ABIOMED INC Form 10-Q November 10, 2008 Table of Contents

## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## **FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2008

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** 

04-2743260

(IRS Employer

**Identification No.)** 

## **DANVERS, MASSACHUSETTS 01923**

(Address of principal executive offices, including zip code)

## (978) 646-1400

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) 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 x No  $\ddot{}$ 

Indicate by check mark whether the registrant is, a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

 Large accelerated filer "
 Accelerated filer x

 Non-accelerated filer "
 Smaller reporting company "

 Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes " No x

As of November 4, 2008, there were 36,594,652 shares outstanding of the registrant s Common Stock, \$.01 par value.

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## ABIOMED, INC. AND SUBSIDIARIES

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PART 1. FINANCIAL INFORMATION

## ITEM 1: FINANCIAL STATEMENTS

## ABIOMED, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	-	mber 30, 2008 Jnaudited)	Mar	ch 31, 2008
ASSETS				
Current assets:				
Cash and cash equivalents	\$	2,916	\$	2,042
Restricted securities		15,789		
Short-term marketable securities		47,606		36,257
Accounts receivable, net		14,603		14,071
Inventories		18,758		17,428
Prepaid expenses and other current assets		971		1,705
Total current assets		100,643		71,503
Property and equipment, net		6,866		7,551
Intangible assets, net		5,422		6,921
Goodwill		33,112		31,563
Other assets		485		493
Total assets	\$	146,528	\$	118,031
LIABILITIES AND STOCKHOLDERS EQUITY				
Current liabilities:				
Accounts payable	\$	5,539	\$	9,024
Accrued expenses		7,748		9,290
Deferred revenue		911		1,162
Total current liabilities		14,198		19,476
Long-term deferred tax liability		4,877		4,740
Other long-term liabilities				221
Total liabilities		19,075		24,437
Commitments and contingencies (Note 15)				
Stockholders equity:				
Class B Preferred Stock, \$.01 par value				
Authorized - 1,000,000 shares; Issued and outstanding - none				
Common stock, \$.01 par value		368		328
Authorized - 100,000,000 shares;				
Issued - 36,660,608 shares at September 30, 2008 and 32,779,404 shares at March 31, 2008;				
Outstanding - 36,612,652 shares at September 30, 2008 and 32,768,385 shares at March 31, 2008				
Additional paid-in-capital		357,089		300.787
Accumulated deficit		(227,838)		(212,394)
		(,,)		(212,021)

Treasury stock at cost - 47,956 shares at September 30, 2008 and 11,019 at March 31, 2008	(774)	(116)
Accumulated other comprehensive (loss) income	(1,392)	4,989
Total stockholders equity	127,453	93,594
Total liabilities and stockholders equity	\$ 146,528	\$ 118,031

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

## ABIOMED, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

## (Unaudited)

(in thousands, except per share data)

	Septem	Three Months Ended September 30, 2008 2007		hs Ended ber 30, 2007			
Revenue:	2000	2007	2008	2007			
Product	\$ 19,777	\$11,272	\$ 36,047	\$ 25,173			
Funded research and development	222	83	309	246			
Total Revenue	19,999	11,355	36,356	25,419			
Costs and expenses:							
Cost of product revenue excluding amortization of intangibles	4,793	2,877	10,420	6,409			
Research and development	6,850	5,832	12,994	11,348			
Selling, general and administrative	13,898	12,257	27,412	24,699			
Arbitration decision		(26)		1,206			
Amortization of intangible assets	411	386	837	766			
	25,952	21,326	51,663	44,428			
Loss from operations	(5,953)	(9,971)	(15,307)	(19,009)			
Other income and expense:							
Investment (expense) income, net	(43)	802	201	1,709			
Other (expense) income, net	(61)	(68)	80	(67)			
	(104)	734	281	1,642			
Loss before provision for income taxes	(6,057)	(9,237)	(15,026)	(17,367)			
Provision for income taxes	273	145	418	290			
Net loss	\$ (6,330)	\$ (9,382)	\$ (15,444)	\$ (17,657)			
	¢ (0.10)	¢ (0.20)	<b>•</b> (0.15)				
Basic and diluted net loss per share	\$ (0.18)	\$ (0.29)	\$ (0.46)	\$ (0.55)			
Weighted average shares outstanding	34,475	32,422	33,393	32,379			
See Accompanying Notes to Condensed Consolidated Financial Statements (Unaudited).							

## ABIOMED, INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	Six mont Septem 2008	
Operating activities:		
Net loss	\$ (15,444)	\$ (17,657)
Adjustments required to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	2,570	2,191
Bad debt expense	247	101
Stock-based compensation	5,114	2,934
Write-down of inventory	1,217	243
Loss on disposal of fixed assets	93	7
Deferred tax provision	337	290
Arbitration decision		728
Change in unrealized gain on short-term marketable securities	(183)	
Changes in assets and liabilities source (use):		
Accounts receivable	(1,056)	2,301
Inventories	(4,295)	(6,362)
Prepaid expenses and other current assets	684	131
Accounts payable	(2,640)	111
Accrued expenses	(1,754)	(433)
Deferred revenue	(245)	76
Net cash used for operating activities	(15,355)	(15,339)
Investing activities:		
Proceeds from the sale and maturity of short-term marketable securities	26,868	5,479
Purchases of short-term marketable securities	(53,824)	
Expenditures for intangible assets		(15)
Expenditures for property and equipment	(1,410)	(2,323)
Net cash (used for) provided by investing activities	(28,366)	3,141
Financing activities:		
Issuance of common stock	41,970	874
Proceeds from the exercise of stock options	3,564	1,044
Payment in lieu of issuance of stock for payroll taxes	(658)	
Proceeds from the issuance of employee stock purchase plan	117	128
Net cash provided by financing activities	44,993	2,046
Effect of exchange rate changes on cash	(398)	24
Net increase/(decrease) in cash and cash equivalents	874	(10,128)
Cash and cash equivalents at beginning of period	2,042	69,646
Cash and cash equivalents at end of period	\$ 2,916	\$ 59,518

Supplemental disclosures:

Common shares issued for business acquisition	\$ 5,574	\$
Fixed asset additions included in accounts payable	530	424
Reclassification of short-term marketable securities to restricted securities	22,739	
See Accompanying Notes to Condensed Consolidated Financial Statements (Unaudited).		

## 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. (together with its subsidiaries, 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, or 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, 2008 that has been filed with the Securities Exchange Commission, or 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

## Goodwill and Intangible Assets

In accordance with the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, the Company assesses the realizability of goodwill annually, at October 31, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. These events or circumstances generally include operating losses or a significant decline in earnings associated with the acquired business or asset. The Company s ability to realize the value of the goodwill will depend on the future cash flows of the business. If the Company is not able to realize the value of goodwill, the Company may be required to incur material charges relating to the impairment of those assets. The Company completed its annual review of goodwill as of October 31, 2007 and determined that no write-down for impairment was necessary.

In June 2008, the Company received U.S. Food and Drug Administration (FDA) 510(k) clearance of its Impella 2.5 product, triggering an obligation to pay \$5.6 million of contingent payments related to the May 2005 acquisition of Impella (Note 7). As permitted by the share purchase agreement, the Company elected to make this milestone payment on June 30, 2008 in shares of its common stock. As a result, during the quarter ended June 30, 2008, the Company issued 343,075 shares of its common stock to the former Impella shareholders and recorded an increase to goodwill of \$5.6 million. As a result of achieving this milestone, the Company reassessed the realizability of goodwill and concluded there was no impairment.

## Investment in WorldHeart Corporation

The Company entered into a convertible note purchase agreement with World Heart Corporation (WorldHeart) in December 2007 (Note 9). Under the agreement, the Company loaned \$5.0 million to WorldHeart, with the note and accrued interest, at 8% per annum, convertible at the Company s option into common stock of WorldHeart. The Company advanced \$1.0 million of the loan in December 2007 with the remaining \$4.0 million advanced in January 2008.

In May 2008, WorldHeart filed a Form 8-K disclosing that it had limited cash available to continue operations and that if it was unable to secure additional funding, it would be forced to take extraordinary business measures which could include filing for bankruptcy, ceasing operations and liquidating assets. Due to these events, the Company recorded an impairment charge of \$5.0 million during fiscal 2008 relating to its note receivable from WorldHeart and its associated derivative instruments (embedded conversion feature and warrant). As discussed in Note 9,

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WorldHeart completed the transactions contemplated by the recapitalization agreement dated June 20, 2008, as amended on July 31, 2008, among the Company, WorldHeart, and the other parties named therein. As a result of the transaction, the Company received 86 million common shares of WorldHeart, which represents approximately 21.6% of WorldHeart s issued and outstanding common shares following the transaction. The shares were received as a result of the Company s conversion of the full amount of principal and interest owed on the \$5.0 million convertible note previously issued to the Company by WorldHeart, the Company s release of the security interest in all of the assets of WorldHeart that secured the note, termination of the warrant the Company held to purchase 3.4 million common shares of WorldHeart, and forgiveness of other amounts owed to the Company by WorldHeart. In October 2008, WorldHeart completed a 30-to-1 reverse stock split, as the result of which the Company now holds 2,866,666 common shares of WorldHeart. The Company is accounting for this investment using the equity method of accounting. The carrying value of this investment is zero at September 30, 2008.

## **Revenue Recognition**

The Company recognizes revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectibility is reasonably assured in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104). The Company also follows the guidance of Emerging Issues Task Force (EITF) No. 00-21, *Revenue Arrangements with Multiple Deliverables* when transactions include multiple elements. Revenue from product sales to new customers is deferred until training on the use of the products has occurred. All costs related to product shipment are recognized at time of shipment. The Company does not provide for rights of return to customers on product sales.

Maintenance and service support contract revenues are recognized ratably over the term of the service contracts based upon the elapsed term of the service contract. In limited instances, the Company rents console medical devices on a month-to-month basis or for a longer specified period of time to customers for which revenue is recognized as earned.

## ABIOMED, INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

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

## 2. Significant Accounting Policies (continued)

Government-sponsored research and development contracts and grants generally provide for payment on a cost-plus-fixed-fee basis. Revenues from these contracts and grants are recognized as work is performed, provided the government has appropriated sufficient funds for the work. Under contracts in which the Company elects to spend significantly more on the development project during the term of the contract than the total contract amount, the Company prospectively recognizes revenue on such contracts ratably over the term of the contract as related research and development costs are incurred.

## New Accounting Pronouncements

*SFAS No. 157* - In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements* effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. In February 2008, the FASB issued FASB Staff Position FAS 157-2, *Partial Deferral of the Effective Date of Statement 157*. The Company adopted this pronouncement in the quarter ended June 30, 2008 and adoption did not have a material impact on its financial position or results of operations.

*SFAS No. 159* - In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007. The Company adopted this pronouncement in the quarter ended June 30, 2008 and adoption did not have a material impact on its financial position or results of operations.

*EITF 07-03* - In June 2007, the Emerging Issues Task Force, or EITF, reached a final consensus on Issue No. 07-03 (EITF No. 07-03), *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, effective on a prospective basis for fiscal years beginning after December 15, 2007. This EITF did not have an impact on the Company s financial position or results of operations for the three and six months ended September 30, 2008.

*SFAS No. 141(R)* - In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*. SFAS No. 141(R) applies to any transaction or other event that meets the definition of a business combination. Where applicable, SFAS No. 141(R) establishes principles and requirements for how the acquirer recognizes and measures identifiable assets acquired, liabilities assumed, noncontrolling interest in the acquiree and goodwill or gain from a bargain purchase. In addition, SFAS No. 141(R) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This statement is to be applied prospectively for transactions occurring in fiscal years beginning after December 15, 2008. The Company does not expect the adoption of SFAS No. 141(R) to have a material impact on its financial position or results of operations.

*SFAS No. 160* - In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, an amendment of ARB No. 51. SFAS No. 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of the consolidation procedures under ARB No. 51 for consistency with the requirements of FASB Statement No. 141(R). This statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The statement shall be applied prospectively as of the beginning of the fiscal year in which the statement is initially adopted. The Company does not expect the adoption of SFAS No. 141(R) to have a material impact on its financial position or results of operations.

*SFAS No. 161* - In March 2008, the FASB issued Statement No. 161, *Disclosures About Derivative Instruments and Hedging Activities*. This statement is intended to improve financial reporting about derivative instruments and hedging activities by enhanced disclosures to better understand their effects on a company s financial position, results of operation and cash flows. This standard is effective for interim and annual financial statements beginning after November 15, 2008. The Company does not expect the adoption of SFAS No. 161 to have a material impact on its financial position or results of operations.

## Note 3. Restricted Securities and Cash

In June 2008, the Company entered into a revolving line of credit facility with Blue Ridge Investments L.L.C., an affiliate of Bank of America (Note 15), with a term expiring in June 2009. The credit facility is secured by a first priority security interest in the Company s holdings in the Columbia Fund and the Company pledged these holdings to Blue Ridge Investments, L.L.C. during the term of the credit facility. Any amounts borrowed under the credit facility will be reduced by any cash distributions made on the Columbia Fund. As a result, the Company has segregated the marketable securities held in the Columbia Fund as restricted securities while the credit facility is in place. As of September 30, 2008, the Company has \$15.8 million in restricted securities.

## ABIOMED, INC. AND SUBSIDIARIES

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

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

## Note 4. Fair Value Measurements

Effective April 1, 2008, the Company implemented SFAS No. 157, *Fair Value Measurement* (SFAS 157), for financial assets and liabilities that are re-measured and reported at fair value at each reporting period and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The adoption of SFAS 157 did not have a material impact on financial results.

As defined in SFAS 157, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

Level 1 primarily consists of financial instruments whose value is based on quoted market prices such as exchange-traded instruments and listed equities.

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

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

The following table presents information about the Company s assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2008 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value:

	Level 1	Level 2 (in	Level 3 \$000 s)	Total
Assets:				
Columbia Strategic Cash Portfolio	\$	\$	\$ 15,789	\$ 15,789
U.S. Treasury Securities	47,511			47,511
	\$ 47,511	\$	\$ 15,789	\$ 63,300

Level 3 financial assets include the Columbia Fund recorded in restricted securities. The Columbia Fund is an investment portfolio sponsored by Bank of America that contains over \$1.3 billion in assets at September 30, 2008. Most of the securities in the Columbia Fund have their fair values determined through readily available market data, but there are some securities in the Fund for which there is limited market activity such that the determination of fair value requires significant judgment or estimation. Given current market conditions, as these securities are not actively traded, certain significant inputs (e.g. yield curves, spreads, prepayments and volatilities) are unobservable. These securities are valued

primarily using broker pricing models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity. As a result, the Company has categorized these securities in Level 3 of the fair value hierarchy. At September 30, 2008, approximately 73% of the assets in the Columbia Fund were invested in mortgage-backed securities (U.S. subprime and non-subprime residential mortgages, U.S. commercial mortgages and foreign residential mortgages) and asset-backed securities (credit card, auto loan and student loan backed securities). The remaining assets in the Fund are in cash, corporate bonds and other assets. These securities are valued based on recently executed prices.

The table below provides a summary of the changes in fair value, including net transfers, of all financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the quarter ended September 30, 2008:

	Level 3 Columbia Strategic Cash Portfolio (in \$000s)	:
Balance at March 31, 2008	\$ 28,826	
Total realized and unrealized losses included in earnings	(252	)
Cash received in settlement	(12,785)	)
Balance at September 30, 2008	\$ 15,789	

## ABIOMED, INC. AND SUBSIDIARIES

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

## (In thousands, except share data)

## Note 5. Marketable Securities

The Company has marketable securities at September 30, 2008 and March 31, 2008 that consist of and are classified on the balance sheet as follows:

	Amortized Unrealized Cost Gains (in				uns Losses		Gains Losses		Gains Losses		Fair Value
At September 30, 2008:											
Restricted securities:											
Columbia Strategic Cash Portfolio	\$ 16,495	\$	\$	(706)	\$ 15,789						
	\$ 16,495	\$	\$	(706)	\$ 15,789						
Short-term marketable securities:											
US Government Securities	\$ 47,511	\$	\$		\$47,511						
Accrued Interest	95				95						
	\$ 47,606	\$	\$		\$ 47,606						
At March 31, 2008:											
Short-term marketable securities:											
Columbia Strategic Cash Portfolio	\$ 29,715	\$	\$	(889)	\$ 28,826						
US Government Securities	7,323				7,323						
Accrued Interest	108				108						
	\$ 37,146	\$	\$	(889)	\$ 36,257						

The Columbia Fund is comprised of investments in cash, corporate bonds, other assets, mortgage-backed securities and asset-backed securities. On December 6, 2007, the Columbia Fund ceased accepting redemption requests from new or current investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. As a result, the Company reclassified the securities in the Columbia Fund from cash equivalents to short-term marketable securities as the Columbia Fund was no longer expected to have a maturity of less than 90 days. The Company deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 96% of its carrying value at September 30, 2008. The Company recorded realized and unrealized losses of \$0.3 million related to the Columbia Fund in the statements of operations for the six months ended September 30, 2008. The Columbia Fund is being liquidated with distributions to the Company occurring and expected to occur during the next twelve months. Since December 6, 2007 and March 31, 2008, and through October 31, 2008, the Company has received disbursements of approximately \$34.2 million and \$12.8 million, respectively, from the Columbia Fund, with the most recent disbursement occurring on October 30, 2008 at approximately 93% of original value.

## Note 6. Inventories

The components of inventories are as follows:

	September 30, 2008	Marc	ch 31, 2008
	(in 5	\$000 s)	
Raw materials and supplies	\$ 8,114	\$	7,419
Work-in-progress	5,544		4,748
Finished goods	5,100		5,261
	\$ 18,758	\$	17,428

All of the Company s inventories relate to circulatory care product lines that include the Impella, iPulse, AB5000, BVS 5000, and AbioCor product platforms. Finished goods and work-in-process inventories consist of direct material, labor and overhead.

## ABIOMED, INC. AND SUBSIDIARIES

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

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

## Note 6. Inventories (continued)

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

	September 30, 2008	Mare	ch 31, 2008		
	(in \$0	(in \$000 s)			
Cost of inventory used for demo purposes	\$ 4,404	\$	3,815		
Accumulated amortization	(3,741)		(3,148)		
	\$ 663	\$	667		

Amortization expense related to demo inventory was \$0.2 million and \$0.2 million for the three months ended September 30, 2008 and 2007, respectively. Amortization expense related to demo inventory was \$0.6 million and \$0.3 million for the six months ended September 30, 2008 and 2007, respectively.

## Note 7. Goodwill and Intangible Assets

The carrying amount of goodwill at September 30, 2008 and March 31, 2008 was \$33.1 million and \$31.6 million, respectively, and has been recorded in connection with the Company s acquisition of Impella. In June 2008, the Company received FDA 510(k) clearance of its Impella 2.5 product, triggering an obligation to pay approximately \$5.6 million of contingent payments related to the May 2005 acquisition of Impella. During the three months ended June 30, 2008 the Company issued 343,075 shares of its common stock to the former Impella shareholders and recorded an increase to goodwill of \$5.6 million. The remaining change in carrying value from March 31, 2008 to September 30, 2008 was due to a change in the foreign currency translation rate during the six months ended September 30, 2008.

The components of intangible assets are as follows:

	S	eptember 30, 200	March 31, 2008						
	Cost	Accumulated Amortization (in \$000 s)	Net Book Value	Cost	Accumulated Amortization (in \$000 s)		Cost Amortization		Net Book Value
Patents	\$ 8,010	4,374	\$ 3,636	\$ 8,836	\$ 4	4,192	\$ 4,644		
Trademarks and tradenames	485	269	216	527		259	268		
Distribution agreements	689	336	353	774		322	452		
Acquired technology	2,378	1,161	1,217	2,669		1,112	1,557		
	\$11,562	6,140	\$ 5,422	\$ 12,806	\$ :	5,885	\$ 6,921		

Amortization of intangible assets was \$0.4 million for each of the three months ended September 30, 2008 and 2007. Amortization of intangible assets was \$0.8 million for each of the six months ended September 30, 2008 and 2007. The Company s expected amortization expense will be

\$1.5 million for each of fiscal 2009 through fiscal 2011 and \$1.2 million for fiscal 2012.

## Note 8. Arbitration Decision

## Arbitration Decision and Warrant Repurchase

In May 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a demand for arbitration (subsequently amended) with the American Arbitration Association. The claims arose out of the Company s purchase of intellectual property rights relating to the Penn State Heart program and the related warrant agreements. In June 2007, the Arbitrator issued his ruling and 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 program 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. Furthermore, the Arbitrator issued his ruling that certain holders of the warrants covered by the warrant agreement were 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.

During the three months ended June 30, 2007, the Company expensed \$1.2 million for the aggregate arbitrator award, 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, which is reflected in the accompanying statements of operations under the line item arbitration decision. During the quarter ended December 31, 2007, the Company repurchased all outstanding warrants held by the claimants for cash consideration of approximately \$2.2 million in settlement of any remaining claims held by the selling stockholders related to the Company s acquisition of the Penn State Heart. In exchange for the cash consideration, the warrants were cancelled and the claimants released the Company from any future obligations or liabilities related to this matter. There will be no other future payments to claimants relating to this arbitration decision

## ABIOMED, INC. AND SUBSIDIARIES

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

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

## Note 9. Investment in WorldHeart

In December 2007, the Company entered into a convertible note purchase agreement with WorldHeart, a developer of implantable mechanical circulatory support systems for chronic heart failure patients. The Company loaned \$5.0 million in a convertible secured note to WorldHeart with a term of two years and bearing interest at 8% per annum. No payments were required by WorldHeart until the end of the note s term. The Company advanced \$1.0 million of the loan in December 2007 and the remaining \$4.0 million was advanced in January 2008. The note was secured by all of the assets of WorldHeart, including its intellectual property. The principal amount of the note, the Company was issued a warrant for the purchase of up to 3.4 million common shares of WorldHeart at \$0.01 per share. The warrant was to expire in December 2012. The Company recorded this investment as a note receivable with an embedded conversion feature and a warrant. The conversion feature on the note receivable and warrants were valued on the transaction dates based on the Black-Scholes model. Due to WorldHeart s liquidity problems, the Company recorded an impairment charge of \$5.0 million during fiscal 2008 relating to its note receivable from WorldHeart and associated derivative instruments (the warrant and conversion feature on the note receivable). As a result, the Company wrote down its investment in its note receivable and these derivative instruments to zero at March 31, 2008.

On July 31, 2008, WorldHeart completed the transactions contemplated by the recapitalization agreement dated June 20, 2008, as amended on July 31, 2008, among the Company, WorldHeart, World Heart, Inc., Venrock Partners V, L.P., Venrock Associates V, L.P., Venrock Entrepreneurs Fund V, L.P., Special Situations Fund III QP LP, Special Situations Cayman Fund, L.P., Special Situations Private Equity Fund, L.P., Special Situations Life Sciences Fund, L.P., Austin Marxe and New Leaf Ventures II, L.P. As a result of the transaction, the Company received 86 million common shares of WorldHeart, which represents approximately 21.6% of WorldHeart s issued and outstanding common shares following the transaction. The shares were received as a result of the Company s conversion of the full amount of principal and interest owed on the \$5.0 million convertible secured note issued in December 2007, the Company s release of the security interest in all of the assets of WorldHeart that secured the note, termination of the warrant the Company held to purchase 3.4 million common shares of WorldHeart issued in December 2007, and forgiveness of other amounts owed to the Company by WorldHeart. In October, 2008, WorldHeart completed a 30-to-1 reverse stock split, as a result of which the Company now holds 2,866,666 common shares of WorldHeart. The Company is accounting for this investment using the equity method of accounting. The carrying value of this investment was zero at September 30, 2008.

## Note 10. Accounting for Stock-Based Compensation

In August 2008, the Company s stockholders approved the Company s 2008 Stock Incentive Plan (the Plan ). The Plan authorizes the grant of a variety of equity awards to the Company s officers, directors, employees, consultants and advisers, including awards of unrestricted and restricted stock, incentive and nonqualified stock options to purchase shares of common stock, performance share awards, and stock appreciation rights. The Plan provides that options may only be granted at the current market value on the date of grant. The maximum number of shares of the Company s common stock issuable under the Plan is equal to 2,308,688 shares, which included 308,688 shares that remained available for future awards as of August 12, 2008 under the Company s 1989 Non-Qualified Stock Option Plan for Non-Employee Directors, the 1998 Equity Incentive Plan and 2000 Stock Incentive Plan. This amount may be increased by up to 4,191,312 shares to the extent that any stock options or other equity awards that have been issued under the other plans are forfeited or terminated after August 13, 2008. Each share of stock issued pursuant to a stock option or stock appreciation right counts as 1.5 shares against the maximum number of shares issuable under the Plan. At September 30, 2008, a total of 1,421,502 shares were reserved and available for issuance under the Plan.

Total stock-based compensation recognized in the Company s condensed consolidated statements of operations for the three and six months ended September 30, 2008 and 2007 was as follows:

Three Months EndedSix MonthSeptember 30,Septem

Six Months Ended September 30,

	200	)8	2007	2008	2007	
		(in \$000 s)			(in \$000 s)	
Cost of product revenue	\$	99 \$	68	\$ 201	\$ 163	
Research and development	,	736	253	1,127	673	
Selling, general and administrative	2,	563	940	3,786	2,098	
	\$ 3,	398 \$	1,261	\$ 5,114	\$ 2,934	

The \$3.4 million in stock-based compensation expense for the three months ended September 30, 2008 includes \$1.2 million related to stock options and \$2.2 million related to restricted stock and the Company s Employee Stock Purchase Plan (ESPP). 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 ESPP.

The \$5.1 million in stock-based compensation expense for the six months ended September 30, 2008 includes \$2.5 million related to stock options and \$2.6 million related to restricted stock and the Company s 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, 2008 was approximately \$10.3 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, 2008.

## ABIOMED, INC. AND SUBSIDIARIES

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

## (In thousands, except share data)

Note 10. Accounting for Stock-Based Compensation (continued)

## Stock Option Activity

The following table summarizes the stock option activity for the six months ended September 30, 2008:

Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
4,436	\$ 11.49		
662	15.47		
(451)	8.07		
(66)	12.58		
(2)	5.63		
4,579	\$ 12.36	6.88	\$ 25,672
2,705	\$ 11.63	5.72	\$ 17,389
	(in thousands) 4,436 662 (451) (66) (2) 4,579	Average Exercise Price           4,436         \$ 11.49           662         15.47           (451)         8.07           (66)         12.58           (2)         5.63           4,579         \$ 12.36	Weighted Average (in thousands)Weighted Average Exercise PriceAverage Remaining Contractual Term (years)4,436\$ 11.4966215.47(451)8.07(66)12.58(2)5.634,579\$ 12.366.88

The total intrinsic value of options exercised during the six months ended September 30, 2008 and 2007 was \$2.9 million and \$0.3 million, respectively. The total fair value of options vested during the six months ended September 30, 2008 and 2007 was \$1.2 million and \$5.2 million, respectively.

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model. The fair value of options granted during the three and six months ended September 30, 2008 were calculated using the following weighted-average assumptions:

		Three Months Ended September 30,		is Ended ber 30,
	2008	2007	2008	
Risk-free interest rate	2.88%	4.48%	3.01%	4.59%
Expected option life (years)	5.21	6.25	5.12	6.25
Expected volatility	48.22%	58.60%	49.28%	56.87%

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on a combination of the historical volatility of the Company s stock and adjustments for factors not reflected in historical volatility that are more indicative of future volatility. Through December 31, 2007, 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*. Beginning on January 1, 2008, the Company estimated the expected term based on historical experience.

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 six months ended September 30, 2008 and 2007 was \$6.61 and \$7.22 per share, respectively.

## **Restricted Stock**

The following table summarizes restricted stock activity for the six months ended September 30, 2008:

	Six Months Ended September 30, 2008			
		Weighted Average		
	Number of Shares (in 000 s)	Grant Date Fair Value		
Restricted stock awards at March 31, 2008	54	\$	11.52	
Granted	666		15.76	
Vested	(130)		11.27	
Restricted stock awards at September 30, 2008	590	\$	16.36	

## ABIOMED, INC. AND SUBSIDIARIES

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

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

## Note 10. Accounting for Stock-Based Compensation (continued)

The remaining unrecognized compensation expense for restricted stock awards at September 30, 2008 was approximately \$5.0 million and the weighted-average time over which this cost will be recognized is 2.32 years.

In May 2008, 260,001 shares of restricted stock were issued to certain executive officers and certain members of senior management of the Company, of which 130,002 of these shares vest upon achievement of a prescribed performance milestone. In September 2008, the Company met the prescribed performance milestone, and all of these performance-based shares vested. The Company recorded stock compensation expense of \$1.5 million and \$1.8 million for the three months and six months ended September 30, 2008, respectively, for these performance shares. In connection with the vesting of these shares, these employees paid withholding taxes due with respect to the vesting of these shares by returning 36,937 shares valued at \$0.7 million. These shares have been recorded as treasury stock as of September 30, 2008. The remaining 129,999 of the restricted shares award vest ratably over four years from the grant date. The stock compensation expense for the restricted stock awards is recognized on a straight-line basis over the vesting period, based on the probability of achieving the performance milestones.

In August 2008, 406,250 shares of restricted stock were issued to certain executive officers and certain members of senior management of the Company, all of which could vest upon achievement of a prescribed performance milestone. The stock compensation expense for the restricted stock awards is being recognized on a straight-line basis over the vesting period through March 31, 2011 based on the probability of achieving the performance milestones. The cumulative effects of changes in the probability of achieving the milestones will be recorded in the period in which the changes occur.

During the six months ended September 30, 2007, 50,000 shares of restricted stock were issued to certain executive officers of the Company.

## Note 11. Capital Stock

In August 2008, the Company issued 2,419,932 shares of its common stock at a price of \$17.3788 in a public offering, which resulted in net proceeds to the Company of approximately \$42.0 million, after deducting offering expenses.

## Note 12. Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carry forwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates. A valuation reserve is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. The tax benefit associated with the stock option compensation deductions will be credited to equity when realized. 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.

As of September 30, 2008, the Company has accumulated a net deferred tax liability in the amount of \$4.9 million which is the result of a difference in accounting for the Company s goodwill which is amortized over 15 years for tax purposes, but not amortized for book purposes. The net deferred tax liability cannot be offset against the Company s deferred tax assets since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period. For the three months ended September 30, 2008 and 2007, the Company recorded a provision for income taxes of \$0.2 million and \$0.1 million, respectively. For the six months ended September 30, 2008 and 2007, the Company recorded a provision for income taxes of \$0.4 million and \$0.3 million, respectively.

On April 1, 2007, the Company adopted Financial Interpretation FIN No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109 (FIN No. 48), 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 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 initiated a voluntary disclosure plan with many of these states and has filed these tax returns or reached agreements with many of the states to settle the tax liability. 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. A reconciliation of the beginning and ending balance of unrecognized tax benefits, excluding accrued interest recorded at September 30, 2008 (in thousands) is as follows:

Balance at March 31, 2008	\$ 168
Reductions in tax positions for payments and other adjustments	(168)
Balance at September 30, 2008	\$

On a quarterly basis, the Company accrues for the effects of open uncertain tax positions and the related potential penalties and interest. 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.

The Company and its subsidiaries are subject to U.S. federal income tax, as well as income tax of multiple state and foreign jurisdictions. The Company has accumulated significant losses since its inception in 1981. All tax years remain subject to examination by major tax jurisdictions, including the federal government and the Commonwealth of Massachusetts. However, 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.

## ABIOMED, INC. AND SUBSIDIARIES

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

## (In thousands, except share data)

## Note 13. Comprehensive Loss

The components of comprehensive loss are as follows:

	Three Months Ended September 30,		Six Months Ended September 30,		
	2008	2008 2007		2007	
	(in \$0)	(in \$000 s)		000 s)	
Net loss	\$ (6,330)	\$ (9,382)	\$ (15,444)	\$ (17,657)	
Foreign currency translation adjustments	(6,248)	1,228	(6,381)	1,465	
Comprehensive loss	\$ (12,578)	\$ (8,154)	\$ (21,825)	\$ (16,192)	

## Note 14. 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, 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.

Excluded from the calculation of diluted weighted-average shares outstanding are 4,579,304 and 4,715,358 stock options outstanding as of September 30, 2008 and 2007, respectively and unvested shares of restricted stock in the amount of 590,249 shares and 52,000 shares as of September 30, 2008 and 2007, respectively. The calculation of weighted-average shares outstanding for the three and six months ended September 30, 2007 also excluded warrants to purchase up to 143,497 shares of common stock.

## Note 15. Commitments and Contingencies

#### Impella Milestone

The Company s acquisition of Impella provides that Abiomed may be required to make an additional contingent payment to Impella s former shareholders upon FDA approval of the Impella 5.0 device.

If the average market price per share of Abiomed s common stock, as determined in accordance with the purchase agreement, as of the date this milestone is achieved is \$22 or more, no additional contingent consideration will be required with respect to the milestone. If the average market price is between \$18 and \$22 on the date of the Company s achievement of the milestone, the milestone payment will be reduced ratably. This milestone payment may be made, at the Company s option, with cash or by a combination of cash or stock, except that no more than an aggregate of approximately \$3.8 million of this milestone payment may be made in the form of stock. If this contingent payment is made, it will result in an increase in the carrying value of goodwill.

## Danvers Lease

In June 2008, the Company amended the lease for its Danvers, Massachusetts facility. The amendment extends the lease from February 28, 2010 to February 28, 2016. The amendment changes the rent under the lease from \$64,350 per month to the following schedule:

The base rent for July 2008 through October 2008 will be \$0 per month;

The base rent for November 2008 through June 2010 will be \$40,000 per month;

The base rent for July 2010 through February 2014 will be \$64,350 per month; and

The base rent for March 2014 through February 2016 will be \$66,000 per month. In addition, the Company has certain rights to terminate the lease early, subject to the payment of a specified termination fee based on the timing of the termination, as further outlined in the amendment.

## Ireland Lease

In July 2008, the Company entered into a lease agreement providing for the lease of a 33,000 square foot manufacturing facility in Athlone, Ireland. The lease agreement is for a term of 25 years and one week, commencing on April 18, 2008. The monthly rent due under the lease agreement and payable monthly is 22,455.33 (Euro) (approximately U.S. \$32,000) per month or 269,464 (Euro) (approximately U.S. \$379,000) per year for the first five years of the lease, through April 17, 2013. On April 18, 2013 and each fifth anniversary thereafter, the rental rate will be set to a current market rate, as determined by the procedures set forth in the lease agreement. The Company has the right to terminate the lease after five years, subject to the payment of a termination fee equal to 18 months rent, and the right to terminate the lease after 10 years, subject to the payment of a termination fee equal to six months of the then current rent.

## ABIOMED, INC. AND SUBSIDIARIES

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

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

## **Revolving Line of Credit Facility**

In June 2008, the Company entered into a revolving line of credit facility with Blue Ridge Investments, L.L.C., an affiliate of Bank of America. The credit facility is secured by a first priority security interest in the Company sholdings in the Columbia Fund. The Company is able to borrow up to a maximum of \$20 million or 95% of the fair value of the Columbia Fund. As of September 30, 2008, the Company had the availability to borrow \$15.0 million under the line of credit. Under the terms of the credit facility, any amounts borrowed bear interest at a per annum rate of LIBOR plus .25%. During the term of the credit facility, the Company will pay unused commitment fees of .25% on any difference between the total amount available to borrow under the facility and the amount of credit actually utilized, calculated on an annual basis and to be paid monthly. Assuming no amounts are borrowed during the full one-year term of the credit facility, the maximum unused annual commitment fees owed would be \$50,000. The credit facility is available until June 2009 and the Company can cancel the facility at any time, at which point the Company would not be obligated to pay future unused commitment fees. As of September 30, 2008, the Company had made no borrowings under the facility.

## Litigation

From time-to-time, the Company is involved in legal and administrative proceedings and claims of various types. While any litigation contains an element of uncertainty, management presently believes that the outcome of each such 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 16. Segment and Enterprise Wide Disclosures

The Company operates in one business segment the research, development and sale of medical devices to assist or replace the pumping function of the failing heart. The Company s chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company s consolidated operating results. Approximately 63% and 54% of the Company s total consolidated assets are located within the U.S. as of September 30, 2008 and March 31, 2008, respectively. Remaining assets are located in Europe, primarily related to our Impella production facility, and include goodwill and intangibles of \$38.3 million and \$38.2 million at September 30, 2008 and March 31, 2008, respectively, associated with the Impella acquisition from May 2005. Total assets in Europe excluding goodwill and intangibles were \$15.6 million and \$16.4 million at September 30, 2008 and 2008 and March 31, 2008, respectively, and amounted to 11% and 7% of total consolidated assets. For the three months ended September 30, 2008 and 2007, international sales accounted for 13% and 14% of total product revenue, respectively. For the six months ended September 30, 2008 and 2007, international sales accounted for 12% and 16% of total product revenue, respectively.

The Company considers its Impella product line as a group of similar products in which revenues should be reported separately under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*. Impella revenues were \$10.5 million and \$1.4 million for the three months ended September 30, 2008 and 2007, respectively. Impella revenues were \$16.3 million and \$3.2 million for the six months ended September 30, 2008 and 2007, respectively.

## ITEM 2: MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FORWARD LOOKING STATEMENTS

Abiomed s discussion of financial condition and results of operations may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Our actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, anticipated future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, market acceptance of our new products, technological change, government regulation, future capital needs and uncertainty of additional financing and other risks detailed in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this Report. In particular, we encourage you to review the risks and uncertainties discussed under Item 1A of Part I of our Annual Report on Form 10-K, for the year ended March 31, 2008. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this Report or to reflect the occurrence of unanticipated events.

## **OVERVIEW**

We are a leading provider of medical devices in circulatory support and we offer a continuum of care in heart recovery 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 from all causes by the U.S. 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 shock, pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab. Our circulatory care products are designed to provide hemodynamic support for acute patients from the cath lab to the surgery suite, with a goal of heart recovery and sending the patient home with his or her native heart. We believe heart recovery is the optimal clinical outcome for patients because it provides a better quality of life than alternatives. In addition, we believe heart recovery is the most cost-effective path for the healthcare system. Since 2004, our executive team has focused our efforts on expanding our product portfolio. We have significantly increased our product portfolio, which now includes several circulatory care products that either have been approved or cleared by the FDA in the U.S., have received CE mark approval in Europe, or have received registration or regulatory approval in numerous other countries. We also have additional new circulatory care products under development.

Our strategic focus and the driver of the most recent revenue growth in our business is the market penetration of our Impella 2.5 product, which recently received 510(k) clearance in June 2008. In addition to the 510(k) clearance, we are also conducting clinical trials of our Impella 2.5 for additional indications of use, with the goal of establishing Impella as the standard of care in the cath lab. We are also in clinical trials with our Impella 5.0 device, which is larger and provides more blood flow than the Impella 2.5.

In order for our manufacturing to meet the expected demand for our Impella 2.5 product, we have been increasing our inventory levels and implementing process improvements at our manufacturing facilities in Aachen, Germany, to increase the output that we can produce at the facility. We also recently signed a lease for a facility in Athlone, Ireland, where we plan to establish a high-throughput manufacturing facility for the production of our Impella products in order to meet anticipated sales volumes of Impella 2.5. We expect our Ireland facility to be operational by the end of fiscal year 2010.

Revenues from our other heart recovery products have been relatively flat recently as we have strategically shifted our sales and marketing efforts towards our Impella products. We expect that sales from these other products will have limited or no growth as we dedicate the majority of our focus and resources on our Impella products. We have from time to time engaged in console placement programs related to our iPulse consoles, in order to encourage utilization of our BVS and AB5000 disposables. We have also developed a portable driver for our AB5000 product for which we are currently seeking FDA approval. Once approved, we believe that the added mobility afforded by the portable driver will help our overall AB5000 revenues. Our BVS product was launched over 15 years ago and revenue from this product has been declining as AB5000, 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. We expect revenue from BVS to continue to decline as our customers transition more to AB5000 disposables and also as our new Impella products are introduced in the U.S. We expect limited or no growth in our revenues from our AB5000 business for the remainder of fiscal 2009 as we continue to focus on our Impella products. We do not expect that revenues from sales of our replacement heart product, the AbioCor, will be a material portion of our total revenues for the foreseeable future as our primary strategic focus is centered around heart recovery for acute heart failure patients. We have not recognized any AbioCor revenue during the first six months of fiscal 2009.

We have incurred net losses since our inception, including net losses of \$6.3 million and \$15.4 million for the three and six months, respectively, ended September 30, 2008. We expect to incur additional net losses in the future as we continue to invest in research and development expenses

related to our products, increase our inventory levels, and ramp up our manufacturing facility in Ireland.

Our financial condition has been bolstered by our recent public offering, which yielded us approximately \$42.0 million in net proceeds after deducting offering expenses. We expect that our existing cash resources, together with our revenues, will be sufficient to fund our operations for at least the next 12 months.

## Impella 2.5, Impella 5.0, and Impella LD

Our Impella 2.5, Impella 5.0, and Impella LD 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 or first use in surgery for patients who may require assistance to maintain their circulation. 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 have CE mark approval in Europe, are approved in over 40 countries, have already been used to treat numerous patients in Europe and other countries outside the U.S. and have been the subject of over 50 peer-reviewed publications and other clinical presentations and publications.

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

## Impella 2.5, Impella 5.0, and Impella LD continued

These catheters can be quickly inserted via 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 into circulation, thereby reducing ventricular work (resting the heart) and providing flow to the rest of the organs. The Impella 2.5 is introduced with normal interventional cardiology procedures, while the Impella 5.0 is implanted via a small incision in 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 five 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 iPulse, AB5000 and BVS 5000 systems.

We are pursuing FDA approval for our Impella heart pumps through a pre-market approval, or PMA path, for our Impella 2.5 and 5.0 products. In August 2007, we received approval from the FDA to begin a high-risk percutaneous coronary intervention or PCI, pivotal clinical trial for the Impella 2.5. This approval was based on 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, or IAB, 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 Medicaid Services, or CMS. The randomized pivotal study, at up to 150 hospitals and 654 patients undergoing high-risk PCI procedure, is comprised of two arms comparing nearly equal number of Impella 2.5 supported patients and IAB supported patients during the procedure. Patients receiving the Impella 2.5 can be supported for up to five days as a left ventricular assist device (VAD). As of September 30, 2008, 187 hospitals are pursuing the study, with 67 hospitals ready for enrollment of patients, 35 with investigational review board, or IRB, approval, but not yet enrolling, and 85 hospitals having submitted to the IRB or submission is pending. We have completed 141 patients, or 22% of the 654 patients required.

In March 2008, we received approval from the FDA to begin a second pivotal study for our Impella 2.5 in the U.S. under an investigative device exemption, or IDE, for hemodynamically unstable patients undergoing a PCI procedure due to acute myocardial infarction, or AMI, commonly referred to as heart attack. The AMI study will determine the safety and effectiveness of the Impella 2.5 as a left ventricular assist device for heart attack patients as compared to optimal medical management with an IAB. The study is approved under category B2 status and the trial sites are eligible for full CMS reimbursement. The randomized study, at up to 150 hospitals, is comprised of two arms; those patients that receive the Impella 2.5 for up to five days and patients that receive IAB therapy. The study will compare 192 Impella 2.5 patients to 192 IAB patients relative to a composite end point comparing safety and efficacy. The proposed primary endpoint will be a composite endpoint of major events assessed at 30 days post-AMI. These major events include but are not limited to: death, acute renal failure, and need for a major cardiovascular operation. The secondary endpoint will be a composite of cardiac function such as ejection fraction, requirement for inotropic support and cardiac power output. As of September 30, 2008, 88 U.S. hospitals are pursuing the study. One hospital is enrolling patients, 9 hospitals have received IRB approval, and 79 have submitted to the IRB or submission is pending.

Our Impella 2.5 device recently received 510(k) clearance from the FDA for partial circulatory support for up to six hours, which allows for immediate commercial launch of our Impella 2.5 in the U.S. There are an estimated 14,000 interventional cardiologists at approximately 1,900 hospitals in the U. S. which represents the primary target market in the U.S. for our Impella 2.5 device.

We are making steady progress with our clinical trials on Impella 2.5 including completing our U.S. safety pilot clinical trial. Factors that affect the length of time to complete the pivotal studies in the U.S. study include the timing of each center receiving IRB approval, the timing of the training we will provide each center, and the rate of patient enrollment. As a result of these factors, at this time we cannot estimate the duration of the two Impella 2.5 pivotal studies discussed above. However, there can be no assurance that our Impella 2.5 clinical trials will be successful or that we will receive FDA approval for the indications that are the subject of the clinical trials.

The Impella 5.0 is in a pilot clinical study that is enrolling up to 20 patients at 15 U.S. sites. The study includes postcardiotomy patients who have been weaned from heart-lung machines and whose hearts require added support to maintain good blood flow. The study is enrolling those patients that would typically need more flow and hemodynamic support than provided by an IAB.

IAB and iPulse

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. To support the IAB, we developed our iPulse combination console. The iPulse console is also designed to support our AB5000 ventricle and BVS 5000 blood pump, other manufacturers IABs 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.

The iPulse console is designed to support our IAB as well as other manufacturers IABs, which are used in the cath lab and surgery suite. Because our multi-functional console also supports our AB5000 ventricle and BVS 5000 blood pump, we believe the iPulse will provide our customers additional flexibility in allocating console resources between the surgery suite and the cath lab. In addition, because a significant portion of IABs are used in the surgery suite, we believe adoption of our iPulse console and Portable Driver, as discussed below, will increase utilization of our AB5000 ventricle.

We received 510(k) clearance from the FDA for our IAB in December 2006 and CE Mark approval in January 2007. The iPulse console has received CE mark approval in Europe and was approved by the FDA in December 2007 for commercial sale in the U.S. We expect customer demand to shift over time from our AB5000 console to our iPulse combination console.

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

## AB5000 and BVS 5000

We manufacture and sell the AB5000 Circulatory Support System and the BVS 5000 Biventricular Support System for the temporary support of acute heart failure patients in profound shock, including patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock, or myocarditis. 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, 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 and was approved by the FDA in 2003. 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 system s high flow rates, ease of implant and historically low incidence of adverse events facilitate heart recovery, for patients with potential for recovery, potentially avoiding the need for heart transplantation and thereby improving patient outcomes. We announced in January 2008 that we received FDA labeling approval of one year bench reliability for our AB5000 ventricle. Our iPulse combination console can run our AB5000 ventricle, our BVS 5000 blood pump, our IAB and other manufacturers IABs.

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. We expect customer demand to shift from the AB5000 console to our recently FDA-approved iPulse combination console.

## Portable Driver

We recently have developed a new Portable Circulatory Support Driver for both in-hospital and out-of-hospital patients. The Portable Driver is designed to support our AB5000 VAD. The combination of our new Portable Driver and FDA-approved AB5000 VAD is designed to provide support of acute heart failure patients. In many cases, profound shock heart patients require biventricular support (both sides of the heart). The AB5000 can assume the pumping function of a patient s failing heart, allowing the heart to rest, heal and potentially recover. The AB5000 is designed to provide either univentricular or biventricular support. We received FDA labeling approval of one year bench reliability for our AB5000 VAD, which is expected to complement the Portable Driver reliability. We received CE mark approval for our Portable Driver in March 2008. In May 2008, we received conditional approval for the Portable Driver for an IDE to conduct a U.S. patient discharge study at 20 hospitals for 30 patients. The Portable Driver is not yet approved by the FDA.

## 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. Our integrated cannula system was approved by the FDA in July 2006. This integrated cannula system, 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.

## AbioCor

Our AbioCor Implantable Replacement Heart is the first completely self-contained artificial heart. Designed to sustain the body s circulation, the AbioCor is intended for end-stage biventricular heart failure patients whose other treatment options have been exhausted. Patients with advanced age, impaired organ function or cancer are generally ineligible for a heart transplant and are potential candidates to receive the AbioCor implantable heart. 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.

We received HDE supplement approval from the FDA for product enhancement of the AbioCor in January 2008. HDE approval signifies that no comparable alternative therapy exists for patients facing imminent death without the technology. HDE approval allows the AbioCor to be made available to a limited patient population, with no more than 4,000 patients receiving the technology in the U.S. each year under HDE approval limits. Because the AbioCor is only available to a limited patient population, we do not expect that demand will meet the 4,000 patient limit under HDE approval. As a result, we have no current plans to seek a broader regulatory approval of the AbioCor. We began selling the AbioCor in the fourth quarter of fiscal 2008 in a controlled roll-out to a limited number of heart centers in the U.S. We have selected the following sites to date as AbioCor centers: The Johns Hopkins Hospital in Baltimore, MD; Robert Wood Johnson University Hospital in New Brunswick, NJ; and St. Vincent s Hospital in Indianapolis, IN. We are unable to determine how many patient procedures will be performed after the centers are trained. In May 2008, we received a positive National Coverage Determination, or NCD, from CMS to reimburse hospitals for the cost of the AbioCor replacement heart and the cost of implanting the device as part of Coverage with Evidence Development, or CED. Three insurance companies have existing coverage policies for the AbioCor: Cigna, Humana and Healthnet. We do not expect that revenues from sales of the AbioCor will be a material portion of our total revenues for the foreseeable future as our primary strategic focus is centered around heart recovery for acute heart failure patients. The use of AbioCor is limited to normal to larger sized male patients and has a product life expectancy of 18-24 months. We are testing a newer version of the AbioCor, the Abiocor II, that will be smaller and may have a longer product life expectancy than the AbioCor.

## 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 ended September 30, 2008 and 2007, respectively:

	Three Months Ended September 30, 2008 2007		Six Months Ended September 30, 2008 2007	
Revenues:				
Product	98.9%	99.3%	99.1%	99.0%
Funded research and development	1.1	0.7	0.9	1.0
	100.0	100.0	100.0	100.0
Costs and expenses:				
Cost of product revenue excluding amortization of intangibles	24.0	25.3	28.7	25.2
Research and development	34.2	51.4	35.7	44.6
Selling, general and administrative	69.5	107.9	75.4	97.2
Arbitration decision	0.0	(0.2)	0.0	4.8
Amortization of intangible assets	2.1	3.4	2.3	3.0
	129.8	187.8	142.1	174.8
Loss from operations	(29.8)	(87.8)	(42.1)	(74.8)
Other income and expense:				
Investment (expense) income, net	(0.2)	7.1	0.6	6.7
Other (expense) income, net	(0.3)	(0.6)	0.2	(0.3)
	(0.5)	6.5	0.8	6.4
Loss before provision for income taxes	(30.3)	(81.3)	(41.3)	(68.4)
Provision for income taxes	1.4	1.3	1.1	1.1
Net loss	(31.7)%	(82.6)%	(42.4)%	(69.5)%

Three and six months ended September 30, 2008 compared with the three and six months ended September 30, 2007

## Revenues

Our revenues are comprised of the following:

Three MonthsEndedSix Months EndedSeptember 30,September 30,200820072008

	(in \$	000 s)	(in \$	000 s)
Impella	\$ 10,507	\$ 1,374	\$ 16,299	\$ 3,151
Other	9,270	9,898	19,748	22,022
Total product revenues	\$ 19,777	\$11,272	\$ 36,047	\$ 25,173
Funded research and development	222	83	309	246
Total revenues	\$ 19,999	\$ 11,355	\$ 36,356	\$ 25,419

Impella revenue encompasses our Impella 2.5, Impella 5.0, and Impella LD platforms. Our revenue from other products include AB5000, BVS5000, IAB, iPulse, Portable Driver, Abiocor and cannulae and service agreements.

Product revenues for the three months ended September 30, 2008 increased by \$8.5 million, or 75%, to \$19.8 million from \$11.3 million for the three months ended September 30, 2007. The increase in product revenue was primarily due to an increase in Impella revenue of 670% due to greater demand in the U.S. following 510(k) clearance of the Impella 2.5 in June 2008 and increased enrollment in our Impella 2.5 PCI pivotal trial, offset by a decrease in other revenue attributable to our strategic focus on increasing penetration of our Impella 2.5 product. Most of our Impella revenue was from disposable product sales of Impella 2.5 with very few console sales. Our launch strategy of Impella 2.5 has been focused on increasing demand for disposable products by providing consoles to initial sites at no cost. We expect these console promotions to decrease as the number of hospitals using our Impella 2.5 products increase.

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

Product revenues for the six months ended September 30, 2008 increased by \$10.8 million or 43%, to \$36.0 million from \$25.2 million for the six months ended September 30, 2007. The increase in product revenue was primarily due to an increase in Impella revenue of 420% due to greater demand in the U.S. following 510(k) clearance in June 2008 and increased enrollment in our Impella 2.5 PCI pivotal trial. This increase was partially offset by a decrease in other revenue attributable to our strategic focus on increasing penetration of our Impella 2.5 product.

We expect that demand for our Impella 2.5 should increase in the future based on the recent 510(k) clearance of the product in June 2008 and as we enroll more patients in our PCI and AMI pivotal studies. As a result, we expect limited or no growth in our other products for the remainder of fiscal 2009 as we continue to focus our sales and marketing efforts in fiscal 2009 on growing our Impella product line.

## **Cost of Product Revenues**

Cost of product revenues, excluding amortization of intangibles, for the three months ended September 30, 2008 increased by \$2.0 million, or 69%, to \$4.9 million from \$2.9 million for the three months ended September 30, 2007. This resulted in gross margin for the three months ended September 30, 2008 of 76% compared to 75% for the three months ended September 30, 2007. The slight increase in gross margin was primarily related to sales of Impella product, which have higher profit margins. Cost of product revenues also increased as a result of higher revenues in the quarter ended September 30, 2008 compared to the same period of the prior year.

Cost of product revenues for the six months ended September 30, 2008 increased by \$4.0 million, or 63%, to \$10.4 million from \$6.4 million for the six months ended September 30, 2007. This resulted in gross margin for the six months ended September 30, 2008 of 71% compared to 75% for the six months ended September 30, 2007. The decrease in gross margin was primarily due to the effect of certain Impella, AB5000 and iPulse console programs implemented to generate future disposable revenue and the scrapping of approximately \$1.2 million of inventory for slow moving or obsolete products during the six months ended September 30, 2008. Our launch strategy for Impella 2.5 has been focused on increasing demand for disposable products by providing consoles to certain initial sites at little or no cost. We expect that these initial console promotions to decrease as the number of hospitals using our Impella 2.5 products increase. During the quarter ended June 30, 2008, a total of 70 consoles, including 46 consoles related to Impella orders were transferred to customers in connection with disposable orders and in anticipation of future disposable orders.

## **Research and Development Expenses**

Research and development expenses for the three months ended September 30, 2008 increased by \$1.1 million, or 19%, to \$6.9 million from \$5.8 million for the three months ended September 30, 2007. Research and development expenses for the three months ended September 30, 2008 and 2007 included \$2.3 million and \$0.3 million, respectively, in clinical trial expenses primarily associated with our Impella 2.5 and 5.0 U.S. trials. Our increase in product development costs reflects our efforts to expand and enhance our product lines across a clinical spectrum of circulatory care, particularly due to increased clinical trial activity on Impella 2.5. Research and development expenses for the six months ended September 30, 2007, reflecting our increased spending on clinical trials as discussed above.

## Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2008 increased by \$1.6 million, or 13%, to \$13.9 million from \$12.3 million for the three months ended September 30, 2007. The increase was primarily due to \$1.5 million in stock-based compensation associated with the achievement of a performance milestone during the quarter on grants of restricted stock made in May 2008.

Selling, general and administrative expenses for the six months ended September 30, 2008 increased \$2.7 million or 11%, to \$27.4 million from \$24.7 million for the six months ended September 30, 2007. The increase was during the quarter primarily due to an increase of \$2.6 million in stock-based compensation associated with the achievement of a performance milestone during the quarter on grants of restricted stock made in May 2008. The additional increase is related to increased investments in our international global distribution network, and was also due to increased investments in marketing initiatives to commercialize the Impella and iPulse products.

We expect to continue to increase our expenditures on sales and marketing activities throughout fiscal 2009, with particular investments in clinical personnel with cath lab expertise and also plan to increase our marketing, service and training investments to support the efforts of the sales and clinical teams to drive recovery awareness for acute heart failure patients globally.

#### **Arbitration Decision**

As discussed in Note 8, the aggregate arbitrator award for the three months ended September 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 from the arbitration decision made in June 2007.

#### **Amortization of Intangibles**

Amortization of intangible assets was \$0.4 million for both the three months ended September 30, 2008 and 2007, and \$0.8 million for both the six months ended September 30, 2008 and 2007. Amortization expense primarily is related to specifically identified assets from the Impella acquisition.

#### **Investment Expense and Income, net**

Investment expense, net, was \$43,000 for the three months ended September 30, 2008, representing a decrease of \$0.9 million from investment income of \$0.8 million for the three months ended September 30, 2007. Investment income, net, was \$0.2 million for the six months ended September 30, 2008, representing a decrease of \$1.5 million from \$1.7 million for the six months ended September 30, 2007. The decrease in investment income for the three and six months ended September 30, 2008 was due to realized and unrealized losses incurred on the Columbia Fund (Note 5). Investment income and expense, net, consists primarily of interest earned on our cash and investments and changes in the value of the Columbia Fund.

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

#### **Other Income (Expense)**

Other expense was \$0.1 million for the three months ended September 30, 2008 and 2007, respectively. Other income was \$0.1 million for the six months ended September 30, 2008, compared with other expense of \$0.1 million for the six months ended September 30, 2007. The increase in other income (expense) is mainly due to foreign exchange effects.

#### **Provision for Income Taxes**

We recorded a provision for income taxes of \$0.3 million and \$0.1 million for the three months ending September 30, 2008 and 2007, respectively. During the six months ended September 30, 2008 and 2007, we recorded a provision for income taxes of \$0.4 million and \$0.3 million, respectively. The income tax provision is primarily due to a deferred tax related to a difference in accounting for our goodwill, which is amortizable over 15 years for tax purposes but not amortized for book purposes. The net deferred tax liability cannot be offset against our deferred tax assets since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period.

#### Net Loss

During the three months ended September 30, 2008, we incurred a net loss of \$6.3 million, or \$0.18 per share, compared to a net loss of \$9.4 million, or \$0.29 per share, for the three months ended September 30, 2007. The decrease in the net loss for the three months ended September 30, 2007 was due to an increase in our product revenues, primarily from Impella.

During the six months ended September 30, 2008, we incurred a net loss of \$15.4 million, or \$0.46 per share, compared to a net loss of \$17.7 million, or \$0.55 per share, for the six months ended September 30, 2007. Included in the net loss for the six months ended September 30, 2007 is \$1.2 million relating to the arbitration award as previously discussed in Note 8.

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 invest in research and development and our Impella pivotal studies to bring Impella and other new products to market.

#### Liquidity and Capital Resources

At September 30, 2008, our cash, restricted securities and short-term marketable securities totaled \$66.3 million, an increase of \$28.0 million compared to \$38.3 million in cash and short-term marketable securities at March 31, 2008. In August 2008, we completed a public offering in which we received net proceeds of \$42.0 million. We believe that our revenue from product sales together with existing resources, including the cash from our public offering and the ability to use our revolving facility, will be sufficient to fund our operations for at least the next twelve months.

Restricted securities at September 30, 2008 consist of \$15.8 million of marketable securities held in the Columbia Fund. In December 2007, the Columbia Fund ceased accepting redemption requests from new or current investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. As a result, we reclassified the securities in the Columbia Fund from cash equivalents to short-term marketable securities as the Columbia Fund was no longer expected to have a maturity of less than 90 days. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 96% of its carrying value at September 30, 2008. The Columbia Fund is being liquidated with distributions to us occurring during calendar 2008 and through September 30, 2009. Since December 6, 2007, we have received disbursements of approximately \$34.2 million from the Columbia Fund with the most recent disbursement occurring on October 30, 2008 at approximately 93% of its original value.

The recent and unprecedented disruption in the current credit markets has had a significant adverse impact on a number of financial and other institutions. Our investments in the Columbia Fund have been frozen since December 2007 and we are subject to redemptions of these investments based on the discretion of the fund (Note 5). When redemptions have occurred, we have realized losses on our original investment and we expect to incur losses on future redemptions. Since December 2007, we have incurred \$0.9 million in realized losses on the Columbia Fund through October 31, 2008. We are not a party to any interest rate swaps, currency hedges or derivative contracts of any type and have no exposure to commercial paper or auction rate securities markets.

Financial instruments, such as the Columbia Fund for which the fair value is derived primarily from broker quotes or pricing services may fall within Level 1, 2 or 3 of the SFAS 157 fair value hierarchy, depending on the observability of the inputs used to determine fair value. We review with Bank of America the pricing assumptions, inputs and methodologies in determining an instrument s fair value as a basis for classification within the SFAS 157 fair value hierarchy. If we believe that these estimates of fair value differ significantly from our internal expectations, we review our findings with respect to data sources or assumptions used to determine whether the value is appropriate.

At September 30, 2008, our other short-term marketable securities consist of \$47.6 million held in funds that invest solely in U.S. Treasury securities.

In June 2008, we entered into a revolving line of credit facility with Blue Ridge Investments L.L.C, an affiliate of Bank of America, with a term expiring in June 2009. We are able to borrow up to a maximum of \$20.0 million or 95% of the fair value of the Columbia Fund. As of September 30, 2008, we had the ability to borrow \$15.0 million under the line of credit. The credit facility is secured by a first priority security interest in our holdings in the Columbia Fund and we pledged these holdings to Blue Ridge Investments, L.L.C. during the term of the credit facility. Any amounts borrowed under the credit facility will be reduced by any cash distributions made on the Columbia Fund As a result, we have segregated the marketable securities held in the Columbia Fund as restricted securities while the credit facility is in place. As of September 30, 2008, we have not made any borrowings against this credit facility.

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

Our operating activities during the six months ended September 30, 2008 used cash of \$15.4 million as compared to \$15.3 million during the same period in the prior year. Our net loss for the six months ended September 30, 2008 of \$15.4 million was the primary cause of our cash use from operations. In addition, our inventories used cash of \$4.3 million during the six months ended September 30, 2008, reflecting our inventory build-up to support anticipated increases in global demand for our products, particularly Impella 2.5. Additionally, we scrapped \$1.2 million of inventory during the six months ended September 30, 2008 as a result of this inventory build up to support anticipated increases in global demand. These decreases in cash were partially offset by non-cash adjustments of \$5.1 million related to stock-based compensation expense and \$2.6 million of depreciation and amortization.

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

#### Liquidity and Capital Resources continued

Our investing activities during the six months ended September 30, 2008 used cash of \$28.4 million as compared to cash provided by investing activities of \$3.1 million during the same period in the prior year. Cash used by investment activities for the six months ended September 30, 2008 consisted primarily of \$27.0 million of purchases of short-term marketable securities, net of sales of short-term marketable securities during the quarter. Additionally, we incurred \$1.4 million related to cash expenditures for property and equipment primarily on computer software projects and manufacturing equipment.

Our financing activities during the six months ended September 30, 2008 provided cash of \$45.0 million as compared to \$2.0 million during the same period in the prior year. Cash provided by financing activities for the six months ended September 30, 2008 was comprised of \$3.5 million attributable to the exercise of stock options and \$42.0 million in net proceeds related to our August 2008 public offering. This was offset by a \$0.6 million related to cancellation of common stock, as discussed in Note 10.

Capital expenditures for fiscal 2009 are estimated to be \$3.0 to \$5.0 million, which relate primarily to our planned manufacturing capacity increases for Impella and our expansion in Ireland.

#### **Critical Accounting Policies**

We continue to monitor our accounting policies to ensure proper application of current rules and regulations. 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, 2008.

#### **New Accounting Pronouncements**

SFAS No. 157 - In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. In February 2008, the FASB issued FASB Staff Position FAS 157-2, *Partial Deferral of the Effective Date of Statement 157*. We adopted this pronouncement in the quarter ended June 30, 2008 and adoption did not have a material impact on our financial position or results of operations.

*SFAS No. 159* - In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007. We adopted this pronouncement in the quarter ended June 30, 2008 and adoption did not have a material impact on our financial position or results of operations.

*EITF 07-3* - In June 2007, the EITF reached a final consensus on Issue No. 07-3 (EITF No. 07-3), Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities, effective on a prospective basis for fiscal years beginning after December 15, 2007. This EITF did not have an impact on our financial position or results of operations for the three and six months ended September 30, 2008.

*SFAS No. 141(R)* - In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations.* SFAS No. 141(R) applies to any transaction or other event that meets the definition of a business combination. Where applicable, SFAS No. 141(R) establishes principles and requirements for how the acquirer recognizes and measures identifiable assets acquired, liabilities assumed, noncontrolling interest in the acquiree and goodwill or gain from a bargain purchase. In addition, SFAS No. 141(R) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This statement is to be applied prospectively for transactions occurring in fiscal years beginning after December 15, 2008. We do not expect the adoption of SFAS No. 141(R) to have a material impact on our financial position or results of operations.

*SFAS No. 160* - In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, an amendment of ARB No. 51. SFAS No. 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of the consolidation procedures under ARB No. 51 for consistency with the requirements of FASB Statement No. 141(R). This statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The statement shall be applied prospectively as of the beginning of the fiscal year in which the statement is initially adopted. We do not expect the adoption of SFAS No. 141(R) to have a material impact on our financial position or results of operations.

*SFAS No. 161* - In March 2008, the FASB issued Statement No. 161, *Disclosures About Derivative Instruments and Hedging Activities*. This statement is intended to improve financial reporting about derivative instruments and hedging activities by enhanced disclosures to better understand their effects on a company s financial position, results of operation and cash flows. This standard is effective for interim and annual financial statements beginning after November 15, 2008. We do not expect the adoption of SFAS No. 161 to have a material impact on our financial position or results of operations.

#### **Contractual Obligations and Commercial Commitments**

#### Impella Milestone

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 contingent payments in the amount of \$5.6 million made on each of January 30, 2007 and June 30, 2008 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. The purchase price also allowed for additional contingent consideration to Impella s former shareholders based on additional milestone payments related to FDA approval of Impella 5.0 in the amount of \$5.6 million. If this additional payment is triggered, at least \$1.8 million of this payment must be made in cash.

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

#### Danvers Lease

In June 2008 we amended the lease for our facility in Danvers, Massachusetts. The amendment extends the lease from February 28, 2010 to February 28, 2016. The amendment changes the rent under the lease from \$64,350 per month to the following schedule:

The base rent for July 2008 through October 2008 is \$0 per month;

The base rent for November 2008 through June 2010 will be \$40,000 per month;

The base rent for July 2010 through February 2014 will be \$64,350 per month; and

The base rent for March 2014 through February 2016 will be \$66,000 per month.

In addition, we have certain rights to terminate the lease early, subject to the payment of a specified termination fee based on the timing of the termination, as further outlined in the amendment.

#### Ireland Lease

In July 2008 we entered into a lease agreement providing for the lease of a 33,000 square foot manufacturing facility in Athlone, Ireland. The lease agreement is for a term of 25 years and one week, commencing on April 18, 2008. The monthly rent due under the lease agreement and payable monthly is 22,455.33 (Euro) (approximately U.S. \$32,000) per month or 269,464 (Euro) (approximately U.S. \$379,000) per year for the first five years of the lease, through April 17, 2013. On April 18, 2013 and each fifth anniversary thereafter, the rental rate will be set to a current market rate, as determined by the procedures set forth in the lease agreement. We have the right to terminate the lease after five years, subject to the payment of a termination fee equal to 18 months rent, and the right to terminate the lease after 10 years, subject to the payment of a termination fee equal to six months of the then current rent.

#### **Revolving Line of Credit Facility**

In June 2008, we entered into a revolving line of credit facility with Blue Ridge Investments, L.L.C., an affiliate of Bank of America. The credit facility is secured by a first priority security interest in our holdings in the Columbia Fund. We are able to borrow up to a maximum of \$20 million or 95% of the fair value of the Columbia Fund. As of September 30, 2008, we had the availability to borrow \$15.0 million under the line of credit. Under the terms of the credit facility, any amounts borrowed bear interest at a per annum rate of LIBOR plus .25%. During the term of the credit facility, we will pay unused commitment fees of .25% on any difference between the total amount available to borrow under the facility and the amount of credit actually utilized, calculated on an annual basis and to be paid monthly. Assuming no amounts are borrowed during the full one-year term of the credit facility, the maximum unused annual commitment fees owed would be \$50,000. The credit facility is available until June 2009 and we can cancel the facility at any time, at which point we would not be obligated to pay future unused commitment fees. As of September 30, 2008, we had made no borrowings under the facility.

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

Certain of our outstanding non-derivative financial instruments at September 30, 2008 are subject to interest rate risk, but not subject to foreign currency or commodity price risk. The conversion feature and warrant associated with our note receivable from WorldHeart were determined to be derivative financial instruments. We mark to market these instruments on a quarterly basis, utilizing various assumptions and modeling techniques. We monitor our investment in the note receivable and warrant on a quarterly basis to determine whether any impairment is required. We consider available evidence, including the duration and extent to which the market value has been less than cost, if applicable, to evaluate the extent to which the decline is other-than-temporary. If the decline is considered other-than-temporary, the carrying value of the financial instruments will be written down to estimated realizable value. We recorded an impairment charge during the fourth quarter of fiscal 2008 writing down our \$5.0 million investment in WorldHeart. As such the carrying value of the note receivable and warrant is zero at September 30, 2008. We do not participate in any other 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. Our restricted cash and short-term marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at September 30, 2008, we believe the decline in fair market value of our investment portfolio would be immaterial. Restricted securities at September 30, 2008 consist of \$15.8 million in the Columbia Fund. Short-term marketable securities consist of \$47.6 million in five funds that invest in U.S. Treasury securities and related interest. In December 2007, the Columbia Fund ceased accepting redemption requests from new or current investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. As a result, we reclassified the securities in the Columbia Fund from cash equivalents to short-term marketable securities as the Columbia Fund was no longer expected to have a maturity of less than 90 days. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 96% of its carrying value at September 30, 2008. The Columbia Fund is being liquidated with distributions to us occurring during calendar 2008 and through the next twelve months. Since December 6, 2007 and through October 31, 2008, we have received disbursements of approximately \$34.2 million from the Columbia Fund with the most recent disbursement occurring on October 30, 2008 at approximately 93% of its original value. While it is our intent to liquidate securities in the Columbia Fund in future periods to reduce our exposure to future deterioration of these securities, we believe that operating results and cash flows could be affected significantly by market value adjustments to the Columbia Fund. There can be no assurance that we will not have to take additional losses on the Columbia

#### ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK (continued)

In June 2008, we entered into a revolving line of credit facility with Blue Ridge Investments, L.L.C. to serve as a contingent financing facility. We can borrow up to a maximum of \$20 million or 95% the fair value of the Columbia Fund. The credit facility is secured by a first priority security interest in our holdings in the Columbia Fund, and amounts available under the credit facility will be reduced by any cash distributions made on the Columbia Fund. Under the terms of the credit facility, any amounts borrowed bear interest at a per annum rate of LIBOR plus 0.25%. During the term of the credit facility, we will pay unused commitment fees of 0.25% on any difference between the total commitment and the amount of credit facility, the maximum unused annual basis and to be paid monthly. Assuming no amounts are borrowed during the full one-year term of the credit facility, the maximum unused annual commitment fees owed would be \$50,000, or \$12,500 per quarter. The credit facility is available until June 2009 and we can cancel the facility at any time, at which point we would not be obligated to pay future unused commitment fees. As of September 30, 2008, we have not made any borrowings against this credit facility.

In July 2008, WorldHeart completed the transactions contemplated by the recapitalization agreement dated June 20, 2008, as amended on July 31, 2008, among us, WorldHeart, World Heart, Inc., Venrock Partners V, L.P., Venrock Associates V, L.P., Venrock Entrepreneurs Fund V, L.P., Special Situations Fund III QP LP, Special Situations Cayman Fund, L.P., Special Situations Private Equity Fund, L.P., Special Situations Life Sciences Fund, L.P., Austin Marxe and New Leaf Ventures II, L.P. As a result of the transaction, we received 86 million common shares of WorldHeart, which represents approximately 21.6% of WorldHeart s issued and outstanding common shares following the transaction. The shares were received as a result of our conversion of the full amount of principal and interest owed on the \$5.0 million convertible secured note issued in December 2007, our release of the security interest in all of the assets of WorldHeart that secured the note, termination of the warrant we held to purchase 3.4 million common shares of WorldHeart issued in December 2007, and forgiveness of other amounts owed to us by WorldHeart. In October 2008, WorldHeart completed a 30-to-1 reverse stock split, as a result of which we now hold 2,866,666 common shares of WorldHeart. We are accounting for this investment using the equity method of accounting. The carrying value of this investment was zero at September 30, 2008.

#### **Currency Exchange Rates**

Our Germany subsidiary s functional currency is the Euro. Therefore, our investment in our Germany subsidiary 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 foreign currencies occurred relative to the US dollar as of September 30, 2008, the result would have been a reduction of stockholders equity of approximately \$5.3 million.

#### Fair Value of Financial Instruments

At September 30, 2008, our financial instruments consist primarily of cash and cash equivalents, short-term marketable securities, accounts receivable, accounts payable and revolving line of credit facility. The estimated fair values of the financial instruments have been determined by us using available market information and appropriate valuation techniques. Considerable judgment is required, however, to interpret market data to develop the estimates of fair value. Accordingly, the estimates presented are not necessarily indicative of the amounts that we could realize in a current market exchange. This determination of the fair value of our holdings in the Columbia Fund requires significant judgment or estimation. As discussed in Note 4, certain of these securities were valued primarily using broker pricing models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value amounts.

#### ITEM 4. CONTROLS AND PROCEDURES Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act )), as of September 30, 2008. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2008, 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 interim principal

financial officer, as appropriate to allow timely decisions regarding required disclosure.

#### **Evaluation of Changes in Internal Control over Financial Reporting**

During the second quarter of our fiscal year ended March 31, 2009, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### PART II OTHER INFORMATION

#### Item 1. Legal Proceedings

We are from time to time involved in various legal actions, the outcomes of which are not within our complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages, as well as other relief, which, if granted, would require significant expenditures. We record a liability in our consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. We review these estimates each accounting period as additional information is known and adjust the loss provision when appropriate. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in the consolidated financial statements.

#### PART II OTHER INFORMATION (continued)

#### Item 1A. <u>Risk Factors</u>

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, 2008, 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 changes to the risk factors described in our Annual Report on Form 10-K are to replace the risk factors titled Our short term marketable securities are subject to market risks and decreased liquidity, We own patents, trademarks, trade secrets, copyrights and other intellectual property and know-how that we believe gives us a competitive advantage. If we cannot protect our intellectual property and develop or otherwise acquire additional intellectual property, competition could force us to lower our prices, which could hurt our profitability, Future milestone payments relating to our acquisition of Impella could harm our financial position or result in dilution, Our strategic investment in WorldHeart Corporation, or WorldHeart, is subject to risk and we have recorded impairment charges against it, and We must comply with healthcare fraud and abuse laws, and we could face substantial penalties for non-compliance and be excluded from government healthcare programs, which would adversely affect our business, financial condition and results of operations and to add some additional risk factors, all as listed below:

#### Our short term marketable securities are subject to market risks and decreased liquidity.

Our short-term marketable securities at September 30, 2008 consist of \$15.8 million in the Columbia Fund, \$47.6 million in five funds that invest in U.S Treasury securities and related interest. In December 2007, the Columbia Fund ceased accepting redemption requests from investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. As a result, we reclassified the securities in the Columbia Fund from cash equivalents to short-term marketable securities as the Columbia Fund was no longer expected to have a maturity of less than 90 days. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 96% of its carrying value. This determination of the fair value of our holdings in the Columbia Fund requires significant judgment or estimation. As discussed in Note 4, certain of these securities were valued primarily using broker pricing models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity. The Columbia Fund is being liquidated during calendar 2008 and through the next twelve months. Since December 6, 2007 and through October 31, 2008, we have received disbursements of approximately \$34.2 million from the Columbia Fund with the most recent disbursement occurring on October 30, 2008 at approximately 93% of its original value. We expect conditions in the credit markets to remain uncertain for the foreseeable future. While it is our intent to liquidate securities in the Columbia Fund in future periods to reduce our exposure to future deterioration of these securities, we believe that operating results or cash flows could be affected significantly by fair value adjustments to the Columbia Fund. There can be no assurance that we will not have to take additional losses on the Columbia Fund. In June 2008, we entered into a revolving line of credit facility with Blue Ridge Investments, L.L.C. to serve as a contingent financing facility. We are able to borrow up to a maximum of \$20 million or 95% of the fair value of the Columbia Fund. As of September 30, 2008, we had the availability to borrow \$15.0 million under the line of credit. The credit facility is secured by a first priority security interest in our holdings in the Columbia Fund, and amounts available under the credit facility will be reduced by any cash distributions made on the Columbia Fund. As a result, we have segregated the marketable securities held in the Columbia Fund as restricted securities while the credit facility is in place.

We own patents, trademarks, trade secrets, copyrights and other intellectual property and know-how that we believe gives us a competitive advantage. If we cannot protect our intellectual property and develop or otherwise acquire additional intellectual property, competition could force us to lower our prices, which could hurt our profitability.

Our intellectual property rights are and will continue to be a critical component of our success. A substantial portion of our intellectual property rights relating to the AB5000, BVS 5000, Impella products, AbioCor, AbioCor II and other products under development is in the form of trade secrets, rather than patents. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot assure you that consultants, employees, and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge, that we will have adequate remedies for any such breach, or that our trade secrets will not become known to or be independently developed by our competitors. The loss of trade secret protection for technologies or know-how relating to our product portfolio and products under development could adversely affect our business and our prospects.

Our business position also depends in part on our ability to maintain and defend our existing patents and obtain, maintain, and defend additional patents and other intellectual property rights. We intend to seek additional patents, but our pending and future patent applications may not be approved, may not give us a competitive advantage, could be challenged by others, or if issued, could be deemed invalid or unenforceable. Patent prosecution, related proceedings, and litigation in the U.S. and in other countries may be expensive, time consuming and ultimately unsuccessful. In addition, patents issued by foreign countries may afford less protection than is available under U.S. patent law and may not adequately protect our proprietary information. Our competitors may independently develop proprietary technologies and processes that are the same as or substantially equivalent to ours or design around our patents. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect our business and our prospects.

Companies in the medical device industry typically obtain patents and frequently engage in substantial intellectual property litigation. Our products and technologies could infringe on the rights of others. If a third party successfully asserts a claim for infringement against us, we may be liable for substantial damages, be unable to sell products using that technology, or have to seek a license or redesign the related product. These alternatives may be uneconomical or impossible. Intellectual property litigation could be costly, result in product development delays and divert the efforts and attention of management from our business.

#### PART II OTHER INFORMATION (continued)

#### Item 1A. <u>Risk Factors continued</u>

#### Product liability claims could damage our reputation and hurt our financial results.

The clinical use of medical products, even after regulatory approval, poses an inherent risk of product liability claims. We maintain limited product liability insurance coverage, subject to deductibles and exclusions. We cannot be sure that product liability insurance will be available in the future or will be available on acceptable terms or at reasonable costs, or that such insurance will provide us with adequate coverage against potential liabilities. Claims against us, regardless of their merit or potential outcome, may also hurt our ability to obtain physician endorsement of our products or expand our business. As we continue to introduce more products, we face an increased risk that a product liability claim will be brought against us.

Many of our products are designed for patients who suffer from late-stage or end-stage heart failure, and many of these patients do not survive, even when supported by our products. There are many factors beyond our control that could result in patient death, including the condition of the patient prior to use of the product, the skill and reliability of physicians and hospital personnel using and monitoring the product, and product maintenance by customers. However, the failure of the products we distribute for clinical testing or sale could give rise to product liability claims and negative publicity.

The risk of product liability claims will increase as we sell more products that are intended to support a patient until the end of life. The finite life of our products, as well as complications associated with their use, could give rise to product liability claims whether or not the products have extended or improved the quality of a patient s life. For example, the AbioCor will have a finite life and could cause unintended complications to other organs and may not be able to support all patients successfully. Its malfunction could give rise to product liability claims whether or not it has extended or improved the quality of the patient s life. If we have to pay product liability claims in excess of our insurance coverage, our financial condition will be adversely affected.

#### Future milestone payments relating to our acquisition of Impella could harm our financial position or result in dilution

We may be required to make an additional contingent payment of up to \$5.6 million under the terms of our acquisition of Impella, based on our future stock price performance and milestones related to FDA approval of Impella s products. This contingent payment may be made at our option with cash or a combination of cash and stock, with at least \$1.8 million of such contingent payment being paid in cash. If we pay any part of the milestone payment in shares of our common stock, our stockholders may experience dilution. Our financial resources will be diminished by the amount of cash we use to make any such payment and, as a result, we may be unable to pursue other activities, such as research and development, the expansion of our sales force or the acquisition of other new products

#### Our investment in WorldHeart Corporation is subject to risk.

In fiscal 2008, we invested \$5.0 million in WorldHeart in the form of a convertible note and warrant. On July 31, 2008, our investment in WorldHeart was converted to 86,000,000 shares of WorldHeart s common stock, which represents approximately 21.6% of WorldHeart s outstanding shares. Following a reverse stock split that WorldHeart completed in October 2008, we now hold 2,866,666 shares of WorldHeart. Our investment in WorldHeart is subject to a number of risks and uncertainties. WorldHeart currently is not profitable and has limited financial resources and we may lose some or all of our investment. In addition, applicable securities law restrictions and low trading volumes may result in an inability to liquidate our WorldHeart investment.

# If we are not able to attract and retain key management, financial and scientific personnel and advisors, we may not successfully achieve our business objectives.

The growth of our business and our success depends in large part on our ability to attract and retain key management, finance and research and development personnel. Our key personnel include our senior officers, many of whom have very specialized scientific, medical or operational knowledge. On October 1, 2008, we accepted the resignation of our chief financial officer. Our corporate controller is performing the functions of principal financial officer and principal accounting officer on an interim basis as we search for a permanent replacement. The loss of the service of any of the key members of our senior management team may significantly delay or prevent our achievement of our business objectives. Our ability to attract and retain qualified personnel, consultants and advisors is critical to our success. We face intense competition

for qualified individuals from numerous medical devices and life sciences companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would have an adverse effect on our business.

We must comply with healthcare fraud and abuse laws, and we could face substantial penalties for non-compliance and be excluded from government healthcare programs, which would adversely affect our business, financial condition and results of operations.

Our business is regulated by laws pertaining to healthcare fraud and abuse, including:

the Federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the furnishing, recommending, or arranging for, a good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid; and

state law equivalents to the Anti-Kickback Statute, which may not be limited to government-reimbursed items. We have various arrangements with customers that may implicate these laws. For example, some physicians who use our products also provide medical advisory and other consulting and personal services. Some of these physician arrangements may not meet Anti-Kickback Statute safe harbor requirements, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws. Additionally, we do not maintain a formal compliance plan concerning interactions with healthcare professionals nor have we formally adopted the recommendations issued by the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG. The OIG may interpret the absence of such formal plan negatively in the case of an enforcement action, which could result in a material adverse effect on our financial condition and results of operations. Further, the absence of a formal compliance plan causes us to be out of compliance with certain state laws such as in Nevada and California that require drug and device companies to have formal compliance plans.

#### PART II OTHER INFORMATION (continued)

#### Item 1A. **Risk Factors continued**

If our operations are found to be in violation of any of these or similar laws or regulations, we or our officers may face significant civil and criminal penalties, damages, fines, imprisonment and exclusion from the Medicare and Medicaid programs. Any violations may lead to curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention from the operation of our business and damage our reputation. If enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action. Similarly, if the physicians or other providers or entities with whom we do business are found not to comply with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

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

None

Item 3. **Defaults Upon Senior Securities** 

None

#### Item 4. Submission of Matters to a Vote of Security Holders

We held our annual meeting of stockholders on August 13, 2008. At the meeting, our stockholders elected Ronald W. Dollens, Desmond H. O Connell, Jr. and Dorothy E. Puhy to serve as Class I directors for three-year terms. In addition, the terms of office of our other directors, Dr. W. Gerald Austen, Louis E. Lataif, Michael R. Minogue, Dr. Eric A. Rose, Martin P. Sutter and Henri A. Termeer continued after our annual meeting of stockholders. Our stockholders also voted to approve our 2008 Stock Incentive Plan and 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, 2009.

The votes cast to elect our Class I directors were:

<b>Director</b> Ronald W. Dollens	<b>Votes For</b> 25,022,948	Votes Withheld 666,857
Desmond H. O Connell, Jr.	25,535,469	154,336
Dorothy E. Puhy	25,538,599	151,206

The votes cast to approve our 2008 Stock Incentive Plan were:

For:	Against:	Abstain:			
14,266,963	3,009,174	155,398			
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, 2009 were:					

For:	Against:
25,572,673	50,969

**Abstain:** 66,163

### Item 5. <u>Other Information</u>

On November 5, 2008, we agreed to extend the exercise period of the vested stock options held by our former chief financial officer from three months to twelve months from his date of departure.

Item 6. <u>Exhibits</u>

#### EXHIBIT INDEX

#### Filed with

		This			
Exhibit No.	Description	Form 10-Q	Form	Incorporated by Reference Filing Date	Exhibit No.
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 <b>-</b> K	May 27, 2004	3.2
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock.		S-3	September 29, 1997	3.3
3.4	Amendment to the Company s Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000.		8-K	March 21, 2007	3.4
4.1	Specimen Certificate of common stock.		S-1	June 5, 1987	4.1
10.1	Amendment No. 1 to Recapitalization Agreement dated June 31, 2008 by and among World Heart Corporation, World Heart Inc., ABIOMED, Inc., Venrock Partners V, L.P., Venrock Associates V, L.P. and Venrock Entrepreneurs Fund V, L.P., Special Situations Fund III QP LP, Special Situations Cayman Fund, L.P., Special Situations Private Equity Fund, L.P., Special Situations Life Sciences Fund, L.P., Austin Marxe and New Leaf Ventures II, L.P		8-К	August 6, 2008	99.1
10.2	Lease Agreement dated as of July 18, 2008 and among Abiomed, Inc., Abiomed Athlone Limited, and J.J. Rhatigan and Co.		8-K	July 30, 2008	10.1
10.3	2008 Stock Inventive Plan.		Schedule 14A	July 9, 2008	Appendix A
10.4*	Form of Non-Statutory Stock Option Agreement for Employees and Consultants under 2008 Stock Incentive Plan.		8-K	August 18, 2008	10.1
10.5*	Form of Non-Statutory Stock Option Agreement for Non-Employee Directors under 2008 Stock Incentive Plan.		8-K	August 18. 2008	10.2
10.6*	Form of Restricted Stock Agreement under 2008 Stock Incentive Plan.		8-K	August 18, 2008	10.3
10.7*	Form of Change of Control Agreement.		8-K	August 18, 2008	10.4
10.8	Underwriting Agreement dated August 18, 2008 between Abiomed, Inc. and Morgan Stanley & Co. Incorporated.		8-K	August 20, 2008	1.1
11.1	Statement regarding computation of Per Share Earnings (see Note 14, Notes to Condensed Consolidated Financial Statements)	Х			
31.1	Rule 13a 14(a)/15d 14(a) certification of principal executive	Х			

Х

- 31.1 Rule 13a 14(a)/15d 14(a) certification of principal executive officer.
- 31.2 Rule 13a 14(a)/15d 14(a) certification of principal accounting officer.

# Table of Contents

32.1 Section 1350 certification. X

\* Management contract or compensatory plan.

#### 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 10, 2008

/s/ Ian W. McLeod Ian W. McLeod Corporate Controller

(Interim Principal Accounting Officer and Interim Principal Financial Officer)