million for the six months ended September 30, 2007 and 2006, respectively.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued**

(In thousands, except share data)

**Note 7. Property and Equipment**

The components of property and equipment are as follows:

	September 30, 2007	March 31, 2007
Machinery and equipment	\$ 17,180	\$ 15,513
Furniture and fixtures	1,468	1,367
Leasehold improvements	2,527	2,522
Construction in progress	1,238	654
<b>Total cost</b>	<b>22,413</b>	<b>20,056</b>
Less accumulated depreciation	(15,380)	(14,292)
<b>Total</b>	<b>\$ 7,033</b>	<b>\$ 5,764</b>

The Company provides for depreciation on property and equipment by charges to operations in amounts that allocate the cost of depreciable assets over their estimated useful lives on a straight-line basis as follows:

Classification	Estimated useful life
Machinery and equipment	2 10 years
Furniture and fixtures	4 10 years
Leasehold improvements	Lower of life of asset or life of lease

Depreciation expense related to property and equipment was \$0.5 million for the three months ended September 30, 2007 and 2006, respectively. Depreciation expense related to property and equipment was \$1.1 million and \$0.9 million for the six months ended September 30, 2007 and 2006, respectively.

**Note 8. Goodwill and Intangible Assets**

The carrying amount of goodwill at September 30, 2007 and March 31, 2007 was \$28.4 and \$26.7 million, respectively, and has been recorded in connection with the Company's acquisition of Impella. The change in carrying value was due to a change in the foreign currency translation rate.

The components of intangible assets are as follows:

	September 30, 2007			March 31, 2007		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Patents	\$ 8,038	\$ 3,337	\$ 4,701	\$ 7,625	\$ 2,681	\$ 4,944
Trademarks and tradenames	472	212	260	444	175	269
Distribution agreements	696	240	456	655	179	476

Edgar Filing: ABIOMED INC - Form 10-Q

Acquired technology	2,401	829	1,572	2,258	618	1,640
	\$ 11,607	\$ 4,618	\$ 6,989	\$ 10,982	\$ 3,653	\$ 7,329

Amortization of intangible assets was \$0.4 million and \$0.5 million for the three months ended September 30, 2007 and 2006, respectively. Amortization of intangible assets was \$0.8 million and \$0.9 million for the six months ended September 30, 2007 and 2006, respectively.

**Note 9. Warranties**

The Company routinely accrues for estimated future warranty costs on its product sales at the time of sale. The following table summarizes the activities of the warranty reserves for the six months ended September 30, 2007 and 2006:

	<b>Six Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
Balance at March 31	\$ 157	\$ 167
Accrual for warranties	89	74
Warranty cost incurred during the period	(76)	(33)
Balance at September 30	\$ 170	\$ 208

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued****(In thousands, except share data)*****Note 10. Research and Development***

The Company's research and development efforts are focused on the development of new products related to circulatory care and enhancing and improving its existing products. Research and development costs are expensed when incurred and include direct materials and labor, depreciation, contracted services and other costs associated with developing new products and making significant enhancements to existing products. Research and development costs consist of the following amounts:

	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Internally funded	\$ 5,758	\$ 5,272	\$ 11,177	\$ 10,671
Incurred under government contracts and grants	74	13	171	33
<b>Total research and development expense</b>	<b>\$ 5,832</b>	<b>\$ 5,285</b>	<b>\$ 11,348</b>	<b>\$ 10,704</b>

***Note 11. Expensed In-Process Research and Development***

The Company recorded a charge of \$0.8 million during the quarter ended June 30, 2006 in connection with the acquisition of certain circulatory care device patents and know-how. This charge relates to costs to acquire in-process research and development projects and technologies, which have not reached technological feasibility at the date of the asset acquisition and have no alternative future use.

***Note 12. Arbitration Decision and Warrants Repurchase******Arbitration Decision***

On May 15, 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a Demand for Arbitration (subsequently amended) with the Boston Office of the American Arbitration Association. The claims arose out of the Company's purchase of intellectual property rights relating to the Penn State Heart and the related warrant agreements entered into by the Company. The claims sought 600,000 unrestricted shares of the Company's common stock and attorney's fees for an alleged breach of the Company's obligation to fund development of the Penn State Heart program and an alleged cancellation of the Penn State Heart development project. The Company instituted a legal action in Federal Court to determine the arbitrability of the claims asserted and the Federal Court stayed the arbitration of a portion of the claims.

On June 27, 2007 the Arbitrator issued his ruling. In his award the Arbitrator found that, during the period between July 2003 and September 2004, the Company terminated all material staffing and funding for development of the Penn State Heart for a continuous period of three months, other than for reasons outside of the Company's control, which constituted a "Cancellation" under the terms of the warrant agreement. The ruling does not impact the Company's continued investment in its AbioCor II program. In his award, the Arbitrator ruled that certain holders of the warrants covered by the warrant agreement are entitled to exercise their warrants to purchase 143,496.50 shares of the Company's common stock for \$0.01 per share pursuant to the warrant agreement and that the Company should pay to the claimants \$0.5 million representing reimbursement for legal and arbitration fees and other disbursements. Of the 143,496.50 warrants awarded, the Company had previously recognized expense for the fair value of 78,923 warrants in its financial statements in the fiscal year ended March 31, 2001. The estimated fair value of the residual 64,573.50 warrants totaling \$0.7 million were expensed for the three months ended June 30, 2007.

The aggregate arbitrator award for the period ended June 30, 2007 was \$1.2 million, comprised of \$0.5 million representing reimbursement for legal and arbitration fees and other disbursements and \$0.7 million related to the fair value of the warrants not previously expensed by the Company. The Company expensed this \$1.2 million during the three months ended June 30, 2007, and this is reflected in the accompanying statements of operations under the line item arbitration decision.

***Warrants Repurchase***

The Company has reached agreement with the selling stockholder representative whereby for cash consideration of approximately \$2.2 million, the claimants would surrender to the Company all outstanding warrants issued under the warrant agreement discussed above in the Arbitration Decision section of this note. The settlement will result in the Company's repurchase of all outstanding warrants held by the claimants. In exchange for the cash consideration, the claimants will surrender the respective outstanding warrants and will release the Company from any future obligations or liabilities related to this matter. Management's estimate of the fair value of the warrants to be repurchased is approximately \$1.9 million. This is calculated as 143,496.50 warrants discussed above, valued at the price of the Company's stock per share of \$13.02, which was the price on the close of business on October 3, 2007, the effective date of the settlement. The \$0.3 million excess of the \$2.2 million of cash consideration over the \$1.9 million estimated fair value of the warrants at October 3, 2007, is management's best estimate of the settlement of the threatened claims as of September 30, 2007 and has been accrued at September 30, 2007 as a current liability in accordance with Statement of Financial Accounting Standards (SFAS) No. 5, *Accounting for Contingencies* and is reflected in the accompanying statements of operations under the line item selling, general and administrative. The Company expects to disburse the cash consideration of approximately \$2.2 million in the third quarter of fiscal 2008, and there will be no other future royalties or payouts owed to the selling stockholders on revenue generated from the AbioCor II.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued**

(In thousands, except share data)

**Note 13. Accounting for 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, 2007 and 2006 was as follows:

	Three Months Ended September 30,		Six Months Ended September 30,	
	2007	2006	2007	2006
Cost of sales	\$ 68	\$ 47	\$ 163	\$ 113
Research and development	253	409	673	861
Selling, general and administrative	940	1,133	2,098	2,277
Total stock-based compensation expense	\$ 1,261	\$ 1,589	\$ 2,934	\$ 3,251

The \$1.3 million in stock-based compensation expense for the three months ended September 30, 2007 includes \$1.2 million related to stock options and \$0.1 million related to restricted stock and the Company's Employee Stock Purchase Plan (the Purchase Plan or ESPP). The \$2.9 million in stock-based compensation expense for the six months ended September 30, 2007 includes \$2.8 million related to stock options and \$0.1 million related to restricted stock and the Company's ESPP.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at September 30, 2007 was approximately \$10.4 million, net of forfeitures, and the weighted-average time over which this cost will be recognized is 1.8 years. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow. Because the Company does not recognize the benefit of tax deductions in excess of recognized compensation cost due to its net operating loss position, this had no impact on the Company's consolidated statement of cash flows for the six months ended September 30, 2007.

**Stock Option Activity**

The following table summarizes the stock option activity for the six months ended September 30, 2007:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at March 31, 2007	4,306	\$ 11.04		
Granted	726	12.22		
Exercised	(127)	8.22		
Cancelled	(181)	11.64		
Expired	(8)	15.89		
Outstanding at September 30, 2007	4,716	\$ 11.28	6.98	\$ 9,724

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

Exercisable at September 30, 2007	2,555	\$ 10.85	5.64	\$ 7,172
-----------------------------------	-------	----------	------	----------

The total intrinsic value of options exercised (i.e. the difference between the market price at exercise and the price paid by the employee to exercise the options) during the three and six months ended September 30, 2007 was \$0.1 million and \$0.3 million, respectively. The total fair value of options vested during the three and six months ended September 30, 2007 was \$1.3 million and \$5.2 million, respectively.

### ***Grant-Date Fair Value***

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 months ended September 30, 2007 and 2006 were calculated using the following weighted-average assumptions:

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Risk-free interest rate	4.48%	4.84%	4.59%	5.58%
Expected option life (years)	6.25	6.25	6.25	6.25
Expected volatility	58.60%	65.00%	56.87%	65.00%

The risk-free interest rate is based on the United States 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 a combination of the historical volatility of our stock and adjustments for factors not reflected in historical volatility that are more indicative of future volatility. By using this combination, the Company is taking into consideration estimates of future volatility that the Company believes will differ from historical volatility as a result of product diversification and the Company's acquisition of Impella. The average expected life was estimated using the simplified method for determining the expected term as prescribed by the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued****(In thousands, except share data)****Note 13. Accounting for Stock-Based Compensation (Continued)**

The calculation of the fair value of the options is net of estimated forfeitures. Forfeitures are estimated based on an analysis of actual option forfeitures, adjusted to the extent historic forfeitures may not be indicative of forfeitures in the future. In addition, an expected dividend yield of zero is used in the option valuation model, because the Company does not pay cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The weighted-average grant-date fair value for options granted during the three and six months ended September 30, 2007 was \$7.12 and \$7.22 per share, respectively. The weighted average grant date fair value for options granted during the three and six months ended September 30, 2006 was \$8.83 and \$8.77, respectively.

**Variable Options**

The Company has a consulting agreement with David M. Lederman, Ph.D., its former Chief Executive Officer and former Chairman of its Board of Directors. Under this consulting agreement, Dr. Lederman has agreed to serve as a senior advisor for four years in exchange for \$0.2 million of annual compensation, starting on April 2, 2005. Dr. Lederman's existing non-qualified stock options that were awarded in the past during his tenure as the Company's CEO remain unmodified and will continue to vest during the term of his service as a non-employee advisor. He has the ability to exercise the options during this term. These options are considered variable options, the fair value of which will be expensed over the vesting period of the options, subject to adjustment based on the market price of the Company's common stock at the close of each financial reporting period.

**Restricted Stock**

The following table summarizes restricted stock activity for the six months ended September 30, 2007:

	<b>Six Months Ended September 30, 2007</b>	
	<b>Number of Shares</b>	<b>Grant Date Fair Value</b>
Restricted stock awards at March 31, 2007	8	\$ 10.80
Granted	50	11.27
Vested		
Forfeited	(6)	
Restricted stock awards at September 30, 2007	52	\$ 11.20

At September 30, 2007, there was \$0.4 million of unrecognized compensation cost related to restricted stock awards. During the six months ended September 30, 2007, an aggregate of fifty thousand shares of restricted stock were issued to certain executive officers of the Company. Stock-based compensation expense related to restricted stock awards was approximately \$58,000 and \$22,000 during the three months ended September 30, 2007 and 2006. Stock-based compensation expense related to restricted stock awards was approximately \$93,000 and \$43,000 during the six months ended September 30, 2007 and 2006, respectively. The weighted average remaining contractual life for restricted stock awards at September 30, 2007 was approximately 2.3 years. The restricted stock compensation expense is recognized on a straight-line basis over the vesting period. On March 1, 2005, the Company granted 24,000 shares of restricted stock to an officer of the Company, of which 16,000 shares vested in 8,000 increments on March 1, 2006 and March 1, 2007. The remaining restricted stock award of 8,000 shares vests on March 1, 2008. The restricted stock awards issued during the six months ended September 30, 2007 vest on the third anniversary of the date of grant.

***Employee Stock Purchase Plan***

Compensation expense recognized related to the Company's ESPP was approximately \$20,000 and \$0 for the three months ended September 30, 2007 and 2006, respectively. Compensation expense recognized related to the Company's ESPP was approximately \$40,000 and \$24,000 for the six months ended September 30, 2007 and 2006, respectively. For the first half of fiscal 2008, compensation expense for the Company's ESPP was valued using the Black-Scholes option valuation model using the following assumptions: an expected life of six months, a weighted average volatility of 38.96% and a weighted average risk free rate of 5.06%.

---

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued****(In thousands, except share data)****Note 14. Income Taxes**

The Company has recorded a valuation allowance in excess of its net deferred tax assets to the extent the difference between the book and tax basis of indefinite lived intangible assets, recognized in the 2006 acquisition of Impella, are not expected to reverse during the net operating loss carry forward period.

As of September 30, 2007, the Company has accumulated a net deferred tax liability in the amount of \$2.5 million which is primarily 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, in accordance with SFAS No. 142. The net deferred tax liability cannot be offset against the Company's deferred tax assets under U.S. generally accepted accounting principles since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period. For the three and six months ended September 30, 2007, the Company has recorded a deferred tax provision relating to amortization of goodwill for tax purposes in the amount of \$0.1 million and \$0.3 million, respectively.

On April 1, 2007, the Company adopted FIN No. 48, *Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109*, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN No. 48 prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. FIN No. 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition and defines the criteria that must be met for the benefits of a tax position to be recognized. As a result of its adoption of FIN No. 48, the Company has recorded the cumulative effect of the change in accounting principle of \$0.3 million as a decrease to opening retained earnings and an increase to other long-term liabilities as of April 1, 2007. This adjustment relates to state nexus for failure to file tax returns in various states for the years ended March 31, 2003, 2004, and 2005. The Company has determined it will proceed with a voluntary disclosure plan. The Company has elected to recognize interest and/or penalties related to income tax matters in income tax expense in its consolidated statement of operations. As of April 1, 2007, accrued interest was not significant and was recorded as part of the \$0.3 million adjustment to the opening balance of retained earnings. As of September 30, 2007, no penalties have been accrued.

As of the date of adoption, the Company had a long-term deferred tax asset of \$82.9 million, a long-term deferred tax liability of \$4.0 million and a valuation allowance of \$80.1 million. The deferred tax assets are primarily composed of federal and state tax net operating loss ( NOL ) carry forwards and federal and state research and development ( R&D ) credit carry forwards. At April 1, 2007, the Company has NOL carry forwards of \$79.2 million and \$36.9 million, for federal and states, respectively, which begin to expire in fiscal 2008.

On a quarterly and annual basis, the Company accrues for the effects of open uncertain tax positions and the related potential penalties and interest. There were no material adjustments to the recorded liability for unrecognized tax benefits during the six months ended September 30, 2007, other than those made in connection with the adoption of FIN 48 that are described above. It is reasonably possible that the amount of the unrecognized tax benefit with respect to certain of the unrecognized tax positions will increase or decrease during the next 12 months; however, it is not expected that the change will have a significant effect on the Company's results of operations or financial position.

Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the Company's net deferred tax assets and liabilities. Additionally, the future utilization of the Company's NOL and R&D credit carry forwards to offset future taxable income may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to ownership changes that have occurred previously or that could occur in the future. Ownership changes, as defined in Section 382 of the Internal Revenue Code, may have limited the amount of net operating loss carry forwards and research and development credit carry forwards that the Company can use each year to offset future taxable income and taxes payable. Subsequent ownership changes could impose additional limitations. The Company has not done a complete analysis to determine whether changes in the composition of its stockholders, including the Company's acquisition of Impella or the Company's recent public offering, have resulted or will result in an ownership change for purposes of Section 382; however, such a study is underway as of September 30, 2007. Any limitation to all or a portion of the NOL or R&D credit carry forwards, before they can be utilized, would reduce the Company's gross deferred tax assets.



**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued****(In thousands, except share data)****Note 14. Income Taxes (continued)**

The Company acquired Impella, a German-based company, in May 2005. Impella had pre-acquisition net operating losses of approximately \$21.9 million at the time of acquisition (which is denominated in Euros and is subject to foreign exchange remeasurement at each balance sheet date presented), and has since incurred net operating losses in each fiscal year since the acquisition. The utilization of the German pre-acquisition net operating losses in future periods is subject to certain statutory approvals.

The Company recorded a \$0.1 million reduction to each of its federal and state research and experimentation credit carry forwards of approximately \$6.3 million and \$4.3 million, respectively at March 31, 2007. Therefore, the Company's federal and state research and experimentation credit carry forwards at September 30, 2007 are approximately \$6.2 million and \$4.2 million, respectively.

The Company and its subsidiaries are subject to United States 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, since the Company has net operating loss and tax credit carry forwards 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 15. Comprehensive Loss**

The components of comprehensive loss are as follows:

	<b>Three Months Ended September 30,</b>		<b>Six Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net loss	\$ (9,382)	\$ (8,676)	\$ (17,657)	\$ (14,807)
Foreign currency translation adjustments	1,228	(233)	1,465	1,287
Comprehensive loss	\$ (8,154)	\$ (8,909)	\$ (16,192)	\$ (13,520)

**Note 16. Net Loss Per Share**

In accordance with SFAS No. 128, *Earnings Per Share*, basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net 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 (unissued) shares of common stock from outstanding stock options and warrants based on the treasury stock method. In periods when a net loss is reported, such as the three and six months ended September 30, 2007 and 2006, 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 the calculation of basic and dilutive loss per share results in the same value.

The calculation of diluted weighted average shares outstanding for the three and six months ended September 30, 2007 and 2006 excludes warrants to purchase up to 143,496.50 and 400,000 shares, respectively, of common stock issued in connection with the purchase of intellectual property as discussed in Note 12. Also excluded from the calculation of diluted weighted-average shares outstanding are stock options outstanding in the amount of 4,715,358 and 4,604,395 as of September 30, 2007 and 2006, respectively, and unvested shares of restricted stock in the amount of 52,000 shares and 16,000 shares as of September 30, 2007 and 2006, respectively.



---

**Table of Contents**

**ABIOMED, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued**

**(In thousands, except share data)**

***Note 17. Commitments and Contingencies***

The Company's acquisition of Impella provides that Abiomed may be required to make additional contingent payments to Impella's former shareholders as follows:

upon FDA approval of Impella's 2.5 liter pump system, a payment of \$5,583,333, and

upon FDA approval of Impella's 5.0 liter pump system, a payment of \$5,583,333

These milestone payments may be made, at the Company's option, by a combination of cash or stock, except that no more than an aggregate of approximately \$9.4 million of these milestone payments may be made in the form of stock. If any of these contingent payments are made, they will result in an increase in the carrying value of goodwill. If the average market price per share of Abiomed's common stock, as determined in accordance with the purchase agreement, as of the date of one of these milestones is achieved is \$22 or more, no additional contingent consideration will be required with respect to that milestone. If the average market price is between \$18 and \$22 on the date of the Company's achievement of a milestone, the relevant milestone payment will be reduced ratably.

The Company applies the disclosure provisions of FIN No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others, and Interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34* (FIN No. 45) to its agreements that contain guarantee or indemnification clauses. These disclosure provisions expand those required by SFAS No. 5, *Accounting for Contingencies*, by requiring that guarantors disclose certain types of guarantees, even if the likelihood of requiring the guarantor's performance is remote. The following is a description of arrangements in which the Company is a guarantor.

**Product warranties** The Company routinely accrues for estimated future warranty costs on its product sales at the time of sale. Operating results could be adversely effected if the actual cost of product failures exceeds the estimated warranty provision.

**Patent indemnifications** In many sales transactions, the Company indemnifies customers against possible claims of patent infringement caused by the Company's products. The indemnifications contained within sales contracts usually do not include limits on the claims. The Company has never incurred any material costs to defend lawsuits or settle patent infringement claims related to sales transactions. Under the provisions of FIN No. 45, intellectual property indemnifications require disclosure only.

The Company enters into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. Abiomed has never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of September 30, 2007.

**Clinical study agreements** In the Company's clinical study agreements, Abiomed has agreed to indemnify the participating institutions against losses incurred by them for claims related to any personal injury of subjects taking part in the study to the extent they relate to uses of the Company's devices in accordance with the clinical study agreement, the protocol for the device and Abiomed's instructions. The indemnification provisions contained within the Company's clinical study agreements do not generally include limits on the claims. The Company has never incurred any material costs related to the indemnification provisions contained in its clinical study agreements.



---

**Table of Contents**

**ABIOMED, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited) Continued**

**(In thousands, except share data)**

***Note 17. Commitments and Contingencies (continued)***

On July 24, 2007, Susan Doukides, as Administratrix of the Estate of Nicholas A. Petas, deceased, filed suit against the Company in the Court of Common Pleas of Hamilton County, OH. The claim alleges that on October 11, 2005 a ventricular cardiac assist device manufactured by the Company became disconnected from the deceased's chest causing his death. The claim asks for greater than \$50,000 in damages plus interest. The Company does not believe that the accident was caused by device malfunction and plans to defend against the claims asserted.

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 other proceedings or claims which are pending or known to be threatened, or all of them combined, is not expected to have a material adverse effect on the Company's financial position, cash flow and results.

***Note 18. Segment and Enterprise Wide Disclosures***

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, requires certain financial and supplementary information to be disclosed on an annual and interim basis for each reportable segment of an enterprise. 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 64% of the Company's total consolidated assets are located within the United States as of September 30, 2007. Remaining assets are located in Europe, primarily related to our Impella production facility, and include goodwill and intangibles of \$35.1 million at September 30, 2007 associated with the Impella acquisition from May 2005. Total assets in Europe excluding goodwill and intangibles were \$10.1 million at September 30, 2007 and amounted to 8% of total consolidated assets. For the three months ended September 30, 2007 and 2006, international sales accounted for 14% and 11% of total product revenue, respectively. For the six months ended September 30, 2007 and 2006, international sales accounted for 16% and 10% of total product revenue, respectively.

***Note 19. Recent Accounting Pronouncements***

***SFAS No. 157***

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. Among other requirements, SFAS No. 157 defines fair value and establishes a framework for measuring fair value and also expands disclosure requirements regarding fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. The Company is evaluating the impact that the adoption of SFAS No. 157 may have on its consolidated financial statements.

***SFAS No. 159***

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which provides companies with an option to report selected financial assets and liabilities at fair value in an attempt to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. This Statement is effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. The Company is evaluating the impact that the adoption of SFAS No. 159 may have on its consolidated financial statements.

**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 the Company's 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, 2007. The Company undertakes 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 to acute heart failure patients. Our strategy is focused on establishing heart recovery as the goal for all acute cardiac attacks. 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. We believe we are the only company with commercially available cardiac assist devices approved for heart recovery by the Food and Drug Administration, or FDA, and our products have been used to treat thousands of patients to date. Our products can be used in a broad range of clinical settings, including by heart surgeons for patients in profound shock and by interventional cardiologists for patients who are in pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab. We are focused on increasing awareness of heart recovery and establishing it as the goal for patients with failing but potentially recoverable hearts. We expect recovery awareness and utilization of our products will significantly increase the number of patients able to return home from the hospital with their own hearts. Since 2004, our executive team has focused our efforts on expanding our product portfolio, and we have numerous circulatory care disposable products that have either been approved or cleared by the FDA or have received CE mark approval, as well as several additional circulatory care products in development.

***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 patients in profound shock, including patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock, or myocarditis. The AB5000 and BVS 5000 systems, which are implanted in the surgery suite, can assume the full pumping function of a patient's failing heart, allowing the heart to rest, heal and potentially recover. Both systems are designed to provide either univentricular or biventricular support. We believe the AB5000 and BVS 5000 systems are the only commercially available cardiac assist devices that are approved by the FDA for heart recovery for 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.

The BVS 5000 Biventricular Support System was our first product and has been available for sale since 1992. It was the first FDA-approved heart assist device capable of assuming the pumping function of the heart. Since its introduction in 1992, the BVS 5000 has supported thousands of patients in the U.S., Europe and other countries.

The AB5000 Circulatory Support System, our next-generation product for heart recovery, is designed to provide a longer duration of support than the BVS 5000 and facilitates patient mobility in the hospital. The AB5000 can provide up to 6.0 liters of pulsatile blood flow per minute to support patients in profound shock. The AB5000 was approved by the FDA in 2003 and has supported hundreds of patients globally. Our AB5000 is designed to provide enhanced patient mobility within and between medical centers and to provide enhanced features and ease of use for caregivers. We believe the AB5000's high flow rates, ease of implant and historically low incidence of adverse events facilitate heart recovery, potentially avoiding the need for heart transplantation and improving patient outcomes. We expect to rely increasingly on sales of the AB5000 ventricular assist device, as sales of the BVS 5000 decline. As discussed in the section to follow entitled "IAB and iPulse", we recently developed a new iPulse combination console that can support our AB5000 and BVS 5000 systems and our intra-aortic balloon (IAB). The iPulse combination console is currently under regulatory review by the FDA for PMA supplement approval. We expect FDA supplemental approval on our iPulse combination console in calendar 2007, however, there can be no assurance or guarantees that we will receive such approval.

**Table of Contents****ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
(continued)*****AB5000 and BVS 5000 (continued)***

Each of the AB5000 and BVS 5000 systems consists of a ventricle or blood pump, one atrial or ventricular cannula, one arterial cannula and a driver console to operate the pump. Other than the console, each component is a disposable item. The AB5000 console supports biventricular BVS 5000 blood pumps, AB5000 ventricles or a combination of the two. Both the AB5000 and BVS 5000 systems use the same cannulae and console, allowing for seamless transition of devices without requiring an additional surgical procedure. If we receive FDA approval of our iPulse console, we expect customer demand to shift from the AB5000 console to our iPulse combination console. As our iPulse console is not currently approved by the FDA, we believe it has impacted demand for our AB5000 console for the six months ended September 30, 2007, and in turn revenue for the respective period, and may impact revenue in future quarters.

***Impella Product Portfolio***

Our Impella 2.5 and 5.0 catheters are percutaneous micro heart pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. These devices are designed for use by interventional cardiologists to support pre-shock patients in the cath lab who may not require as much support as patients in the surgery suite. Our Impella catheters are also designed to provide ventricular support for patients requiring hemodynamic stabilization or suffering from reduced cardiac output, and can aid in recovering the hearts of patients following a heart attack. These products increase flow to the heart and organs without the need for drugs such as inotropes while reducing the workload of the heart. Our Impella devices are approved in over 40 countries, have already been used to treat more than 1,000 patients in Europe and other countries outside the U.S. and have been the subject of over 20 peer-reviewed publications and other clinical presentations and publications.

These catheters can be quickly inserted through the femoral artery using a guide wire to reach the left ventricle of the heart where they are directly deployed to draw blood out of the ventricle and deliver it to the circulation, thereby reducing ventricular work (resting the heart) and providing flow to the rest of the organs. The Impella 2.5 is implanted percutaneously, while the Impella 5.0 is implanted via a small cut-down of the femoral artery in the groin. The Impella 2.5 can pump up to 2.5 liters of blood per minute, and the Impella 5.0 can pump up to 5.0 liters of blood per minute. The Impella 5.0 has 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, or as a bridge to other circulatory support devices, including our AB5000 and BVS 5000 systems. Our Impella RD is a right side of the heart support pump, and our Impella LD is a left side of the heart support pump. Both the Impella RD and Impella LD are surgically implanted.

Our Impella 2.5 and 5.0 catheters and Impella RD and LD heart pumps are already available in Europe under CE mark approval. We are pursuing FDA approval through a PMA path for our Impella 2.5 and 5.0 products. The Impella 2.5 pilot clinical trial was designed to study the use of the Impella 2.5 to support high-risk angioplasty procedures as a left ventricular assist device. The Impella 2.5 patient enrollment for the pilot clinical trial has been completed through enrollment of 20 patients. The participating hospitals in the pilot trial included: Brigham & Women's Hospital, Massachusetts General Hospital, Columbia Presbyterian, Scripps Clinic, Cedars-Sinai Medical Center, Texas Heart Institute, William Beaumont Hospital and Academic Medical Centre of the University of Amsterdam. In August 2007, we received approval from the FDA to begin our pivotal clinical trial for the Impella 2.5. This approval is the result of the submission of the clinical results of the safety pilot clinical trial. The pivotal study will determine the safety and effectiveness of the Impella 2.5 as compared to optimal medical management with an Intra-Aortic Balloon Pump (IABP) during high-risk angioplasty procedures. The study inclusion criteria have been extended to include patients with triple vessel disease with low ejection fraction. The study is approved under category B2 status and the trial sites are eligible for full reimbursement from the Centers for Medicare and Medicaid Services (CMS). The randomized pivotal study, at up to 150 hospitals, will compare 327 Impella 2.5 patients to 327 IABP patients and is comprised of two arms made up of patients receiving the Impella 2.5 for up to five days as a left ventricular assist device (VAD) and patients receiving IABP therapy. Following Institutional Review Board (IRB) approval at each participating hospital, the investigator's agreement to accept responsibilities of conducting the trial and requisite training, we plan to ship Impella 2.5 disposables and Impella consoles to the pivotal sites. The clinical experience to-date with our Impella 2.5 has been favorable, including our recently completed U.S. safety pilot clinical trial. The market for percutaneous coronary intervention (PCI), which includes high-risk patients, provides a significant addressable market opportunity for the Impella 2.5 and represents the highest individual utilization for IABPs. More than 20,000 IABPs are used per year in the U.S. alone for PCI. Factors that affect the length of time to complete this study include the timing of each center receiving respective IRB approval, the timing of the training we will provide each center, and the timing of patient enrollment. As a result of these factors, at this time we cannot estimate the duration of this study.

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

Angioplasty, performed in the cath lab, is the insertion of a catheter-guided balloon and is used to open a narrowed coronary artery. A stent, or a wire-mesh tube that expands to hold the artery open, is usually placed at the narrowed section. According to the American Heart Association, there are approximately 1.3 million in-patient angioplasty procedures in the U.S. annually, of which only a fraction are high-risk. For purposes of our clinical trials, high-risk angioplasty is generally defined as a procedure on patients undergoing angioplasty on an unprotected left main coronary artery lesion, or the last patent coronary conduit, or triple vessel disease, and who have poor cardiac function. In addition to the PMA regulatory approval path in the U.S. for our Impella 2.5, we are seeking 510(k) clearance of our Impella 2.5 catheter for short duration use. Regardless of the outcome of our 510(k) submission, we plan to pursue PMA approval for other clinical indications. We cannot assure you that we will receive PMA approval or 510(k) clearance for our Impella 2.5 or that we will be able to sell the product at anticipated prices. On August 9, 2007 we announced that we have provided a formal written response to questions from the FDA on our 510(k) submission for the Impella 2.5 and have provided the FDA with a report on our recently completed 20-patient U.S. pilot study. On October 11, 2007, we announced that the FDA provided a written response outlining four areas of concern on our 510(k) submission for the Impella 2.5. Two of the questions requested clarification and additional information related to labeling within the 510(k) submission. A third question requested additional information related to bench-testing of the device. A fourth question requested that the company provide an updated clinical review of the global experience with the Impella 2.5 since the original 510(k) submission, including up to date information from the U.S. safety pilot clinical trial for the Impella 2.5. We plan to respond shortly to this recent request for information. While there are no guarantees for a 510(k) clearance, we believe that we are on a 510(k) path with a potential clearance for the Impella 2.5 sometime between November 2007 and March 2008.

The Impella 5.0 is currently in a pilot clinical study that will enroll up to 20 patients at seven U.S. sites including: the University of Maryland, Massachusetts General Hospital, Lankenau Hospital in Pennsylvania, Robert Wood Johnson Hospital in New Jersey, New York Presbyterian Hospital, Texas Heart Institute and Penn State Milton S. Hershey Medical Center in Pennsylvania. The study will include postcardiotomy patients who have been weaned from heart-lung machines and whose hearts require added support to maintain good blood flow. The study will enroll those patients that would typically need more flow and hemodynamic support than provided by an Intra-Aortic Balloon Pump (IABP). The pilot study is expected to be completed by the end of our fiscal year 2008.

---

**Table of Contents****ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
(continued)*****IAB and iPulse***

We recently introduced our percutaneous intra-aortic balloon, or IAB. An IAB is typically used in the cath lab as an initial line of therapy for patients with diminished heart function, although a substantial number of IABs are used in the surgery suite. Our IAB is easy to insert and is designed to enhance blood flow to the heart and other organs for patients with diminished heart function. Our IAB is inserted percutaneously into a patient's descending aorta and inflates and deflates in counterpulsation to the patient's heart rhythm. The IAB extends our clinical and market reach further upstream in the care of acute heart disease patients, including direct usage in the intensive care unit, cath lab and surgery suite. We began selling IABs in the fourth quarter of fiscal 2007.

To support the IAB, we developed our iPulse combination console. The iPulse console is also designed to support our AB5000 and BVS 5000 systems, other manufacturers' intra-aortic balloons and products we may offer in the future. We believe the ability of the iPulse console to support multiple devices will make it more attractive than consoles designed to operate a single device. The new iPulse console will support procedures with associated Medicare reimbursement that extends across four diagnostic related groups, which further enhances its attractiveness to customers.

We received 510(k) clearance from the FDA for our new IAB in December 2006 and CE Mark approval in January 2007. The iPulse console has CE mark approval in Europe but has not been approved for commercial sale in the United States. To obtain FDA approval of the iPulse console, we have filed a supplement to our PMA application for our existing AB5000 console. We believe there will be U.S. market demand for our iPulse console following FDA supplement approval anticipated in our third quarter of fiscal 2008; however, we cannot guarantee approval. If our iPulse console is approved by the FDA, we expect customer demand to shift over time from the AB5000 console to our iPulse combination console.

***AbioCor***

Our AbioCor Implantable Replacement Heart is the first completely self-contained artificial heart. The complete AbioCor system consists internally of a thoracic unit, a rechargeable battery, an electronics package and a power receiver coil, and externally, a power transmitter coil, power and battery pack, handheld alarm monitor, patient home electronics and an in hospital console. Once implanted, the AbioCor system does not penetrate the skin, reducing the chance of infection. This technology provides patients with mobility and remote diagnostics.

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.

We received Humanitarian Device Exemption, or HDE, approval from the FDA for the AbioCor in September 2006. HDE approval signifies that no comparable alternative therapy exists for patients facing imminent death without the technology. Under this approval, only a limited number of patients may receive the AbioCor per year. Under HDE approval, the FDA may request a panel review of the post-approval study data.

We expect to begin selling the AbioCor in late calendar 2007 in a controlled roll-out to approximately five heart centers in the U.S. We expect eventually to expand availability to up to ten hospitals in the U.S., including qualified clinical trial sites and additional qualified centers once they have completed a comprehensive and rigorous training program. We are unable to determine how many patient procedures will be performed after the respective centers are trained. We do not expect that revenues from sales of the AbioCor will be a material portion of our total revenues for the foreseeable future.

***Cannulae***

Each of our AB5000 and BVS 5000 systems requires two cannulae, or tubes, that connect the ventricle or blood pump to the heart and an associated artery. We offer a variety of cannulae. We recently introduced our new integrated cannula system, which was approved by the FDA in July 2006. The new cannula, which is easier to implant and can be removed through a small incision, has the potential for use off-pump (also called beating heart) with minimally invasive procedures. For example, although removal of the cannulae requires a surgical procedure, it does not require a sternotomy, a substantially more invasive procedure that separates the breastbone in order to access the heart. Moreover, because the AB5000 and the BVS 5000 blood pumps use the same cannulae, clinicians can seamlessly transfer patients from one device to another

without requiring an additional surgical procedure.

**Table of Contents****ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
(continued)****Results of Operations**

The following table sets forth certain consolidated statements of operations data for the periods indicated as a percentage of total revenues (which includes revenues from products and funded research and development) for the three months and six months ended September 30, 2007 and 2006, respectively:

	Three Months Ended September 30,		Six Months Ended September 30,	
	2007	2006	2007	2006
<b>Revenues:</b>				
Products	99.3%	99.8%	99.0%	99.9%
Funded research and development	0.7	0.2	1.0	0.1
<b>Total revenues</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>
<b>Costs and expenses:</b>				
Cost of product revenue excluding amortization of intangibles	25.3	26.9	25.2	26.8
Research and development	51.4	48.5	44.6	44.8
Selling, general and administrative	107.9	101.5	97.2	85.6
Arbitration decision	(0.2)		4.8	
Expensed in-process research and development				3.4
Amortization of intangible assets	3.4	4.6	3.0	3.6
<b>Total costs and expenses</b>	<b>187.8</b>	<b>181.5</b>	<b>174.8</b>	<b>164.2</b>
Loss from operations	(87.8)	(81.5)	(74.8)	(64.2)
<b>Other income:</b>				
Investment Income	7.1	2.6	6.7	2.5
Other income, net	(0.6)	0.1	(0.3)	0.7
	6.5	2.7	6.4	3.2
<b>Net loss before provision for income taxes</b>	<b>(81.3)</b>	<b>(78.8)</b>	<b>(68.4)</b>	<b>(61.0)</b>
Provision for income taxes	1.3	0.9	1.1	1.0
<b>Net loss</b>	<b>(82.6)%</b>	<b>(79.7)%</b>	<b>(69.5)%</b>	<b>(62.0)%</b>

**Three months and six months ended September 30, 2007 compared with three and six months ended September 30, 2006****Product Revenues**

Product revenues for the three months ended September 30, 2007 increased by \$0.4 million or 4%, to \$11.3 million from \$10.9 million for the three months ended September 30, 2006. Revenues from disposables, service and other programs (non-console revenues) were \$9.8 million and \$8.5 million for the three months ended September 30, 2007 and 2006, respectively, and comprised approximately 86% and 78% of total revenues, respectively. Total disposables, service, and other revenue increased \$1.3 million, or 15%, for the three months ended September 30, 2007. For the three months ended September 30, 2007, revenues from Impella disposables increased 140%, revenues from AB5000 disposables increased 20% and revenues from BVS disposables declined 10%. Total console revenue for the three months ended September 30, 2007 decreased \$0.8 million, or 33%, for the respective period, due to a 48% decline in AB5000 console revenues. We have submitted our new iPulse combination console (combination driver for our Intra-Aortic Balloon, BVS blood pump and AB5000 ventricular assist device) for FDA supplement approval.

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

We believe there will be U.S. market demand for our new iPulse following FDA supplement approval anticipated later in calendar 2007; however, we cannot guarantee approval. We believe this anticipated regulatory approval of the iPulse combination console has caused a decline in AB5000 console revenue in the U.S. for the six months ended September 30, 2007, and may cause some decline in U.S. AB5000 console revenue in future quarters. We began shipping our iPulse console outside the U.S. in our second quarter of fiscal 2008, however, the amount of revenue during the period was not significant.

The BVS product was launched over 15 years ago and revenue from this product has been declining. We expect revenue from BVS to decline as our new products (Impella and iPulse) are introduced.

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

As discussed in the section above entitled, Impella Product Portfolio, the Impella 2.5 has been recently approved to commence the pivotal study in the U.S. for PMA approval by the FDA. In parallel with the PMA regulatory approval path, we have submitted for 510k clearance of the Impella 2.5 and believe we will receive 510k clearance of the Impella 2.5 sometime between now and March 2008, however, we cannot guarantee FDA approval or clearance. Revenue growth from Impella during the second quarter of fiscal 2008 compared to the same period of fiscal 2007 was primarily from total Impella sales outside the United States. The Impella 2.5, Impella 5.0, Impella RD and Impella LD are approved in Europe under CE-mark, and are now approved in over 40 countries. During the U.S. pivotal study for the Impella 2.5, we expect to generate revenue from the sale of Impella consoles and Impella 2.5 disposables at up to 150 centers. If we receive 510k clearance of the Impella 2.5, the product would be available for immediate commercial launch in the United States.

---

**Table of Contents****ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
(continued)****Product Revenues (continued)**

Product revenues for the six months ended September 30, 2007 increased by \$1.3 million or 5%, to \$25.2 million from \$23.9 million for the six months ended September 30, 2006. Revenues from disposables, service and other programs (non-console revenues) were \$21.9 million and \$19.3 million for the six months ended September 30, 2007 and 2006, respectively, and comprised approximately 86% and 81% of total revenues, respectively. For the six months ended September 30, 2007, revenues from Impella disposables increased 127%, revenues from AB5000 disposables increased 21% and revenues from BVS declined 20%. Total disposables, service, and other revenue increased \$2.6 million, or 13% for the six months ended September 30, 2007. Total console revenue for the six months ended September 30, 2007 decreased \$1.1 million, or 24%, for the respective period, due to the decline in AB5000 console revenues, which we believe is due to the anticipated FDA approval of our new iPulse combination console, as discussed above.

**Cost of Product Revenues**

Cost of product revenues for the three months ended September 30, 2007 was \$2.9 million and approximately flat compared to cost of product revenues for the three months ended September 30, 2006. This was due to lower cost of sales of consoles for the three months ended September 30, 2007 compared to the three months ended September 30, 2006 as fewer consoles were sold. Offsetting this decrease in console cost of sales was an increase in cost of sales of disposable products as more of these products were sold in the three months ended September 30, 2007 compared to the three months ended September 30, 2006.

During the three months ended September 30, 2007, approximately \$0.6 million of incremental costs were in cost of goods sold in connection with the Company's manufacturing capacity ramp-up for its Impella, iPulse and AbioCor products. In advance of potential U.S. regulatory approvals of Impella and iPulse, we are investing in manufacturing capacity to meet expected potential market demand, particularly in the U.S.

Cost of product revenues for the six months ended September 30, 2007 was \$6.4 million and approximately flat compared to cost of product revenues for the six months ended September 30, 2006. This was due to lower cost of sales of consoles for the six months ended September 30, 2007 compared to the six months ended September 30, 2006 as fewer consoles were sold. Offsetting this decrease in console cost of sales was an increase in cost of sales of disposable products as more of these products were sold in the six months ended September 30, 2007 compared to the six months ended September 30, 2006.

**Research and Development Expenses**

Research and development expenses for the three months ended September 30, 2007 increased \$0.5 million or 9%, to \$5.8 million from \$5.3 million for the three months ended September 30, 2006. Our increases in product development costs reflect our efforts to expand and enhance our product lines across a clinical spectrum of circulatory care. Research and development expenses for the six months ended September 30, 2007 increased \$0.6 million or 6%, to \$11.3 million from \$10.7 million for the six months ended September 30, 2006 reflecting our investments in our broader product portfolio and new products as discussed above.

**Selling, General and Administrative Expenses**

Selling, general and administrative expenses for the three months ended September 30, 2007 increased \$1.3 million or 12%, to \$12.3 million from \$11.0 million for the three months ended September 30, 2006. The increase is due to increased investments in our global distribution of sales and clinical representatives, with headcount up approximately 34% as compared to the second quarter of fiscal 2007, and is also due to our increased investments in our Healthcare Solutions and marketing initiatives. In addition, as previously discussed in Note 12, Arbitration Decision, we accrued \$0.3 million on September 30, 2007 as a current liability in accordance with SFAS No. 5, *Accounting for Contingencies* and is reflected in the accompanying statements of operations under the line item selling, general and administrative, which represents the excess of the \$2.2 million of proposed cash consideration over the fair value of the warrants at October 3, 2007. This is management's best estimate of the settlement of the threatened claims as of September 30, 2007.

Selling, general and administrative expenses for the six months ended September 30, 2007 increased \$4.3 million or 21%, to \$24.7 million from \$20.4 million for the six months ended September 30, 2006. The increase is primarily due to increased investments in our global distribution and other field personnel as discussed above. We currently have several products awaiting potential FDA approval or clearance, most notably our Impella 2.5 and 5.0 products. We are investing in our global distribution in advance of these potential FDA approvals to maximize our market

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

penetration and revenue growth following regulatory approval or clearance.

We expect to continue to increase our sales and clinical headcount throughout fiscal 2008, with particular investments in personnel with cath lab expertise, and also plan to increase our marketing, service and training personnel and investments to support the efforts of the sales and clinical teams to drive recovery awareness for acute heart failure patients globally.

**Expensed In-Process Research and Development Expenses**

We recorded a charge of \$0.8 million during the quarter ended June 30, 2006 in connection with the acquisition of certain circulatory care device patents and know-how. This charge relates to costs to acquire in-process research and development projects and technologies, which had not reached technological feasibility at the date of the asset acquisition and had no alternative future use, and were expensed as incurred.

**Arbitration Decision**

The aggregate arbitrator award for the period ended June 30, 2007 was \$1.2 million, comprised of the \$0.7 million related to the fair value of the warrants we had not previously expensed and the \$0.5 million representing reimbursement for legal and arbitration fees and other disbursements.

**Amortization of Intangibles**

Amortization of intangible assets was \$0.4 million and \$0.5 million for the three months ended September 30, 2007 and 2006, respectively. Amortization of intangible assets was \$0.8 million and \$0.9 million for the six months ended September 30, 2007 and 2006, respectively. Amortization primarily relates to specifically identified assets from the Impella acquisition.

---

**Table of Contents****ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
(continued)****Other Income**

Other income increased to \$0.7 million and \$1.6 million for the three and six months ended September 30, 2007, respectively, as compared to \$0.3 million and \$0.8 million for the same periods of 2006 primarily due to higher cash and short-term marketable securities balance of \$59.5 million at September 30, 2007 compared to \$22.0 million at September 30, 2006. Other income consists primarily of interest earned on our cash and investments, foreign exchange effects, and miscellaneous income.

**Tax Provision**

As of September 30, 2007, we have accumulated a net deferred tax liability in the amount of \$2.5 million which is primarily the result of a difference in accounting for our 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 our deferred tax assets under U.S. generally accepted accounting principles since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period. This deferred tax liability cannot be used as a source of taxable income in the determination of the valuation allowance. Valuation allowances for deferred tax assets are established when necessary to reduce deferred tax assets to the amount expected to be realized. Based on expected future operating results, we believe that it is more likely than not that we will not realize the benefits of our deferred tax assets.

For the three and six months ended September 30, 2007, we have recorded a deferred tax provision related to amortization of goodwill in the amount of \$0.1 million and \$0.3 million, respectively. Differences between amounts recorded as a deferred tax liability on the balance sheet versus amounts recorded in the statement of operations result from deferred tax adjustments for foreign currency fluctuations.

**Net Loss**

During the three months ended September 30, 2007, we incurred a net loss of \$9.4 million, or \$0.29 per share, compared to a net loss of \$8.7 million, or \$0.33 per share, for the three months ended September 30, 2006. Included in the net loss for the three months ended September 30, 2007 is \$0.3 million relating to the warrant repurchase as previously discussed in Note 12.

During the six months ended September 30, 2007, we incurred a net loss of \$17.7 million, or \$0.55 per share, compared to a net loss of \$14.8 million, or \$0.56 per share, for the six months ended September 30, 2006. Included in the net loss for the six months ended September 30, 2007 is \$1.5 million relating to the arbitration award and warrant repurchase as previously discussed in Note 12.

We expect to continue to incur net losses for the foreseeable future as we plan to invest in expanding our global distribution to drive revenue growth and as we bring new products to market.

**Liquidity and Capital Resources**

We have supported our operations primarily with revenues from sales of our BVS, AB5000 and Impella circulatory product lines, government contracts, and proceeds from our equity financings and from stock option exercises. At September 30, 2007, our cash and investments totaled \$59.5 million. 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.

Our operating activities during the six months ended September 30, 2007 used cash of \$15.3 million compared to \$8.5 million for the same period of 2006. Net cash used in operating activities resulted from our net loss of \$17.7 million for the six months ended September 30, 2007, increase in inventories of \$6.4 million, and a net decrease in accounts payable and other current liabilities of \$0.3 million offset by a decrease in accounts receivable of \$2.3 million, depreciation and amortization of \$2.2 million, arbitration decision of \$0.7 million, and stock-based compensation expense of \$2.9 million. Our net loss is primarily attributed to increased investments in our global distribution as we continue to drive initiatives to increase recovery awareness as well as our investments in research and development to broaden our circulatory care product portfolio.

Our investing activities during the six months ended September 30, 2007 provided cash of \$3.1 million compared to \$5.7 million for the same period of 2006, comprised primarily of \$5.5 million of proceeds from the maturity of short-term securities which was offset by \$2.3 million related to expenditures for property and equipment.

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

Our financing activities during the six months ended September 30, 2007 provided cash of \$2.0 million compared to \$1.8 million for the same period of 2006, comprised primarily of \$1.0 million attributable to the exercise of stock options, \$0.9 million related to the proceeds from the issuance of common stock and \$0.1 million related to proceeds from the employee stock purchase plan. The \$0.3 million increase compared to the prior year is due to the issuance of common stock for \$0.9 million offset by a decrease of \$0.6 million related to the exercise of stock options. As discussed in Note 12, we expect to disburse approximately \$2.2 million of cash for the warrant repurchase and settlement of certain litigation in our fiscal third quarter of 2008.

---

**Table of Contents**

**ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
(continued)**

**Liquidity and Capital Resources**

Capital expenditures for fiscal 2008 are estimated to be in the range of \$3.0 million to \$4.0 million which primarily relate to our planned manufacturing capacity increases and the international phase of our ERP (SAP) implementation.

**Critical Accounting Policies**

We continue to monitor our accounting policies to ensure proper application of current rules and regulations. Except for income taxes, there have been no changes to these policies as discussed in our Annual Report on Form 10-K for the fiscal year ended March 31, 2007. The methodology applied to management's estimate for income taxes has changed due to the adoption of a new accounting pronouncement as described below.

*Income Taxes*

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes*, which became effective for us beginning in fiscal 2008. FIN 48 addressed the determination of how tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FIN 48, the Company must recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution. Effective April 1, 2007, we adopted the provisions of FIN 48.

For additional information regarding the adoption of FIN 48, see Note 14. For further discussion of our critical accounting estimates related to income taxes, see our Annual Report on Form 10-K for the fiscal year ended March 31, 2007.

**New Accounting Pronouncements**

*SFAS No. 157*

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS No. 157, *Fair Value Measurements*. Among other requirements, SFAS No. 157 defines fair value and establishes a framework for measuring fair value and also expands disclosure requirements regarding fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. We are evaluating the impact that the adoption of SFAS No. 157 may have on our consolidated financial statements.

*SFAS No. 159*

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which provides companies with an option to report selected financial assets and liabilities at fair value in an attempt to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. This Statement is effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. We are evaluating the impact that the adoption of SFAS No. 159 may have on our consolidated financial statements.

**Contractual Obligations and Commercial Commitments**

In May 2005, we acquired all the shares of outstanding capital stock of Impella CardioSystems AG, a company headquartered in Aachen, Germany. The aggregate purchase price excluding a contingent payment in the amount of \$5.6 million made on January 30, 2007 in the form of common stock, was approximately \$45.1 million, which consisted of \$42.2 million of our common stock, \$1.6 million of cash paid to certain former shareholders of Impella, and \$1.3 million of transaction costs, consisting primarily of fees paid for financial advisory and legal services. We may make additional contingent payments to Impella's former shareholders based on additional milestone payments related to FDA approvals in the amount of up to \$11.2 million. These contingent payments may be made in a combination of cash or stock under circumstances described in the purchase agreement. If any contingent payments are made, they will result in an increase to the carrying value of goodwill.

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

We apply the disclosure provisions of FIN No. 45, *Guarantors Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others, and Interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34* (FIN No. 45) to our agreements that contain guarantee or indemnification clauses. These disclosure provisions expand those required by SFAS No. 5 by requiring that guarantors disclose certain types of guarantees, even if the likelihood of requiring the guarantors performance is remote. The following is a description of arrangements in which we are a guarantor.

**Table of Contents****ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS  
(continued)****Contractual Obligations and Commercial Commitments**

We enter into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of September 30, 2007.

**Clinical study agreements** In our clinical study agreements, we have agreed to indemnify the participating institutions against losses incurred by them for claims related to any personal injury of subjects taking part in the study to the extent they relate to use of our devices in accordance with the clinical study agreement, the protocol for the device and our instructions. The indemnification provisions contained within our clinical study agreements do not generally include limits on the claims. We have never incurred any material costs related to the indemnification provisions contained in our clinical study agreements.

**Product warranties** We routinely accrue for estimated future warranty costs on our product sales at the time of shipment. All of our products are subject to rigorous regulation and quality standards. While we engage in extensive product quality programs and processes, including monitoring and evaluating the quality of our component suppliers, our warranty obligations are affected by product failure rates. Our operating results could be adversely affected if the actual cost of product failures exceeds the estimated warranty provision.

**Patent indemnifications** In many sales transactions, we indemnify customers against possible claims of patent infringement caused by our products. The indemnifications contained within sales contracts usually do not include limits on the claims. We have never incurred any material costs to defend lawsuits or settle patent infringement claims related to sales transactions. Under the provisions of FIN No. 45, intellectual property indemnifications require disclosure only.

**ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK*****Derivative Financial Instruments and Derivative Commodity Instruments***

We do not participate in derivative financial instruments or derivative commodity instruments.

***Primary Market Risk Exposures***

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio, which consists primarily of money market funds, commercial paper and corporate bonds with maturities of one year or less at September 30, 2007. The primary objective of our investment activities is to preserve principal while maximizing yields without significantly increasing risk. This is accomplished by investing in high investment grade securities with ratings of at least AA by Moody's or Standard & Poor's as well as investment portfolio diversification. Our held-to-maturity 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, 2007, we believe the decline in fair market value of our investment portfolio would be immaterial. We believe, however, that we have the ability to hold our fixed income investments until maturity and therefore would not expect our operating results or cash flows to be affected to any significant degree by a change in market interest rates on our securities portfolio.

***Currency Exchange Rates***

Our Impella subsidiary's functional currency is the Euro. Therefore, our investment in Impella 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 (loss) component of stockholders' equity. Had a 10% depreciation in the Euro occurred relative to the U.S. dollar as of September 30, 2007, the result would have been a reduction of stockholders' equity of approximately \$4.2 million.



**Table of Contents**

**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 the end of the period covered by this quarterly report (the Evaluation Date ). Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of the Evaluation Date, 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.

**Changes in Internal Controls over Financial Reporting**

During the second quarter of our fiscal year ending March 31, 2008, there were no changes in our internal control over financial reporting identified in connection with the evaluation described above 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 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. During the first quarter of 2008, we recorded a pre-tax charge in the amount of \$1.2 million, which was in addition to the \$6.4 million we had recorded in fiscal year ended March 31, 2001, in connection with an arbitration panel's decision regarding the Penn State Heart proceeding against ABIOMED, Inc. as discussed in Note 12.

On May 15, 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a Demand for Arbitration (subsequently amended) with the Boston Office of the American Arbitration Association. The claims arose out of our purchase of intellectual property rights relating to the Penn State Heart and the related warrant agreements entered into by us. The claims sought 600,000 unrestricted shares of our common stock and attorney's fees for an alleged breach of our obligation to fund development of the Penn State Heart program and an alleged cancellation of the Penn State Heart development project. We instituted a legal action in Federal Court to determine the arbitrability of the claims asserted and the Federal Court stayed the arbitration of a portion of the claims.

On June 27, 2007 the Arbitrator issued his ruling. In his award the Arbitrator found that, during the period between July 2003 and September 2004, we terminated all material staffing and funding for development of the Penn State Heart for a continuous period of three months, other than for reasons outside of our control, which constituted a Cancellation under the terms of the warrant agreement. In his award, the Arbitrator ruled that certain holders of the warrants covered by the warrant agreement are entitled to exercise their warrants to purchase 143,496.50 shares of our common stock for \$0.01 per share pursuant to the warrant agreement and that we should pay to the claimants \$0.5 million representing reimbursement for legal and arbitration fees and other disbursements. Of the 143,496.50 warrants awarded, we previously recognized expense for the fair value of 78,923 warrants in our financial statements for the fiscal year ended March 31, 2001. The estimated fair value of the residual 64,573.50 warrants totaling \$0.7 million were expensed for the three months ended June 30, 2007.

We have reached agreement with the selling stockholder representative whereby for cash consideration of approximately \$2.2 million, the claimants would surrender to us all outstanding warrants issued under the warrant agreement discussed above in the Arbitration Decision section of this note. The settlement will result in our repurchase of all outstanding warrants held by the claimants. In exchange for the cash consideration, the claimants will surrender the respective outstanding warrants and will release us from any future obligations or liabilities related to this matter. Management's estimate of the fair value of the warrants to be repurchased is approximately \$1.9 million. This is calculated as 143,496.50 warrants discussed above, valued at the price of our stock per share of \$13.02, which was the price on the close of business on October 3, 2007, the effective date of the settlement. The \$0.3 million excess of the \$2.2 million of cash consideration over the \$1.9 million estimated fair value of the warrants at October 3, 2007, is management's best estimate of the settlement of the threatened claims as of September 30, 2007 and has been accrued at September 30, 2007 as a current liability in accordance with SFAS No. 5, *Accounting for Contingencies* and is reflected in the accompanying statements of operations under the line item selling, general and administrative. We expect to disburse the cash consideration of approximately \$2.2 million in our third quarter of fiscal 2008, and there will be no other future royalties or payouts owed to the selling stockholders on revenue generated from the AbioCor II.

On July 24, 2007, Susan Doukides, as Administratrix of the Estate of Nicholas A. Petas, deceased, filed suit against us in the Court of Common Pleas of Hamilton County, OH. The claimant alleges that on October 11, 2005 a ventricular cardiac assist device manufactured by us became disconnected from the deceased's chest causing his death. The claim asks for greater than \$50,000 in damages plus interest. We do not believe that the accident was caused by device malfunction and plan to defend against the claims asserted.

**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, 2007, 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 risk factor titled Our rights distribution, certificate of incorporation and Delaware law could make it more difficult for a third party to acquire us and may prevent our stockholders from

realizing a premium on our stock with the following risk factor:

***Our certificate of incorporation and Delaware law could make it more difficult for a third party to acquire us and may prevent our stockholders from realizing a premium on our stock.***

Provisions of our certificate of incorporation and of the Delaware General Corporation Law may make it more difficult for a third party to acquire us, even if doing so would allow our stockholders to receive a premium over the prevailing market price of our stock. Those provisions of our certificate of incorporation and Delaware law are intended to encourage potential acquirers to negotiate with us and allow our Board of Directors the opportunity to consider alternative proposals in the interest of maximizing stockholder value. However, such provisions may also discourage acquisition proposals or delay or prevent a change in control, which could negatively affect our stock price.

**Table of Contents****Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**  
None**Item 3. Defaults Upon Senior Securities**  
None**Item 4. Submission of Matters to a Vote of Security Holders**

On August 8, 2007, we held our annual meeting of stockholders. At the meeting, our stockholders elected Michael R. Minogue and Dr. W. Gerald Austen to serve as Class III directors for three-year terms. In addition, the terms of office of our other directors, Louis E. Lataif, Henri A. Termeer, Ronald Dollens, Desmond H. O'Connell, Dr. Eric A. Rose, M.D. and Dorothy E. Puhly continued after our annual meeting of stockholders. Our stockholders also voted to ratify the appointment by our audit committee of Deloitte & Touche LLP as our independent registered public accounting firm for the fiscal year ending March 31, 2008.

The votes cast to elect our Class III directors were:

Director	Votes For	Votes Withheld
Michael R. Minogue	26,181,562	55,186
Dr. W. Gerald Austen	26,179,416	57,332

The votes cast to ratify the appointment by our audit committee of Deloitte & Touche LLP as our independent registered public accounting firm for the fiscal year ending March 31, 2008 were:

<b>For:</b>	<b>Against:</b>	<b>Abstain:</b>
26,172,124	21,067	43,557

**Item 5. Other Information**  
None**Item 6. Exhibits****EXHIBIT INDEX**

Exhibit No.	Description	Filed with This Form 10-Q	Incorporated by Reference	
			Form	Filing Date
2.1	Share Purchase Agreement for the acquisition of Impella Cardio Systems AG, dated April 26, 2005.	8-K	May 16, 2005	2.1
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

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

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 16, 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		

**Table of Contents**

**ABIOMED, INC. 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 8, 2007

/s/ Daniel J. Sutherby  
Daniel J. Sutherby  
Chief Financial Officer

(Principal Accounting Officer and Principal Financial Officer)