

ABIOMED INC  
Form 10-Q  
February 08, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

\_\_\_\_\_  
**FORM 10-Q**  
\_\_\_\_\_

(Mark One)

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

For the quarterly period ended December 31, 2006

**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)

**04-2743260**  
(IRS Employer

Identification No.)

**22 CHERRY HILL DRIVE**

**DANVERS, MASSACHUSETTS 01923**

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(Address of principal executive offices, including zip code)

(978) 777-5410

(Registrant's telephone number, including area code)

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) or the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

Large accelerated filer  Accelerated Filer  Non-accelerated filer

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

As of February 6, 2007, there were 26,766,455 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 per share data)

	December 31, 2006 (Unaudited)	March 31, 2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 6,081	\$ 7,832
Short-term marketable securities	11,160	23,003
Accounts receivable, net of allowance for doubtful accounts of \$274 at December 31, 2006 and \$211 at March 31, 2006	9,230	8,880
Inventories	6,883	4,868
Prepaid expenses and other current assets	1,640	1,860
Total current assets	34,994	46,443
Property and equipment, net	5,572	4,824
Intangible assets, net	7,613	8,164
Goodwill	26,355	19,106
Total assets	\$ 74,534	\$ 78,537
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,636	\$ 3,070
Accrued expenses	5,786	5,185
Deferred revenue	577	484
Total current liabilities	10,999	8,739
Long-term deferred tax liability	873	310
Accrued costs of acquisition	5,583	
Total liabilities	17,455	9,049
Commitments and contingencies		
Stockholders equity		
Class B Preferred Stock, \$.01 par value		
Authorized 1,000,000 shares; Issued and outstanding none		
Common stock, \$.01 par value	268	265
Authorized 100,000,000 shares;		
Issued 26,775,474 shares at December 31, 2006 and 26,474,270 shares at March 31, 2006;		
Outstanding 26,764,455 shares at December 31, 2006 and 26,468,091 shares at March 31, 2006		
Additional paid-in-capital	221,438	214,666

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Deferred stock-based compensation		(171)	
Accumulated deficit	(164,840)		(143,308)
Treasury stock at cost 11,019 shares at December 31, 2006 and 6,179 shares at March 31, 2006	(116)		(66)
Accumulated other comprehensive income (loss)	329		(1,898)
<b>Total stockholders' equity</b>	<b>57,079</b>		<b>69,488</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 74,534</b>		<b>\$ 78,537</b>

See Accompanying Notes to Condensed Consolidated Financial Statements.

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## ABIOMED, INC. AND SUBSIDIARIES

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(Unaudited)

(in thousands, except per share data)

	<b>Three months ended December 31,</b>		<b>Nine months ended December 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>Revenue:</b>				
Products	\$ 12,823	\$ 10,447	\$ 36,698	\$ 29,605
Funded research and development	81	68	100	269
	12,904	10,515	36,798	29,874
<b>Costs and expenses:</b>				
Cost of product revenue excluding amortization	2,873	3,070	9,281	7,851
Research and development	5,625	4,226	16,329	12,517
Selling, general and administrative	10,917	7,411	31,355	21,558
Expensed in-process research and development			800	13,306
Amortization of intangible assets	373	348	1,243	955
	19,788	15,055	59,008	56,187
Loss from operations	(6,884)	(4,540)	(22,210)	(26,313)
<b>Other income:</b>				
Investment income	240	316	841	876
Foreign exchange gain (loss)	62	(56)	149	(168)
Other income (expense), net	(40)	53	32	91
	262	313	1,022	799
Net loss before provision for income taxes	(6,622)	(4,227)	(21,188)	(25,514)
Provision for income taxes	103	253	344	253
Net loss	\$ (6,725)	\$ (4,480)	\$ (21,532)	\$ (25,767)
Basic and diluted net loss per share	\$ (0.25)	\$ (0.17)	\$ (0.81)	\$ (1.01)
Weighted average shares outstanding	26,712	26,351	26,602	25,447

See Accompanying Notes to Condensed Consolidated Financial Statements.

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## ABIOMED, INC. AND SUBSIDIARIES

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOW**

(Unaudited)

(in thousands)

	<b>Nine months ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
Operating activities:		
Net loss	\$ (21,532)	\$ (25,767)
Adjustments required to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	2,891	2,159
Bad debt expense	84	102
Stock-based compensation	4,652	179
Write-down of inventory	205	269
Deferred tax provision	344	253
Expensed in-process research and development		13,306
Changes in assets and liabilities, net of acquisition		
Accounts receivable	(7)	775
Inventories	(2,416)	(1,429)
Prepaid expenses, other current assets and other assets	399	742
Accounts payable	1,474	75
Accrued expenses	510	17
Deferred revenue	84	256
Net cash used for operating activities	(13,312)	(9,063)
Investing activities:		
Proceeds from the sale and maturity of short-term securities	26,792	36,242
Purchases of short-term securities	(14,949)	(24,293)
Business acquisition, net of cash acquired		(2,562)
Purchase of intangible assets	(50)	(112)
Expenditures for property and equipment	(2,066)	(1,547)
Net cash provided by investing activities	9,727	7,728
Financing activities:		
Proceeds from the exercise of stock options	1,826	1,465
Proceeds from employee stock purchase plan	159	95
Return of common stock from escrow	(50)	(66)
Net cash provided by financing activities	1,935	1,494
Effect of exchange rate changes on cash	(101)	130
Net (decrease) increase in cash and cash equivalents	(1,751)	289
Cash and cash equivalents at beginning of period	7,832	7,618
Cash and cash equivalents at end of period	\$ 6,081	\$ 7,907

See Accompanying Notes to Condensed Consolidated Financial Statements.





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ABIOMED, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

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

Abiomed, Inc. (the Company or Abiomed ) is a leading provider of medical devices that provide circulatory support to acute heart failure patients across the continuum of care in heart recovery. 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 are focused on establishing heart recovery as the standard of care for patients with failing but potentially recoverable hearts. We expect this standard of care 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 accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. These statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company's audited annual financial statements. These audited statements are contained in the Company's shelf registration statement on Form S-3 that has been filed with the SEC on October 2, 2006.

In the opinion of management, the accompanying 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 to summarize fairly the financial position and results of operations as of December 31, 2006 and for the three and nine months then ended. The results of operations for the interim periods may not be indicative of the results that may be expected for the full fiscal year.

On May 10, 2005, the Company acquired all of the shares of outstanding capital stock of Impella CardioSystems AG ( Impella ), a manufacturer of percutaneous cardiovascular support systems headquartered in Aachen, Germany (See Note 9). All significant intercompany accounts and transactions have been eliminated in consolidation.

Certain prior year amounts have been reclassified to conform with the current year presentation. Specifically, amortization of intangibles has been shown separately in the statement of operations in fiscal 2007 versus prior year presentation of reflecting intangibles amortization in research and development and selling, general and administrative expenses to more clearly reflect the amortization impact on the financial statements. Reclassifications have also been made to the Company's statements of cash flow to conform to current year presentation with respect to the inclusion in depreciation and amortization the amount of amortization expense recorded for inventory used for demonstration purposes.

***2. Significant Accounting Policies***

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimated or assumed. The more significant estimates reflected in these financial statements include collectibility of accounts receivable, inventory valuation and accrued expenses.

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### ***Significant Accounting Policies (continued)***

#### ***Goodwill***

The Company periodically evaluates goodwill for impairment using forecasts of discounted future cash flows. Estimates of future cash flows require assumptions related to revenue and operating income growth, asset-related expenditures, working capital levels and other factors. Different assumptions from those made in the analysis could materially affect projected cash flows and the evaluation of goodwill for impairment. Should the fair value of our goodwill decline because of reduced operating performance, market declines, delays in regulatory approval, or other indicators of impairment, or as a result of changes in the discount rate, charges for impairment of goodwill may be necessary. The Company performed its annual impairment review for fiscal 2007 as of October 31, 2006 and determined that goodwill was not impaired. The carrying amount of goodwill at December 31, 2006 was \$26.4 million.

#### ***3. Accounting for Stock-Based Compensation***

In December 2004, the FASB issued SFAS No. 123(R), *Share-based Payment*. SFAS No. 123(R) requires compensation costs related to share-based transactions, including employee share options, to be recognized in the financial statements based on the grant-date fair value.

Effective April 1, 2006, the Company adopted the provisions of SFAS No. 123(R) using the modified prospective application transition method. Under this transition method, the compensation cost recognized beginning April 1, 2006 includes compensation cost for (i) all share-based payments granted prior to, but not yet vested as of April 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (ii) all share-based payments granted subsequent to March 31, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123(R). Compensation cost is recognized on a straight-line basis over the requisite vesting period for those stock options issued subsequent to the adoption of SFAS No. 123(R). For stock options issued prior to the adoption of SFAS No. 123(R), the accelerated method is used for expense recognition.

Prior to April 1, 2006, the Company accounted for stock-based compensation in accordance with the provisions of APB No. 25. The Company elected to follow the disclosure-only alternative requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, the Company did not recognize the compensation expense for the issuance of options with fixed exercise prices at least equal to the fair market value at the date of the grant. The modified prospective transition method of SFAS No. 123(R) requires the presentation of pro forma net income (loss) and net income (loss) per share as if the Company had accounted for its stock plans under the fair value method of SFAS No. 123 for periods presented prior to the adoption of SFAS No. 123(R).

**Table of Contents****3. Accounting for Stock-Based Compensation (continued)**

In the process of adopting SFAS No. 123(R), the Company determined that the historical estimated forfeiture rates used in the SFAS No. 123 pro forma disclosure in the previously issued financial statements were higher than the Company's actual historical forfeiture rates resulting in an understatement of the Company's pro forma stock compensation expense. The Company has revised its pro forma disclosure for the years ended March 31, 2006, 2005 and 2004. This revision resulted in an increase in pro forma expense and pro forma net loss, from amounts previously reported, in the amount of \$0.6 million and \$1.1 million for the three and nine months ended December 31, 2005 and an increase in net loss per share of \$0.02 and \$0.05 for the three and nine months ended December 31, 2005, respectively, which are reflected in the table below.

	<b>Three months ended December 31, 2005</b>	<b>Nine months ended December 31, 2005</b>
Net loss, as reported	\$ (4,480)	\$ (25,767)
Add: Stock-based employee compensation included in reported net loss	89	179
Deduct: Total stock-based employee compensation determined under fair value based method for all awards	(1,562)	(4,335)
Pro forma net loss	\$ (5,953)	\$ (29,923)
<b>Basic and diluted net loss per share:</b>		
As reported	\$ (0.17)	\$ (1.01)
Pro forma	\$ (0.23)	\$ (1.18)

**Stock Option Plans**

Consistent with the policies and practices of the Company pertaining to stock options, all outstanding stock options of the Company as of December 31, 2006 were granted with an exercise price equal to the fair market value on the date of grant with the exception of 3,557 outstanding options that were granted to certain employees during the fiscal year ended March 31, 2004, with an exercise price of \$0.01 per share. For the options granted at \$0.01 per share and restricted stock granted below fair market value, compensation expense is recognized on a straight-line basis over the vesting period. Outstanding stock options, if not exercised, expire 10 years from the date of grant.

The 1992 Combination Stock Option Plan (as amended, the Combination Plan) was adopted in September 1992 as a combination and amendment of the Company's then outstanding Incentive Stock Option Plan and Nonqualified Plan. A total of 2,670,859 options were awarded from the Combination Plan that ended on May 1, 2002. As of December 31, 2006, 145,700 of these options remain outstanding, fully vested and eligible for future exercise.

**Table of Contents****3. Accounting for Stock-Based Compensation (continued)**

The 1998 Equity Incentive Plan (the Equity Incentive Plan ) was adopted by the Company in August 1998. The Equity Incentive Plan provides for grants of options to key employees, directors, advisors and consultants as either incentive stock options or nonqualified stock options as determined by the Company's Board of Directors. A maximum of 1,000,000 shares of common stock may be awarded under this plan. Options granted under the Equity Incentive Plan are exercisable at such times and subject to such terms as the Board of Directors may specify at the time of each stock option grant. Options outstanding under the Equity Incentive Plan have vesting periods of 3 to 5 years from the date of grant.

The 2000 Stock Incentive Plan (as amended, the 2000 Plan ) was adopted by the Company in August 2000. The 2000 Plan provides for grants of options to key employees, directors, advisors and consultants to the Company or its subsidiaries as either incentive or nonqualified stock options as determined by the Company's Board of Directors. Up to 4,900,000 shares of common stock may be awarded under the 2000 Plan and are exercisable at such times and subject to such terms as the Board of Directors may specify at the time of each stock option grant. Options outstanding under the 2000 Plan generally vest 4 years from the date of grant.

The Company has a nonqualified stock option plan for non-employee directors (the Directors Plan ). The Directors Plan, as amended, was adopted in July 1989 and provides for grants of options to purchase shares of the Company's common stock to non-employee directors of the Company. Options for the purchase of up to 400,000 shares of common stock may be awarded under the Directors Plan. Options outstanding under the Director's Plan have vesting periods of 1 to 5 years from the date of grant.

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model, consistent with the provisions of SFAS No. 123(R), SEC SAB No. 107 *Share-based Payment* and the Company's prior period pro forma disclosure of net loss, including stock-based compensation (determined under a fair value method as prescribed by SFAS No. 123). The fair value of options granted during the three and nine months ended December 31, 2006 and December 31, 2005 were calculated using the following assumptions:

	Three Months Ended December 31		Nine Months Ended December 31	
	2006	2005	2006	2005
Risk-free interest rate	4.58	4.69 %	4.58	5.04 %
Expected volatility	65.00%	74.36%	65.00%	73.00%
Expected option life (years)	6.25	6.96	6.25	7.40

The risk-free interest rate is based on the United States Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on a combination of the historical volatility of our stock and adjustments for factors not reflected in historical volatility that are more indicative of future volatility. By using this combination, the Company is taking into consideration estimates of future volatility that the Company believes will differ from historical volatility as a result of product diversification and the Company's acquisition of Impella. The average expected life was estimated using the simplified method for determining the expected term as prescribed by the SEC's Staff Accounting Bulletin No. 107. 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 dividends and does not expect to pay any cash dividends in the foreseeable future.

The weighted average grant-date fair value for options granted during the three and nine months ended December 31, 2006 was \$8.56 and \$8.75 per share, respectively. The weighted average grant date fair value for options granted during the three and nine months ended December 31, 2005 was \$6.46 and \$6.89 per share, respectively.

The application of SFAS No. 123(R) resulted in expense of \$1.4 million and \$4.6 million for the three and nine months ended December 31, 2006 which is recorded within the applicable operating expense where the Company reports the option holders' compensation cost in the condensed consolidated statements of operations. The remaining unrecognized stock-based compensation expense for unvested stock option awards at December 31, 2006 was approximately \$10.2 million, net of forfeitures, and the weighted average time over which this cost will be recognized is 2.0 years. The stock-based compensation expense resulted in a \$0.05 and a \$0.17 decrease in earnings per share for the three and nine months ended December 31, 2006, respectively.

**Table of Contents****3. Accounting for Stock-Based Compensation (continued)**

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 change had no impact on the Company's consolidated statement of cash flows for the nine months ended December 31, 2006.

The following table summarizes the stock option activity for the nine months ended December 31, 2006:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at March 31, 2006	3,962	\$ 10.11		
Granted	1,057	13.54		
Exercised	(287)	7.45		
Cancelled	(261)	11.26		
Outstanding at December 31, 2006	4,471	\$ 11.02	7.27	\$ 15,961
Exercisable at December 31, 2006	1,966	\$ 10.76	5.56	\$ 8,731

The total intrinsic value of options exercised during the three and nine months ended December 31, 2006 was \$0.3 million and \$1.7 million, respectively. The total fair value of stock options which vested during the three and nine months ended December 31, 2006 was \$0.2 million and \$4.5 million, respectively.

**Restricted Stock**

On March 1, 2005, the Company issued a restricted stock grant of 24,000 shares to an officer of the Company, of which 8,000 shares vested on March 1, 2006. The remaining 16,000 shares will vest in 8,000 share increments on March 1, 2007 and 2008, respectively. The restricted stock grant compensation expense is recognized on a straight-line basis over a vesting period of three years. At December 31, 2006, there was \$0.1 million of unrecognized compensation cost related to these restricted shares.

**Employee Stock Purchase Plan**

In March of 1988, the Company adopted the 1988 Employee Stock Purchase Plan ( ESPP ) under which 500,000 shares of common stock were reserved for issuance. Eligible employees may purchase a limited number of shares of the Company's common stock at 85% of the lower of the market value on the offering date or the market value on the purchase date. During the nine months ended December 31, 2006 and December 31, 2005, 14,549 shares of common stock and 11,169 shares of common stock were issued under the ESPP, respectively.

Compensation expense recognized related to the Company's ESPP was \$16,000 and \$39,000 for the three and nine months ended December 31, 2006. The weighted average grant-date fair value of the purchases under the Employee Stock Purchase Plan was \$3.42 per share. The fair value of these purchases was estimated using the Black-Scholes option pricing model with the following assumptions:

Risk-free interest rate	4.79 %
Expected volatility	38.32%
Expected option life (years)	0.50

**Table of Contents****4. Warranties**

The Company routinely accrues for estimated future warranty costs on its product sales at the time of sale. The Company's products are subject to rigorous regulation and quality standards. The following table summarizes the activities of the warranty reserves for the nine months ended December 31, 2006 and 2005 (in thousands):

	Nine months ended December 31,	
	2006	2005
Balance at March 31	\$ 167	\$ 231
Accrual for warranties	84	121
Warranty cost incurred during the period	(42)	(215)
Balance at December 31	\$ 209	\$ 137

**5. Inventories**

Inventories are stated at the lower of cost (first-in, first-out) or market and consist of the following (in thousands):

	December 31, 2006	March 31, 2006
Raw materials and supplies	\$ 3,134	\$ 1,764
Work-in-process	1,318	659
Finished goods	2,431	2,445
Balance at December 31	\$ 6,883	\$ 4,868

All of the Company's inventories relate to circulatory care product lines that include the AB5000, BVS 5000, AbioCor and Impella products. Finished goods and work-in-process inventories consist of direct material, labor and overhead. From time to time, the Company loans finished goods inventory to customers for demonstration purposes. This cost of demo inventory amounted to \$1.2 million at December 31, 2006 and the net carrying value was \$0.5 million. The Company amortizes finished goods that are used for demonstration purposes over a three-year life.

The Company regularly reviews inventory quantities on hand and writes down to its net realizable value any inventory believed to be impaired. If actual demand or market conditions are less favorable than projected demand, additional inventory write-downs may be required that could adversely impact financial results for the period in which the additional excess or obsolete inventory is identified.

**Table of Contents****6. Property and Equipment**

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

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

Depreciation expense related to property and equipment was \$1.4 million and \$1.0 million for the nine months ended December 31, 2006 and 2005, respectively.

Property and equipment consisted of the following (in thousands):

	December 31, 2006	March 31, 2006
Machinery and equipment	\$ 15,141	\$ 12,509
Furniture and fixtures	1,388	1,352
Leasehold improvements	2,619	2,545
Construction in progress	436	987
<b>Total cost</b>	<b>19,584</b>	<b>17,393</b>
Less accumulated depreciation	(14,012)	(12,569)
	<b>\$ 5,572</b>	<b>\$ 4,824</b>

Certain reclassifications were made to property and equipment and accumulated depreciation as previously reported at March 31, 2006 to accurately reflect balances associated with our Europe facility.

**7. Net Loss Per Common Share**

In accordance with SFAS No. 128, *Earnings Per Share*, basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted average number of dilutive common shares outstanding during the period. Diluted shares outstanding is calculated by adding to the weighted shares outstanding any potential (unissued) shares of common stock from outstanding stock options and warrants based on the treasury stock method. In periods when a net loss is reported, such as the three and nine months ended December 31, 2006 and December 31, 2005, all common stock equivalents are excluded from the calculation because they would have an anti-dilutive effect, meaning the loss per share would be reduced. Therefore, in periods when a loss is reported the calculation of basic and dilutive loss per share results in the same value.

The calculation of diluted weighted average shares outstanding for the three and nine months ended December 31, 2006 and 2005 excludes warrants to purchase up to 400,000 shares of common stock issued in connection with the purchase of intellectual property. Also excluded from the calculation of diluted weighted average shares outstanding for the three and nine months ended December 31, 2006 and 2005 are stock options outstanding in the amount of 4,471,277 and 3,964,129, respectively and unvested shares of restricted stock in the amount of 16,000 shares and 24,000 shares, respectively.

**8. Marketable Securities**

The Company classifies any security with a maturity date of greater than 90 days at the time of purchase as marketable securities. In accordance with SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, securities that the Company has the positive intent and ability to hold to maturity are reported at amortized cost and classified as held-to-maturity securities. At December 31, 2006, the held-to-maturity investment portfolio consisted primarily of government securities and corporate bonds with maturities of one year or less.





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The amortized cost including interest receivable approximates market value of held-to-maturity short-term marketable securities and was approximately \$16.9 million and \$10.2 million at March 31, 2006 and December 31, 2006, respectively.

The Company has classified the portion of its investment portfolio consisting of corporate asset-backed securities as available-for-sale securities. The cost of these securities approximates market value and was \$6.1 million and \$1.0 million at March 31, 2006 and December 31, 2006, respectively. Principal payments of these available-for-sale securities are typically made on an expected pre-determined basis rather than on the longer contractual maturity date.

### ***9. Acquisition***

In May 2005, the Company acquired all of the shares of outstanding capital stock of Impella CardioSystems AG ( Impella ). The acquisition of Impella was accounted for under the purchase method of accounting and the results of operations of Impella have been included in the consolidated results of the Company from the acquisition date. The aggregate initial purchase price was approximately \$45.1 million, which consisted of \$42.2 million of the Company's 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 Company issued 4,029,004 shares of common stock, the fair value of which was based upon a five-day average of the closing price two days before and two days after the terms of the acquisition were agreed to and publicly announced.

In addition, the purchase agreement for the acquisition of Impella provides that the Company may be required to make additional contingent payments to Impella's former shareholders based on both the Company's future stock price performance and milestones related to FDA approvals and unit sales of Impella products.

The contingent payment based on stock price performance as of the 18-month anniversary of the closing date was not required to be paid as the average of the daily volume weighted average price per share of Abiomed's common stock for the 20 trading days prior to November 10, 2006 was below \$15.00.

The Company also agreed, subject to certain exceptions based on future stock price performance described below, to make additional payments of up to \$16.75 million based on the following milestones:

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

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

upon the sale of 1,000 units of Impella's products worldwide between the closing and December 31, 2007, a payment of \$5,583,334.

These milestone payments may be made, at the Company's option, by a combination of cash or stock, except that no more than an aggregate of \$15 million of these milestone payments may be made in the form of stock. If any contingent payments are made, they will result in an increase in the carrying value of goodwill. The Company reached the 1,000 unit milestone in the third quarter of fiscal 2007. The Company accounted for this contingent milestone by increasing goodwill and recording a liability at December 31, 2006 for \$5.6 million. The Company expects to issue approximately 403,000 shares of common stock during the fourth quarter of fiscal 2007 to satisfy this milestone obligation of \$5.6 million.

The foregoing notwithstanding, if the average market price per share of Abiomed's common stock, as determined in accordance with the purchase agreement, as of the date that any of the milestones is achieved is \$22 or more, no additional contingent consideration will be required with respect to that milestone. If the average market price is between \$18 and \$22 on the date of the Company's achievement of a milestone, the relevant milestone payment will be reduced ratably.

**Table of Contents****9. Acquisition (Continued)**

The following represents the pro forma results of the ongoing operations for Abiomed and Impella as though the acquisition of Impella had occurred on April 1, 2005, (in thousands, except per share data). The pro forma information, however, is not necessarily indicative of the results that would have resulted had the acquisition occurred on that date.

	<b>Nine months ended December 31, 2005</b>
Revenues	\$ 30,040
Net loss	\$ (15,621)
Net loss per common share (basic and diluted)	\$ (0.60)

**10. Intangible Assets and Goodwill**

The carrying amount of goodwill was \$26.4 million at December 31, 2006 and was recorded in connection with the Company's acquisition of Impella. As part of the Impella acquisition in May of 2005, the Company recorded tax-deductible goodwill amounting to \$15.5 million. As discussed in Note 9, goodwill was increased during the third fiscal quarter of 2007 by \$5.6 million in connection with the Impella 1,000 unit milestone obligation. This increase to goodwill will be tax-deductible once shares of common stock are issued in the fourth quarter. Additional changes in goodwill as compared to March 31, 2006 reflect the fluctuation in foreign currency.

The Company's intangible assets in the accompanying consolidated balance sheets are detailed as follows, each with a weighted average amortization period of seven years (in thousands):

	<b>December 31, 2006</b>		<b>March 31, 2006</b>	
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>
Patents	\$ 7,544	\$ 2,407	\$ 6,990	\$ 1,564
Trademarks and tradenames	438	159	407	109
Distribution agreements	648	154	754	99
Acquired technology	2,235	532	2,054	269
	<b>\$ 10,865</b>	<b>\$ 3,252</b>	<b>\$ 10,205</b>	<b>\$ 2,041</b>

**11. Research and Development**

Research and development costs are expensed when incurred and include direct materials and labor, depreciation, contracted services and other costs associated with developing and testing of new products and significant enhancements to existing products. Research and development costs consist of the following amounts (in thousands):

	<b>Three months ended December 31,</b>		<b>Nine months ended December 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Internally funded	\$ 5,580	\$ 4,128	\$ 16,251	\$ 12,336
Incurred under government contracts and grants	45	98	78	181
<b>Total research and development expense</b>	<b>\$ 5,625</b>	<b>\$ 4,226</b>	<b>\$ 16,329</b>	<b>\$ 12,517</b>

**Table of Contents*****12. Expensed In-Process Research and Development***

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

The Company recorded a \$13.3 million non-cash charge to in-process research and development expense during the quarter ended June 30, 2005 in connection with the Company's acquisition of Impella on May 10, 2005. This charge relates to costs to acquire in-process research and development projects and technologies, which have not reached technological feasibility at the date of the business acquisition and have no alternative future use, and are expensed as incurred.

***13. Comprehensive Loss***

Comprehensive loss details follow (in thousands):

	<b>Three months ended December 31,</b>		<b>Nine months ended December 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Net loss	\$ (6,725)	\$ (4,480)	\$ (21,532)	\$ (25,767)
Other comprehensive loss:				
Foreign currency translation adjustments	940	(537)	2,227	(2,582)
Comprehensive loss	\$ (5,785)	\$ (5,017)	\$ (19,305)	\$ (28,349)

***14. Income Taxes***

As a result of the adoption of SFAS No. 142, Goodwill and Other Intangible Assets ( SFAS No. 142 ) and the acquisition of Impella, the Company has recorded a valuation allowance in excess of its net deferred tax assets to the extent the difference between the book and tax basis of indefinite lived intangible assets is not expected to reverse during the net operating loss carryforward period.

As of December 31, 2006, the Company has accumulated a net deferred tax liability in the amount of \$0.9 million which is primarily the result of a difference in accounting for the Company's goodwill which is amortized over 15 years for tax purposes but not amortized for book purposes, in accordance with SFAS No. 142. The net deferred tax liability cannot be offset against the Company's deferred tax assets under U.S. generally accepted accounting principles since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period. For the three and nine months ended December 31, 2006, the Company has recorded a deferred tax provision relating to amortization of goodwill for tax purposes in the amount of \$0.1 million and \$0.3 million, respectively. For both the three and nine months ended December 31, 2005, the Company recorded a deferred tax provision relating to amortization of goodwill in the amount of \$0.3 million.

**Table of Contents****15. Segment and Enterprise Wide Disclosures**

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, requires certain financial and supplementary information to be disclosed on an annual and interim basis for each reportable segment of an enterprise. The Company operates in one business segment—the research, development and sale of medical devices to assist or replace the pumping function of the failing heart. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results. Approximately 48% of the Company's total consolidated assets are located within the United States as of December 31, 2006. Remaining assets are located in Europe, related to our Impella production facility, and include goodwill of \$26.4 million at December 31, 2006 associated with the Impella acquisition from May 2005 as discussed in Note 9. Total assets in Europe excluding goodwill were \$12.5 million at December 31, 2006 and amounted to 17% of total consolidated assets. International sales (sales outside the United States) accounted for 12% and 11% of total product revenue during the three months ended December 31, 2006 and 2005, respectively. For the nine months ended December 31, 2006 and 2005, international sales accounted for 11% and 14% of total product revenue, respectively.

**16. Commitments and Contingencies**

The Company's acquisition of Impella provides that Abiomed may be required to make additional contingent payments to Impella's former shareholders (see Note 9). As described in Note 9, the Company has accrued \$5.6 million related to the sale of 1,000 Impella units since the date of acquisition. The Company may make additional contingent payments to Impella's former shareholders based on additional milestones related to FDA approvals in the amount of up to \$11.2 million. These contingent payments may be made in a combination of cash or stock under circumstances described in the purchase agreement.

On May 15, 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a Demand for Arbitration (subsequently amended) with the Boston office of the American Arbitration Association. The claim seeks 600,000 unrestricted shares of Abiomed common stock for an alleged breach of our obligation to fund development of the Penn State Heart program and an alleged cancellation of the Penn State Heart development project. The Company instituted a legal action in Federal Court to determine the arbitrability of the claims asserted and the Federal Court has stayed the arbitration of a portion of the claim. Arbitration has commenced and the Company continues to vigorously defend against the claims asserted. The Company has applied the concepts of SFAS No. 5 *Accounting for Contingencies*, and has determined that no accrual is warranted.

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

The Company enters into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. Abiomed has never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of December 31, 2006.

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

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***17. New Accounting Pronouncements***

In June 2006, the Financial Accounting Standards Board ( FASB ) released FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the Company has taken or expects to take on a tax return. Under FIN 48, the financial statements will reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without discounting for the time value of money. FIN 48 also revises disclosure requirements and introduces a prescriptive, annual, tabular roll-forward of the unrecognized tax benefits. FIN 48 will become effective with the Company's fiscal year beginning April 1, 2008. The Company is assessing the impact of FIN 48, but does not expect that this standard will have a material impact on its financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB No. 108). SAB No. 108 provides guidance regarding the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of materiality assessments. The method established by SAB No. 108 requires each of our financial statements and the related financial statement disclosures to be considered when quantifying and assessing the materiality of the misstatement. The provisions of SAB No. 108 are effective for the fiscal year ending March 31, 2007. The Company does not expect SAB No. 108 to have a material impact on its financial statements.

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

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ABIOMED, INC. AND SUBSIDIARIES

PART 1. FINANCIAL INFORMATION (continued)

ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS

OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

**FORWARD LOOKING STATEMENTS**

*Abiomed's discussion of financial condition and results of operations may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Our actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, anticipated future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, market acceptance of our new products, technological change, government regulation, future capital needs and uncertainty of additional financing and other risks detailed in the Company's filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this Report. In particular, we encourage you to review the risks and uncertainties discussed under Part II, Item 1A, Risk Factors. The Company undertakes no obligation to publicly release 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 that provide circulatory support to acute heart failure patients across the continuum of care in heart recovery. 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 are currently the only company with commercially available cardiac assist devices approved for heart recovery by the Food and Drug Administration, or FDA, and our products have been used to treat over 10,000 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 pre-shock, or less-severe, patients in the cardiac catheterization lab, or cath lab. We are focused on establishing heart recovery as the standard of care for patients with failing but potentially recoverable hearts. We expect this standard of care will significantly increase the number of patients able to return home from the hospital with their own hearts. Since 2004, our new executive team has focused our efforts on expanding our product portfolio, and we currently have eight disposable products that are either FDA or CE mark approved, as well as several additional products in development.

*AB 5000 and BVS 5000*

The AB5000 Circulatory Support System provides temporary support for one or both sides of the natural heart in circumstances where the heart has failed, giving the patient's heart the opportunity to rest and potentially recover.

Our AB5000 Circulatory Support System is a heart assist system designed to provide enhanced patient mobility within and between medical centers, to facilitate patient ambulation and to provide enhanced features and ease of use for caregivers. We intend to seek expansion of the current FDA-approved indications for use of the AB5000 in order to allow support of expanded patient populations for longer periods of support.

The BVS 5000 Biventricular Support System can support one or both sides of the failing heart and can be operated with the AB5000 Console. The BVS 5000 Blood Pumps use the same cannula as the AB5000 Ventricle, allowing for seamless transition of devices without requiring an additional surgical procedure. The BVS 5000 is designed to provide short-term support and recovery to the failing heart.

Each of the BVS 5000 and AB5000 systems each consist of a blood pumps, or ventricle, one atrial cannula, one arterial cannula, and a console to operate the ventricle. Each component, other than the console, is a disposable item. Both are capable of assuming the full pumping function of a patient's failing heart, and are designed to provide either univentricular or biventricular support. Both are currently approved by the FDA for temporary use while the patient's heart is allowed to rest, heal and recover. Each console supports a single patient at a time. Customers often initially purchase multiple blood pumps and cannulae for each console and purchase more as needed.

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We derive substantially all of our current revenue from sales of our AB5000 and BVS 5000 systems and related service agreements. The BVS 5000 has been a commercial product for over fourteen years, and we expect that some customers will

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transition to our newer AB5000 system. As a result, we expect that an increase in sales of our AB5000 systems may lead to a decrease in sales of our BVS 5000 systems.

### *Impella*

Our Impella 2.5 and 5.0 catheters are percutaneous micro heart pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. The Impella systems consist of a disposable pump and a reusable console. These devices are primarily designed to provide ventricular support for pre-shock patients requiring hemodynamic stabilization, or suffering from reduced cardiac output and can aid in recovering the hearts of patients suffering from acute myocardial infarction (AMI or heart attack). We have CE Marks for our Impella 2.5, 5.0, RD and LD devices and currently market them throughout Europe and outside the United States. We intend to seek FDA approval to sell certain Impella products in the United States, as well as regulatory approval in other countries, in order to address wider market opportunities for circulatory care.

In preparation for an application for pre-market approval, or PMA, from the FDA, we have begun our pilot clinical trial in the United States for our Impella 2.5. The proposed indication for use is support during high-risk angioplasty as a left ventricular assist device. Angioplasty, performed in the catheterization lab, is the insertion of a catheter-guided balloon and is used to open a narrowed coronary artery. A stent (a wire-mesh tube that expands to hold the artery open) is usually placed at the narrowed section. High-risk angioplasty is defined as a procedure on patients undergoing angioplasty on an unprotected left main coronary artery lesion, or the last patent coronary conduit, and poor cardiac function. In parallel, in December 2006 we submitted for 510(k) clearance of the Impella 2.5. There is no guarantee that we will receive any such 510(k) clearance or PMA approval.

We have begun our pilot clinical trial in the United States for the Impella 5.0. The Impella 5.0 device has been used to treat patients in Europe in need of cardiac support resulting from post-cardiotomy cardiogenic shock, myocarditis, low cardiac output post-acute myocardial infarction, or post-coronary intervention procedures, or as a bridge to other circulatory support devices, including our AB5000 and BVS<sup>®</sup> 5000 Circulatory Support Systems.

### *Intra-Aortic Balloon and iPulse<sup>™</sup> Console*

In December 2006, we announced FDA clearance of our new intra-aortic balloon, or IAB, an easy-to-insert, percutaneous technology designed to enhance blood flow to the heart and other organs for patients with diminished heart function.

To support the IAB, we have also developed a combination console platform, the iPulse, currently under regulatory review at the FDA. The new iPulse console will also support our AB5000 and our BVS 5000 systems, as well as new products that we may introduce in the future. The iPulse is also designed to be compatible with other manufacturers' balloons as well. The new iPulse console will support procedures with associated Medicare reimbursement that extends across four diagnostic related groups.

The IAB extends our clinical and market reach further upstream in acute patient care, including direct usage in the intensive care unit (ICU). The IAB complements our products in the cardiac catheterization (cath) lab and surgical suite, allowing access to more acute patients. Our IAB is inserted percutaneously into a patient's descending aorta and inflates and deflates in counterpulsation to a patient's heart rhythm.

In January 2007, we received CE mark approval for our IAB and iPulse console, and we expect to begin shipping our integrated iPulse console outside the U.S. during the fiscal fourth quarter ending March 31, 2007. We have submitted to the FDA a pre-market approval application (PMA) supplement, but we cannot assure you that we will receive FDA approval.

### *AbioCor*

In September 2006, we received Humanitarian Device Exemption (HDE) approval from the FDA for our AbioCor<sup>®</sup> Implantable Replacement Heart (AbioCor). The AbioCor is the first completely self-contained artificial heart. This technology provides patients with mobility and remote diagnostics. Designed to sustain the body's circulatory system, the AbioCor is intended for end-stage heart failure patients whose other treatment options have been exhausted. Patients with



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advanced age, organ failure or cancer are, in most circumstances, ineligible for a heart transplant and are potential candidates to receive the AbioCor implantable heart. To date, we have not generated revenue from sales of AbioCor. We intend to make the AbioCor available through a controlled roll-out at approximately five to ten heart hospitals in the United States, including qualified clinical trial sites and additional qualified centers once they have completed a comprehensive and rigorous training program which may take six to eight months.

We are also working on the next generation implantable replacement heart, the AbioCor II. Incorporating technology both from Abiomed and Penn State University, the AbioCor II is approximately 30% smaller than the existing AbioCor and is being designed with a goal of five-year reliability.

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**RESULTS OF OPERATIONS**

The unaudited condensed consolidated financial statements presented herein have been prepared in accordance with the instructions to Form 10-Q and do not include all of the information and note disclosures required by generally accepted accounting principles. These statements should be read in conjunction with the consolidated financial statements and notes thereto included in our audited annual financial statements contained in our shelf registration statement on Form S-3 that has been filed with the Securities and Exchange Commission on October 2, 2006.

**THREE AND NINE MONTHS ENDED DECEMBER 31, 2006 COMPARED WITH THREE AND NINE MONTHS  
ENDED DECEMBER 31, 2005**

**PRODUCT REVENUES**

Product revenues for the three months ended December 31, 2006 were \$12.8 million, an increase of \$2.4 million or 23%, compared to \$10.4 million for the three months ended December 31, 2005. The increase during the third quarter of fiscal 2007 compared to the same period of fiscal 2006 was due to increases in sales of our AB5000 and Impella products that offset declines in sales of our BVS products. Comparing the third quarter of fiscal 2007 to the third quarter of fiscal 2006, sales of our AB 5000 platform increased approximately 59%, while sales of our BVS 5000 products declined by approximately 31%. While not a significant contribution in total revenue dollars for the third quarter of fiscal 2007, sales of our Impella products grew approximately 150% during the third quarter of fiscal 2007 compared to the same period of fiscal 2006 and included approximately \$0.5 million of revenue from shipments of Impella products in connection with the commencement of the Impella 2.5 and 5.0 U.S. FDA pilot trials in calendar 2006.

Product revenues for the nine months ended December 31, 2006 were \$36.7 million, an increase of \$7.1 million or 24%, compared to \$29.6 million for the nine months ended December 31, 2005. The increase is due to higher sales of our Impella and AB 5000 products that partially offset declines of sales of our BVS 5000 products during the period. Comparing revenues for the first nine months of fiscal 2007 to the same period of fiscal 2006, sales of our Impella products increased approximately 81% although the Impella products were not a significant contribution in total revenue dollars, sales of our AB 5000 products increased approximately 64%, and sales of our BVS 5000 products declined by approximately 23%.

The increase in revenue for both the three and nine months ended December 31, 2006 as compared to the respective periods ended December 31, 2005 is primarily due to the effects of our strategy to increase global distribution and our ongoing efforts to increase recovery awareness globally in hospitals, open heart centers and transplant centers. Our sales and clinical teams are focused on stimulating demand for our products by educating surgeons and cardiologists about both the clinical benefits of and the increased reimbursement available for our heart recovery products. We expect to continue to increase sales and clinical headcount throughout fiscal 2007 by two to four individuals per quarter and also plan to increase our marketing, service and training personnel and investments to support the efforts of the sales and clinical teams to drive recovery awareness globally.

**COST OF PRODUCT REVENUES**

Cost of product revenues for the three months ended December 31, 2006 was \$2.9 million, representing a decrease of \$0.2 million or 6%, compared to \$3.1 million for the three months ended December 31, 2005. In the third quarter of fiscal 2007, utilization of our German manufacturing capacity was higher than it was in the third quarter of fiscal 2006. Additionally, the lower cost of goods sold from BVS 5000 products offset increased cost of goods sold from AB 5000 products, and our SAP implementation in July of 2006 resulted in improved efficiencies that lowered cost of goods sold during the third quarter of fiscal 2007 compared to the same period of 2006. The aggregate effect of these factors resulted in cost of goods sold during the third quarter of fiscal 2007 being approximately flat with the respective period of the prior year.

Cost of product revenues for the nine months ended December 31, 2006 was \$9.3 million, an increase of \$1.4 million or 18%, compared to \$7.9 million for the nine months ended December 31, 2005. The increase in cost of goods sold year over year is primarily due to the larger volume of Impella and AB5000 products sold in the nine months ended December 31, 2006 as compared to the respective period of the prior fiscal year which was partially offset by lower cost of goods sold from BVS products.

**RESEARCH AND DEVELOPMENT EXPENSES**

Research and development expenses increased by \$1.4 million, or 33%, to \$5.6 million for the three months ended December 31, 2006, from \$4.2 million in the same period of fiscal 2006. Research and development expenses increased by



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\$3.8 million, or 30%, to \$16.3 million for the nine months ended December 31, 2006, from \$12.5 million for the nine months ended December 31, 2005. Research and development expenses included stock compensation expense for the three and nine months ended December 31, 2006 of \$0.4 million and \$1.3 million, respectively. Our increases in product development costs for both the three and nine months ended December 31, 2006 reflect our investments to broaden our circulatory care product portfolio.

### **SELLING, GENERAL AND ADMINISTRATIVE EXPENSES**

Selling, general and administrative expenses were \$10.9 million for the three months ended December 31, 2006, an increase of \$3.5 million or 47%, compared to \$7.4 million for the same period of fiscal 2006. The increase during the third quarter of fiscal 2007 includes a \$1.0 million increase in expenses associated with our increased global distribution, including our sales and clinical headcount that increased 26% as compared to the third quarter of fiscal 2006, and is also due to our increased investments in our Healthcare Solutions and marketing initiatives. The increase is also due to stock-based compensation expense of \$0.9 million included in selling, general and administrative expenses for the third quarter of fiscal 2007, investments associated with our ERP implementation during fiscal 2007 and higher professional fees.

Selling, general and administrative expenses were \$31.4 million for the nine months ended December 31, 2006, an increase of \$9.8 million or 45%, compared to \$21.6 million for the same period of fiscal 2006. The increase during the nine months ended December 31, 2006 is due primarily to increased investments of \$3.8 million associated with our increased sales and clinical headcount, and increased investments in our Healthcare Solutions in marketing programs. Selling, general and administrative expenses for the nine months ended December 31, 2006 also included \$3.1 million of stock-based compensation expense, and investments associated with our ERP implementation, and increased professional fees.

We expect to continue to increase sales and clinical headcount throughout fiscal 2007 by two to four individuals per quarter and also plan to increase our marketing, service and training personnel and investments to support the efforts of the sales and clinical teams to drive recovery awareness globally.

### **EXPENSED IN-PROCESS RESEARCH AND DEVELOPMENT**

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

We recorded a \$13.3 million non-cash charge to in-process research and development expense during the quarter ended June 30, 2005 in connection with our acquisition of Impella on May 10, 2005. This charge relates to costs to acquire in-process research and development projects and technologies, which had not reached technological feasibility at the date of the business acquisition and had no alternative future use, and were expensed as incurred.

### **OTHER INCOME**

Other income consists primarily of interest earned on our cash and investments, foreign exchange effects, and other miscellaneous income. Other income was \$0.3 million for the three months ended December 31, 2006 and for the respective period of fiscal 2006. Other income was \$1.0 million for the nine months ended December 31, 2006, an increase of \$0.2 million, compared to \$0.8 million for the nine months ended December 31, 2005. The year-to-date increase was primarily driven by gains from foreign currency fluctuations.

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### **TAX PROVISION**

Since the acquisition of Impella, we have recorded a valuation allowance in excess of our net deferred tax assets to the extent the difference between the book and tax basis of indefinite-lived intangible assets is not expected to reverse during the net operating loss carryforward period.

As of December 31, 2006, we have accumulated a net deferred tax liability in the amount of \$0.9 million which is primarily the result of a difference in accounting for our goodwill which is amortized over 15 years for tax purposes but not amortized for book purposes. The net deferred tax liability cannot be offset against our deferred tax assets under U.S. generally accepted accounting principles since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period. For the three and nine months ended December 31, 2006, we have recorded a deferred tax provision related to goodwill in the amount of \$0.1 million and \$0.3 million, respectively. Differences between amounts recorded as a deferred tax liability on the balance sheet versus amounts recorded in the statement of operations result from deferred tax adjustments for foreign currency fluctuations.

### **NET LOSS**

During the three months ended December 31, 2006, we incurred a net loss of \$6.7 million, or \$0.25 per share, including the effects of stock-based compensation expense. This compares to a net loss of \$4.5 million, or \$0.17 per share, for the three months ended December 31, 2005. The results for the three months ended December 31, 2006 included total stock-based compensation expense of \$1.4 million, or approximately \$0.05 per share.

During the nine months ended December 31, 2006 we incurred a net loss of \$21.5 million, or \$0.81 per share, including the effects of stock-based compensation expense. This compares to a net loss of \$25.8 million or \$1.01 per share for the nine months ended December 31, 2005. The results for the nine months ended December 31, 2006 included total stock-based compensation expense of \$4.6 million, or approximately \$0.17 per share.

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

### **LIQUIDITY AND CAPITAL RESOURCES**

We have supported our operations primarily with revenues from sales of our BVS, AB5000 and Impella circulatory product lines, government contracts and proceeds from our 2000 equity financing and proceeds from stock option exercises. At December 31, 2006, our cash and investments totaled \$17.2 million, a decrease of \$13.6 million compared to \$30.8 million in cash and investments at March 31, 2006. We expect cash utilization in operations of approximately \$4 to \$5 million for the remainder of fiscal 2007.

During the nine months ended December 31, 2006, cash used by operating activities was \$13.3 million as compared to \$9.1 million during the same period in the prior year. Our net loss of \$21.5 million is the primary cause of our cash use from operations. Our net loss is primarily attributed to increased investments in our global distribution as we continue to drive initiatives to increase recovery awareness as well as our investments in research and development to broaden our circulatory care product portfolio. Our inventories also increased by \$2.4 million from March 31, 2006, reflecting our inventory buildup to support anticipated increases in global demand for our products. Amounts partially offsetting our net loss and inventory build up are increases in accounts payable of \$1.5 million and non-cash positive adjustments of \$4.7 million related to stock-based compensation expense as a result of our adoption of SFAS 123(R), \$2.9 million of depreciation and amortization, and \$0.3 million for changes in our deferred tax liability.

Investing activities for the nine months ended December 31, 2006 provided \$9.7 million, comprised primarily of \$26.8 of proceeds from the sale and maturity of short-term securities offset by purchases of short-term securities of \$14.9 million, and expenditures for property and equipment of \$2.1 million.

Cash provided by financing activities for the nine months ended December 31, 2006 is primarily attributed to the exercise of stock options and proceeds from our ESPP in the amount of \$1.8 million and \$0.2 million, respectively.

We believe that our revenue from product sales together with existing resources will be sufficient to fund our operations during the next twelve months. We may need additional funds for possible strategic acquisitions of businesses or of products or technologies complementary to our business, including their subsequent integration into our operations. We may also need additional funds if we choose to pay potential milestone payments to Impella's former shareholders in cash in accordance with the Impella purchase agreement. If we decide it is desirable to raise additional funds, we may raise such



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funds from time to time through public or private sales of equity or from borrowings, including sales of common stock pursuant to the Shelf Registration Statement we filed with the SEC on Form S-3 in October 2006. Under this shelf registration statement, we may sell up to 7,500,000 shares of common stock in one or more offerings on a delayed or continuous basis. We intend to use the net proceeds from any sale of the securities for building our global distribution, investing in research and development to continue to broaden our portfolio of products across the clinical spectrum of circulatory care, and for general corporate purposes, including, without limitation, making acquisitions of assets, businesses, or securities, share repurchases, capital expenditures, any potential Impella milestone payments, and for working capital.

**CRITICAL ACCOUNTING ESTIMATES**

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our estimates and judgments, including those related to revenue recognition, bad debts, warranty obligations, inventory valuations, income taxes and our recent valuation of the tangible and intangible assets acquired in connection with our acquisition of Impella. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Please refer to the Critical Accounting Estimates section in our audited annual financial statements. These audited statements are contained in our shelf registration statement on Form S-3 that has been filed with the Securities and Exchange Commission on October 2, 2006.

*Stock Options*

In fiscal 2007, in accordance with SFAS No. 123(R) *Share-Based Payment*, we began recording stock-based compensation in our statement of operations based on the fair value method, rather than the intrinsic method. This expense is determined after consideration of several significant judgments and estimates. The fair value of each stock option we granted is estimated using the Black-Scholes option pricing model. Use of a valuation model requires us to make certain assumptions with respect to selected model inputs. The risk-free interest rate is based on the United States Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on a combination of the historical volatility of our stock and adjustments for factors not reflected in historical volatility that are more indicative of future volatility. By using this combination, we are taking into consideration estimates of future volatility that we believe will differ from historical volatility as a result of product diversification and our acquisition of Impella. The average expected life was estimated using the simplified method for determining the expected term as prescribed by the SEC's Staff Accounting Bulletin No. 107 *Share-based Payment*. 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 we do not pay dividends and do not expect to pay any cash dividends in the foreseeable future.

*Goodwill*

We periodically evaluate goodwill for impairment using forecasts of discounted future cash flows. Estimates of future cash flows require assumptions related to revenue and operating income growth, asset-related expenditures, working capital levels and other factors. Different assumptions from those made in our analysis could materially affect projected cash flows and our evaluation of goodwill for impairment. Should the fair value of goodwill decline because of reduced operating performance, market declines, delays in regulatory approval, or other indicators of impairment, or as a result of changes in the discount rate, charges for impairment of goodwill may be necessary. We performed our annual impairment review for fiscal 2007 as of October 31, 2006 and determined that goodwill was not impaired. The carrying amount of goodwill at December 31, 2006 was \$26.4 million.

**Table of Contents****NEW ACCOUNTING PRONOUNCEMENTS**

In June 2006, the Financial Accounting Standards Board ( FASB ) released FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that we have taken or expects to take on a tax return. Under FIN 48, the financial statements will reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without discounting for the time value of money. FIN 48 also revises disclosure requirements and introduces a prescriptive, annual, tabular roll-forward of the unrecognized tax benefits. FIN 48 will become effective with our fiscal year beginning April 1, 2008. We are assessing the impact of FIN 48, but we do not expect that this standard will have a material impact on our financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB No. 108). SAB No. 108 provides guidance regarding the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of materiality assessments. The method established by SAB No. 108 requires each of our financial statements and the related financial statement disclosures to be considered when quantifying and assessing the materiality of the misstatement. The provisions of SAB No. 108 are effective for the fiscal year ending March 31, 2007. We do not expect SAB No. 108 to have a material impact on our financial statements.

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

**CONTRACTUAL OBLIGATIONS AND COMMERCIAL COMMITMENTS**

In May 2005, we acquired all the shares of outstanding capital stock of Impella CardioSystems AG, a company headquartered in Aachen, Germany. As described in Note 9 of our accompanying condensed consolidated financial statements, we have accrued \$5.6 million related to the sale of 1,000 Impella units since the date of acquisition. We expect to issue approximately 403,000 shares of common stock during the fourth quarter of fiscal 2007 to satisfy this milestone obligation of \$5.6 million.

We may make additional contingent payments to Impella's former shareholders based on additional milestones related to FDA approvals in the amount of up to \$11.2 million as discussed in Note 9. These contingent payments may be made in a combination of cash or stock under circumstances described in the purchase agreement and in Note 9.

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

We enter into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of December 31, 2006 and March 31, 2006.

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





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ABIOMED, INC. AND SUBSIDIARIES

PART 1. FINANCIAL INFORMATION (continued)

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURE

ABOUT MARKET RISK

**QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

*Derivative Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments.* We do not participate in derivative financial instruments or other financial instruments for which fair value disclosure would be required under SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, or derivative commodity instruments.

*Primary Market Risk Exposures.* While we do not invest for speculative purposes, we are exposed to market risk related to changes in interest rates. Our guidelines allow for an investment portfolio consisting mainly of U.S. Treasury notes, federal agency obligations, state and municipal bonds and corporate bonds with maturities of one year or less and ratings of at least AA by Moody's or Standard & Poor's. These held-to-maturity securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at December 31, 2006, we believe the decline in fair market value of our investment portfolio would be immaterial. We believe, however, that we have the ability to hold our fixed income investments until maturity and therefore would not expect our operating results or cash flows to be affected by a change in market interest rates on our securities portfolio.

***Currency Exchange Rates***

Our Impella subsidiary's functional currency is the Euro. Therefore, our investment in Impella is sensitive to fluctuations in currency exchange rates. The effect of a change in currency exchange rates on our net investment in international subsidiaries is reflected in the accumulated other comprehensive income (loss) component of stockholders' equity. Had a 10% depreciation in the Euro occurred relative to the U.S. dollar as of December 31, 2006, the result would have been a reduction of stockholders' equity of approximately \$2.9 million.

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ABIOMED, INC. AND SUBSIDIARIES

PART 1. FINANCIAL INFORMATION (continued)

ITEM 4: CONTROLS AND PROCEDURES

**CONTROLS AND PROCEDURES**

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act )) as of the end of the period covered by this quarterly report (the Evaluation Date ). Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of the Evaluation Date, these disclosure controls and procedures are effective to provide reasonable assurance that material information required to be disclosed by us, including our consolidated subsidiaries, in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

**Changes in Internal Controls over Financial Reporting**

During the third quarter of our fiscal year ending March 31, 2007, there were no changes in our internal control over financial reporting identified in connection with the evaluation described above that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. **Legal Proceedings**

On May 15, 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a Demand for Arbitration (subsequently amended) with the Boston office of the American Arbitration Association. The claim seeks 600,000 unrestricted shares of Abiomed common stock for an alleged breach of our obligation to fund development of the Penn State Heart program and an alleged cancellation of the Penn State Heart development project. We instituted a legal action in Federal Court to determine the arbitrability of the claims asserted and the Federal Court has stayed the arbitration of a portion of the claim. Arbitration has commenced and we continue to vigorously defend against the claims asserted.

Item 1A. **Risk Factors**

*An investment in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider these risks as well as the other information we include in our SEC filings, including our consolidated financial statements and the related notes. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties of which we are unaware or that we currently deem immaterial may also adversely affect our business. If any of these risks materializes, the trading price of our common stock could fall and you might lose all or part of your investment.*

*This section includes or refers to forward-looking statements. You should read the explanation of the qualifications and limitations on such forward-looking statements discussed elsewhere in this report.*

***We have not operated at a profit and do not expect to be profitable in the foreseeable future.***

We have had net losses in each of the past three fiscal years and in the nine months ended December 31, 2006. We plan to make large expenditures in fiscal 2007 and subsequent fiscal years for, among other things, the expansion of our global distribution network and ongoing product development, which we expect will result in losses in future periods. These expenditures include costs associated with hiring additional personnel, performing clinical trials, continuing our research and development relating to our products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing. The amount of these expenditures is difficult to forecast accurately, and cost overruns may occur. We also expect that we will need to make significant expenditures to begin to market and manufacture in commercial quantities our Impella products, our IAB, the AbioCor and any other new products for which we may receive regulatory approvals or clearances in the future.

***We may not have sufficient funds to develop and commercialize our new products.***

The development, manufacture and sale of any medical device in the United States and abroad is very expensive. We cannot be sure that we will have the necessary funds to develop and commercialize our new products, or that additional funds will be available on commercially acceptable terms, if at all. If we are unable to obtain the necessary funding to develop and commercialize our products, our business may be adversely affected.

***If we fail to obtain and maintain necessary governmental approvals for our products and indications, we may be unable to market and sell our products in certain jurisdictions.***

Medical devices such as ours are extensively regulated by the FDA in the United States and by other federal, state, local and foreign authorities. Governmental regulations relate to the testing, development, manufacturing, labeling, design, sale, promotion, distribution, importing, exporting and shipping of our products. In the United States, before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we must generally first receive either 510(k) clearance or a premarket approval, or PMA, from the FDA. Both of these processes can be expensive and lengthy and entail significant expenses. The FDA's 510(k) clearance process usually takes from three to 12 months, but it can last longer. The process of obtaining premarket approval is much more costly and uncertain than the 510(k) clearance process. It generally takes from one to three years, or even longer, from the time the PMA application is submitted to the FDA. We cannot assure you that any regulatory clearances or approvals, either foreign or domestic, will be granted on a timely basis, if at all. If we are



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unable to obtain regulatory approvals or clearances for use of our products under development, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of these products could be limited. The FDA may also limit the claims that we can make about our products.

For example, we have recently submitted for 510(k) clearance of our Impella 2.5, and we also plan to pursue premarket approval for each of our Impella 2.5 and Impella 5.0. In addition, we have submitted for premarket approval of our iPulse console. If we do not receive FDA clearance or approval for one of our products, we will be unable to market and sell that product in the United States, which would have a material adverse effect on our operations and prospects.

We intend to market our new products in international markets, including the European Union and Japan. Approval processes differ among those jurisdictions, and approval in the U.S. or any other single jurisdiction does not guarantee approval in any other jurisdiction. Obtaining foreign approvals could involve significant delays, difficulties and costs for us and could require additional clinical trials.

*Our current and planned clinical trials may not begin on time, or at all, and may not be completed on schedule, or at all.*

In order to obtain premarket approval and, in some cases, a 510(k) clearance, we may be required to conduct well-controlled clinical trials designed to test the safety and effectiveness of the product. In order to conduct clinical studies, we must generally receive an investigational device exemption, or IDE, for each device from the FDA. An IDE allows us to use an investigational device in a clinical trial to collect data on safety and effectiveness that will support an application for premarket approval or 510(k) clearance from FDA. We have received IDE approval and are currently conducting pilot clinical trials for each of our Impella 2.5 and Impella 5.0.

Conducting clinical trials is a long, expensive and uncertain process that is subject to delays and failure at any stage. Clinical trials can take months or years to complete. The commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including:

the FDA may not approve a clinical trial protocol or a clinical trial, or may place a clinical trial on hold;

subjects may not enroll in clinical trials at the rate we expect and/or subjects are not followed-up at the rate we expect;

subjects may experience adverse side effects or events related or unrelated to our products;

third-party clinical investigators may not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations may not perform data collection and analysis in a timely or accurate manner;

the interim results of any of our clinical trials may be inconclusive or negative;

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regulatory inspections of our clinical trials or manufacturing facilities may require us to undertake corrective action or suspend or terminate our clinical trials if investigators find us not to be in compliance with regulatory requirements;

our manufacturing process may not produce finished products that conform to design and performance specifications; or

governmental regulations or administrative actions may change and impose new requirements.

The results of pre-clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. A number of companies in the medical industry have suffered delays, cost overruns and project terminations despite achieving promising results in pre-clinical testing or early clinical testing. In addition, the data obtained from clinical trials may be inadequate to support approval or clearance of a submission. The FDA may disagree with our interpretation of the data from our clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate the safety and effectiveness of the product candidate. The FDA may also require us to conduct additional pre-clinical studies or clinical trials, which could further delay approval of our products. If we are unable to receive FDA approval of an IDE to conduct clinical trials or the trials are halted by the FDA or others, or if we are unsuccessful in receiving FDA approval of a product candidate, we would not be able to sell or promote the product candidate in the U.S., which would seriously harm our business. Moreover, we face similar risks in each other jurisdiction in which we sell or propose to sell our products.

If we make modifications to a product, whether in response to results of clinical testing or otherwise, we could be required to start our clinical trials over, which could cause serious delays that would adversely affect our results of operations. Even modest changes to certain components of our products could result in months or years of additional clinical trials.

***If we do not effectively manage our growth, we may be unable to successfully develop, market and sell our products.***

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. Since 2004, we have experienced significant growth in the scope of our operations and the number of our employees, including the addition of our operations in Germany and France. This growth has placed significant demands on our management, as well as our financial and operations resources. In order to achieve our business objectives, we will need to continue to grow. However, continued growth presents numerous challenges, including:

developing our global sales and marketing infrastructure and capabilities;

expanding manufacturing capacity and increasing production;

expansion of foreign regulatory compliance capabilities;

implementing appropriate operational and financial systems and controls;

identifying, attracting and retaining qualified personnel, particularly experienced clinical staff; and

training, managing and supervising our personnel worldwide.

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Any failure to manage our growth effectively could impede our ability to successfully develop, market and sell our products, which could seriously harm our business.

***The markets for most of our products and products under development are unproven, and we may be unable to successfully commercialize our products.***

Our products and products under development may not enjoy commercial acceptance or success, which would adversely affect our business and results of operations. For example, although we recently received HDE approval from the FDA for the AbioCor, we cannot assure you that we will be successful in developing a market for the AbioCor. We need to create markets for our Impella micro heart pumps, AB5000, IAB, iPulse console, AbioCor, AbioCor II and other new products, including achieving market acceptance among physicians, medical centers, patients and third-party payers. The obstacles we will face in trying to create successful commercial markets for our products include:

limitations inherent in first-generation devices, and the potential failure to develop successive improvements, including increases in service life;

the introduction by other companies of new treatments, products and technologies that compete with our products;

the timing and amount of reimbursement for these products, if any, by third-party payers;

the potential reluctance of clinicians to obtain adequate training to use our products;

the lifestyle limitations that patients will have to accept for our AbioCor and AbioCor II products; and

the potential reluctance of physicians, patients and society as a whole to accept medical devices that replace or assist the heart or the finite life and risk of mechanical failure inherent in such devices.

***The commercial success of our products will require acceptance by surgeons and interventional cardiologists, a limited number of whom have significant influence over medical device selection and purchasing decisions.***

We may achieve our business objectives only if our products are accepted and recommended by leading cardiovascular surgeons and interventional cardiologists, whose decisions are likely to be based on a determination by these clinicians that our products are safe and cost-effective and represent acceptable methods of treatment. Although we have developed relationships with leading cardiac surgeons, the commercial success of our Impella products, IAB and iPulse console will require that we also develop relationships with leading interventional cardiologists in cath labs, where we do not yet have a significant presence. We cannot assure you that we can maintain our existing relationships and arrangements or that we can establish new relationships in support of our products. If cardiovascular surgeons and interventional cardiologists do not consider our products to be adequate for the treatment of our target cardiac patient population or if a sufficient number of these clinicians recommend and use competing products, it would seriously harm our business.



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*The training required for clinicians to use our products could reduce the market acceptance of our products and reduce our revenue.*

Clinicians must be trained to use our products proficiently. It is critical to the success of our sales efforts that we ensure that there are a sufficient number of clinicians familiar with, trained on and proficient in the use of our products. Convincing clinicians to dedicate the time and energy necessary to obtain adequate training in the use of our products is challenging, and we may not be successful in these efforts. If clinicians are not properly trained, they may misuse or ineffectively use our products. Any improper use of our products may result in unsatisfactory outcomes, patient injury, negative publicity or lawsuits against us, any of which could harm our reputation and product sales. Furthermore, our inability to educate and train clinicians to use our products may lead to inadequate demand for our products.

*Our products are subject to extensive regulatory requirements, including continuing regulatory review, which could affect the manufacturing and marketing of our products.*

The FDA and other regulatory agencies continue to review products even after they have received initial approval. If and when the FDA or another regulatory agency clears or approves our products under development, the manufacture and marketing of these products will be subject to continuing regulation, including compliance with the FDA's adverse event reporting requirements, prohibitions on promoting a product for unapproved uses, and Quality System Regulation, or QSR, requirements, which obligate manufacturers, including third-party and contract manufacturers, to adhere to stringent design, testing, control, documentation and other quality assurance procedures during the design and manufacture of a device.

Any modification to an FDA-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA may review any such decision. Modifications of this type are common with new products, and we anticipate that the first generation of each of our products will undergo a number of changes, refinements and improvements over time. For example, the current configuration of the AbioCor's thoracic unit, or replacement heart, is sized for patients with relatively large chest cavities, and we anticipate that we will need to obtain regulatory approval of thoracic units of other sizes, such as the AbioCor II. If the FDA requires us to seek clearance or approval for modification of a previously cleared product for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties, which could have a material adverse effect on our financial results and competitive position. We also cannot assure you that we will be successful in obtaining clearances or approvals for our modifications, if required. We and our third-party suppliers of product components are also subject to inspection and market surveillance by the FDA and other regulatory agencies for QSR and other requirements, the interpretation of which can change. Compliance with QSR and similar legal requirements can be difficult and expensive. Enforcement actions resulting from failure to comply with government requirements could result in fines, suspensions of approvals or clearances, recalls or seizure of products, operating restrictions or shutdown, and criminal prosecutions, and could adversely affect the manufacture and marketing of our products. The FDA or another regulatory agency could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements, the occurrence of unanticipated problems with products following approval, or other reasons, which could adversely affect our operating results.

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***Even after receiving regulatory clearance or approval, our products may be subject to product recalls, which may harm our reputation and divert our managerial and financial resources.***

The FDA and similar governmental authorities in other countries have the authority to order mandatory recall of our products or order their removal from the market if the governmental entity finds that our products might cause adverse health consequences or death. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including labeling defects. We have in the past initiated voluntary recalls of some of our products, and we could do so in the future. Any recall of our products may harm our reputation with customers and divert managerial and financial resources.

***Our principal products and current primary source of revenues, the AB5000 and BVS 5000, are vulnerable to competitive pressures.***

To date, we have derived most of our product revenues from sales of the AB5000 and BVS 5000. We believe that we will continue to rely heavily on these products for at least the next several years until we obtain U.S. regulatory approval for new products, including our Impella products and iPulse console. Moreover, we expect to rely increasingly on sales of the AB5000, as sales of the BVS 5000 have been declining. If another company were to introduce new treatments, products or technologies that compete with our products, add new features to its existing products or reduce its prices to make its products more financially attractive to customers, revenue from our AB5000 and BVS 5000 could decline. For example, in the event of the expansion of technologies that allow heart surgical procedures to be performed without stopping the heart, a reduction in the market for these products could result. In addition, variations in the quantity and timing of sales of our AB5000 consoles have a disproportionate effect on our revenues, because the price of the console is substantially greater than the price of our disposable blood pumps. If we cannot maintain and increase our disposable revenues from our AB5000 and BVS 5000, our overall business and financial condition could be adversely affected.

***If we are unable to develop additional, high-quality manufacturing capacity, our growth may be limited and our business could be seriously harmed.***

To be successful, we believe we will need to increase our manufacturing capacity. We do not have experience in manufacturing our Impella products in the commercial quantities that might be required if we receive FDA approval of those products, nor do we have experience manufacturing our AB5000, IAB and AbioCor in large quantities. We may encounter difficulties in scaling up manufacturing of our products, including problems related to product yields, quality control and assurance, component and service availability, adequacy of control policies and procedures, and lack of skilled personnel. If we cannot hire, train and retain enough experienced and capable scientific and technical workers, we may not be able to manufacture sufficient quantities of our current or future products at an acceptable cost and on time, which could limit market acceptance of our products or otherwise damage our business.

***Each of our products is manufactured in a single location, and any significant disruption in production could impair our ability to deliver our products.***

We manufacture our Impella micro heart pumps at our facility in Aachen, Germany, and we manufacture our other products at our facility in Danvers, Massachusetts. Events such as fire, flood, power loss or other disasters could prevent us from manufacturing our products in compliance with applicable FDA and other regulatory requirements, which could result in

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significant delays before we restore production or commence production at another site. These delays may result in lost sales. Our insurance may not be adequate to cover our losses resulting from disasters or other business interruptions. Any significant disruption in the manufacturing of our products could seriously harm our business and results of operations.

*Any failure to achieve and maintain the high manufacturing standards that our products require may seriously harm our business.*

Our products require precise, high quality manufacturing. Achieving precision and quality control requires skill and diligence by our personnel. Our failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, design defects or component failures, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business. We have from time to time voluntarily recalled certain products. Despite our very high manufacturing standards, we cannot completely eliminate the risk of errors, defects or failures. If we are unable to manufacture the AB5000, BVS 5000, Impella products and our iPulse consoles in accordance with necessary quality standards, our business and results of operations may be negatively affected.

Our AbioCor products involve even greater manufacturing complexities than our current commercial products. Our AbioCor products must be significantly more durable and meet different standards, which may be more difficult to achieve, than those that apply to our current products. If we are unable to manufacture our AbioCor products or other future products on a timely basis at acceptable quality and cost, or if we experience unanticipated technological problems or delays in production, our business will suffer.

*We depend on third-party reimbursement to our customers for market acceptance of our products. If third-party payers fail to provide appropriate levels of reimbursement for purchase and use of our products, our sales and profitability would be adversely affected.*

Sales of medical devices largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. The cost of our AB5000 systems, BVS 5000 systems, Impella micro heart pumps and iPulse consoles is substantial, and the cost of implanting the AbioCor in a patient will also be substantial. Without the financial support of government reimbursement for patient care or third-party insurers' payments for patient care, the market for our products will be limited. Medical products and devices incorporating new technologies are closely examined by governments and private insurers to determine whether the products and devices will be covered by reimbursement, and if so, the level of reimbursement which may apply. We cannot be sure that third-party payers will reimburse sales of our Impella products, our iPulse console or our other products under development, or enable us to sell them at profitable prices.

In addition, third-party payers are increasingly requiring evidence that medical devices are cost-effective. If we are unable to meet the standards of a third-party payer, that payer may not reimburse the use of our products, which could reduce sales of our products to health care providers who depend upon reimbursement for payment. We also cannot be sure that third-party payers will continue the current level of reimbursement to physicians and medical centers for use of our AB5000, BVS 5000, Impella products and iPulse consoles. Any reduction in the amount of this reimbursement could harm our business.

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***Changes in health care reimbursement systems in the United States and abroad could reduce our revenues and profitability.***

The federal government has considered ways to change, and has changed, the manner in which health care services are provided and paid for in the U.S. In the future, it is possible that the government may institute price controls and further limits on Medicare and Medicaid spending. These controls and limits could affect the payments we collect from sales of our products. Internationally, medical reimbursement systems vary significantly, with some medical centers having fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we succeed in bringing our new products to market, uncertainties regarding future health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at profitable prices.

***If we cannot attract and retain the management, scientific, sales and other personnel we need, we will not be successful.***

We depend heavily on the contributions of the principal members of our business, financial, technical, sales and support, regulatory and clinical, operating and administrative management and staff, many of whom would be difficult to replace. For example, many of the members of our clinical staff are registered nurses with experience in the surgery suite or cath lab, only a limited number of whom seek employment with a company like ours. Competition for skilled and experienced management, scientific, clinical and sales personnel in the medical devices industry is intense. If we lose the services of any of the principal members of our management and staff, or if we are unable to attract and retain qualified personnel in the future, especially scientific and sales personnel, our business could be adversely affected.

***If our suppliers cannot provide the components we require, our ability to manufacture our products could be harmed.***

We rely on third-party suppliers to provide us with some components used in our existing products and products under development. For example, we outsource the manufacturing of all of our consoles, other than final assembly and testing. Relying on third-party suppliers makes us vulnerable to component part failures and to interruptions in supply, either of which could impair our ability to conduct clinical tests or to ship our products to our customers on a timely basis. Using third-party vendors makes it difficult and sometimes impossible for us to test fully certain components, such as components on circuit boards, maintain quality control, manage inventory and production schedules, and control production costs. Manufacturers of our product components may be required to comply with the FDA or other regulatory manufacturing regulations and to satisfy regulatory inspections in connection with the manufacture of the components. Any failure by a supplier to comply with applicable requirements could lead to a disruption in supply. Vendor lead times to supply us with ordered components vary significantly and can exceed six months or more. Both now and as we expand our manufacturing capacity, we cannot be sure that our suppliers will furnish us with required components when we need them. These factors could make it more difficult for us to effectively and efficiently manufacture our products, and could adversely impact our results of operations.

Some of our suppliers may be the only source for a particular component, which makes us vulnerable to significant cost increases. Sole-source vendors may decide to limit or eliminate sales of certain components to the medical industry due to product liability or other concerns, and we might not be able to find a suitable replacement for those products. Our inventory may run

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out before we find alternative suppliers, and we might be forced to purchase substantial inventory, if available, to last until we qualify an alternate supplier. If we cannot obtain a necessary component, we may need to find, test and obtain regulatory approval or clearance for a replacement component, produce the component ourselves or redesign the related product, which would cause significant delay and could increase our manufacturing costs. Any of these events could adversely impact our results of operations.

*We may not be successful in expanding our sales activities into international markets.*

We are seeking to expand our international sales of the AB5000, BVS 5000 and Impella circulatory assist systems, as well as our iPulse console, by recruiting direct sales and support teams in Germany and France. Our international operations will be subject to a number of risks, which may vary from the risks we experience in the U.S., including:

the need to obtain regulatory approvals in foreign countries before our products may be sold or used;

the need to procure reimbursement for our products in each foreign market;

the generally lower level of reimbursement available in foreign markets relative to the U.S.;

longer sales cycles;

limited protection of intellectual property rights;

difficulty in collecting accounts receivable;

fluctuations in the values of foreign currencies; and

political and economic instability.

If we are unable to effectively expand our sales activities in international markets, our results of operations could be negatively impacted.

*We intend to expand our reliance on distributors in some international markets, and poor performance by a distributor could reduce our sales and harm our business.*

We rely on distributors to market and sell our products in parts of Europe, Asia, South America and Australia. Many of these distributors have the exclusive right to distribute our products in their territory. We may hire distributors to market our products in additional international markets. Our success in these markets will depend almost entirely upon the efforts of our distributors, over whom we have little or no control. If a distributor does not market and sell our products aggressively, we could lose sales and impair our ability to compete in that market.

*Our operating results may fluctuate unpredictably.*

Historically, our annual and quarterly operating results have fluctuated widely, and we expect these fluctuations to continue. Among the factors that may cause our operating results to fluctuate are:

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the timing of customer orders and deliveries, particularly for our consoles, which are substantially more expensive than our disposable products;

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competitive changes, such as price changes or new product introductions that we or our competitors may make;

the timing of regulatory actions, such as product approvals or recalls;

costs we incur developing and testing our Impella micro heart pumps, IAB, iPulse console, AbioCor, AbioCor II and other new products or product enhancements;

costs we incur in anticipation of future sales, such as inventory purchases, expansion of manufacturing facilities, or establishment of international sales offices;

economic conditions in the health care industry; and

efforts by governments, insurance companies and others to contain health care costs, including changes to reimbursement policies.

We believe that period-to-period comparisons of our historical results are not necessarily meaningful, and investors should not rely on them as an indication of our future performance. To the extent we experience the factors described above, our future operating results may not meet the expectations of securities analysts or investors from time to time, which may cause the market price of our common stock to decline.

***Our future success depends in part on the development of new circulatory assist products, and our development efforts may not be successful.***

We are currently devoting our major research and development and regulatory efforts, and significant financial resources, to the development of our Impella micro heart pumps, iPulse console, AbioCor, AbioCor II and product extensions of existing commercial products and new products. The development of new products and product extensions presents enormous challenges in a variety of areas, many or all of which we may have difficulty in overcoming, including blood compatible surfaces, blood compatible flow, manufacturing techniques, pumping mechanisms, physiological control, energy transfer, anatomical fit and surgical techniques. We may be unable to overcome all of these challenges, which could adversely affect our results of operations and prospects.

***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

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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 the AB5000, BVS 5000, Impella products, AbioCor or AbioCor II 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, and could be challenged by others. 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. Finally, 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.

***We may face claims of intellectual property infringement, which could result in significant expenses or the payment of damages or require us to stop selling our products.***

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.

***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



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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. 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.

***Off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.***

The use of our products outside the indications cleared for use, or off-label use, may increase the risk of injury to patients. Clinicians may use our products for off-label uses, as the FDA does not restrict or regulate a clinician's choice of treatment within the practice of medicine. Off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

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

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. If the FDA or another regulatory agency determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion.

***Quality problems can result in substantial costs and write-downs.***

Government regulations require us to track materials used in the manufacture of our products, so that any problem identified in one product can be traced to other products that may have the same problem. An identified quality problem may require reworking or scrapping related inventory and recalling previous shipments. Because a malfunction in our products can be life-threatening, we may be required to recall and replace, free of charge, products already in the marketplace. Any quality problem could cause us to incur significant expenses, lead to significant write-offs, injure our reputation and harm our business and financial results.

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

We may be required to make additional contingent payments of up to \$11.2 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. If we pay any milestone payment in

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shares of our common stock, our stockholders may experience dilution. If we use cash to make any such payment, our financial resources will be diminished and 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.

*If we fail to compete successfully against our existing or potential competitors, our product sales or operating results may be harmed.*

Competition from other companies offering circulatory care products is intense and subject to rapid technological change and evolving industry requirements and standards. We compete with companies that have substantially greater or broader financial, product development, sales and marketing resources and experience than we do. These competitors may develop superior products or products of similar quality at the same or lower prices. Moreover, improvements in current or new technologies may make them technically equivalent or superior to our products in addition to providing cost or other advantages.

Our customers frequently have limited budgets. As a result, our products compete against a broad range of medical devices and other therapies for these limited funds. Our success will depend in large part upon our ability to enhance our existing products, to develop new products to meet regulatory and customer requirements, and to achieve market acceptance. We believe that important competitive factors with respect to the development and commercialization of our products include the relative speed with which we can develop products, establish clinical utility, complete clinical trials and regulatory approval processes, obtain reimbursement, and supply commercial quantities of the product to the market.

Our AB5000 and BVS 5000 systems compete with a temporary cardiac assist device from Thoratec Corporation, which is approved for post-cardiotomy support. In addition, the AB5000 and BVS 5000 compete with other blood pumps, such as intra-aortic balloon pumps (including those offered by Datascope and Arrow International) and centrifugal pumps, that are used in medical centers for a variety of applications. Levitronix is conducting clinical trials in the U.S. for a device that may compete with our current heart assist products in some applications. Levitronix has licensed this product to Thoratec Corporation for distribution in the U.S. The FDA recently approved a product designed by CardiacAssist, Inc. that may compete with our Impella products, and Jarvik Heart is conducting clinical trials for a new ventricular assist device that may compete with our AB5000 and Impella products. Approval by the FDA of products that compete directly with our products would increase competitive pricing and other pressures.

Advances in medical technology, biotechnology and pharmaceuticals may reduce the size of the potential markets for our products or render those products obsolete. We are aware of other heart replacement device research efforts in the U.S., Canada, Europe and Japan. In October 2004, the FDA approved Syncardia Systems' CardioWest Total Artificial Heart for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from non-reversible biventricular failure. In addition, there are a number of companies including Thoratec Corporation, World Heart Corporation, MicroMed Technology, and Ventracor that are developing permanent heart assist products, including implantable left ventricular assist devices and miniaturized rotary ventricular assist devices.

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***If we acquire other companies or businesses, we will be subject to risks that could hurt our business.***

We may pursue acquisitions to obtain complementary businesses, products or technologies. Any such acquisition may not produce the revenues, earnings or business synergies that we anticipate, and an acquired business, product or technology might not perform as we expect. Our management could spend a significant amount of time, effort and money in identifying, pursuing and completing the acquisition. If we complete an acquisition, we may encounter significant difficulties and incur substantial expenses in integrating the operations and personnel of the acquired company into our operations while striving to preserve the goodwill of the acquired company. In particular, we may lose the services of key employees of the acquired company, and we may make changes in management that impair the acquired company's relationships with employees and customers.

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use our stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced. We may be required to capitalize a significant amount of intangibles, including goodwill, which may lead to significant amortization charges. In addition, we may incur significant, one-time write-offs and amortization charges, such as our \$13.3 million write-off of in-process research and development expenses in connection with the Impella acquisition. These amortization charges and write-offs could decrease our future earnings or increase our future losses.

***Fluctuations in foreign currency exchange rates could result in declines in our reported sales and earnings.***

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign currency exchange rates, primarily the Euro. The functional currency of Abiomed Europe is the Euro. At present, we do not hedge our exposure to foreign currency fluctuations. As a result, sales occurring in the future that are denominated in foreign currencies may be translated into U.S. dollars at less favorable rates, resulting in reduced revenues and earnings.

***The market price of our common stock is volatile.***

The market price of our common stock has fluctuated widely and may continue to do so. For example, from December 31, 2005 to December 31, 2006 the price of our stock ranged from a high of \$16.19 per share to a low of \$9.12 per share. Many factors could cause the market price of our common stock to rise and fall. Some of these factors are:

variations in our quarterly results of operations;

the status of regulatory approvals for our products;

the introduction of new products by us or our competitors;

acquisitions or strategic alliances involving us or our competitors;

changes in accounting principles;

changes in health care policy or third-party reimbursement practices;

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changes in estimates of our performance or recommendations by securities analysts;

the hiring or departure of key personnel;

future sales of shares of common stock in the public market; and

market conditions in the industry and the economy as a whole.

In addition, the stock market in general and the market for shares of medical device companies in particular have experienced extreme price and volume fluctuations in recent years. These fluctuations are often unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the market price of our common stock. When the market price of a company's stock drops significantly, stockholders often institute securities class action litigation against that company. Any litigation against us could cause us to incur substantial costs, divert the time and attention of our management and other resources, or otherwise harm our business.

***The sale of additional shares of our common stock, or the exercise of currently outstanding options and warrants to purchase our common stock, could dilute your ownership interest.***

We have issued a substantial number of options and warrants to acquire our common stock, and we expect to continue to issue options to our employees and others. If all currently outstanding stock options and warrants were exercised, you would suffer dilution of your ownership interest. In addition, in connection with our acquisition of Impella CardioSystems in 2005, we may be obligated to make certain milestone payments. These payments may be made in stock, which would also result in a dilution of your ownership interest.

***The sale of material amounts of common stock could encourage short sales by third parties and depress the price of our common stock. As a result, you may lose all or part of your investment.***

The downward pressure on our stock price caused by the sale of a significant number of shares of our common stock, or the perception that such sales could occur, could cause our stock price to decline, thus allowing short sellers of our stock an opportunity to take advantage of any decrease in the value of our stock. The presence of short sellers in our common stock may further depress the price of our common stock.

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

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

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*The market value of our common stock could vary significantly, based on market perceptions of the status of our development efforts.*

The perception of securities analysts regarding our product development efforts could significantly affect our stock price. As a result, the market price of our common stock has and could in the future change substantially when we or our competitors make product announcements. Many factors affecting our stock price are industry related and beyond our control.

*We have not paid and do not expect to pay dividends, and any return on your investment will likely be limited to the value of our common stock.*

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

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

Item 3. Defaults upon Senior Securities  
None

Item 4. Submission of Matters to a Vote of Security Holders  
None

Item 5. Other Information  
None

Item 6. Exhibits

- (2.1) Share Purchase Agreement for the acquisition of Impella Cardio Systems AG, dated April 26, 2005 filed as Exhibit 2.1 to our Form 8-K filed on May 16, 2005.\*
- (3.1) Restated Certificate of Incorporation filed as Exhibit 3.1 to our Registration Statement on Form S-3 (Registration No. 333-36657) (the 1997 Registration Statement ).\*
- (3.2) Restated By-Laws, as amended filed as Exhibit 3.2 to our Annual Report on Form 10-K for the fiscal year ended March 31, 2005.\*
- (3.3) Certificate of Designations of Series A Junior Participating Preferred Stock filed as Exhibit 3.3 to the 1997 Registration Statement.\*
- (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 filed in conjunction with the Company's 2000 definitive proxy statement.\*
- (4.1) Specimen certificate of common stock filed as Exhibit 4.1 to our Registration Statement on Form S-1 (Registration No. 33-14861) (the 1987 Registration Statement ).\*

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- (4.2) Description of Capital Stock (contained in the Restated Certificate of Incorporation filed as Exhibit 3.1 to the 1997 Registration Statement and in the Certificate of Designations of Series A Junior Participating Preferred Stock filed as Exhibit 3.3 to the 1997 Registration Statement).\*

**Table of Contents**Item 6. Exhibits (continued)

- (4.3) Rights Agreement between Abiomed and its transfer agent, as Rights Agent dated as of August 13, 1997 (including Form of Rights Certificate attached thereto as Exhibit A) filed as Exhibit 4 to our Current Report on Form 8-K, dated August 13, 1997.\*
- (10.1) Form of Indemnification Agreement for Directors and Officers filed as Exhibit 10.13 to the 1987 Registration Statement.\*
- (10.2) 1992 Combination Stock Option Plan, as amended filed as Exhibit 10.2 to our Form 10-Q for the fiscal quarter ended September 30, 1997.\* \*\*
- (10.3) 1988 Employee Stock Purchase Plan, as amended filed as Exhibit 10.11 to our Form 10-Q for the quarter ended December 31, 2004.\* \*\*
- (10.4) 1989 Non-Qualified Stock Option Plan for Non-Employee Directors filed as Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended September 30, 1995.\* \*\*
- (10.5) Facility Lease dated January 8, 1999 for the premises at 22 Cherry Hill Drive filed as Exhibit 10 to our Form 10-Q for the fiscal quarter ended December 31, 1998.\*
- (10.6) 1998 Equity Incentive Plan filed as Exhibit 10 to our Form 10-Q/A for the fiscal quarter ended September 30, 1998.\* \*\*
- (10.7) Form of Change of Control Agreement filed as Exhibit 10 to our Form 10-Q for the fiscal quarter ended September 30, 1999.\* \*\*
- (10.8) Schedule related to Change of Control Agreement filed as Exhibit 10 to our Form 10-Q for the fiscal quarter ended September 30, 1999.\* \*\*
- (10.9) 2000 Stock Incentive Plan Agreement, as amended filed as Appendix A to our 2005 Proxy Statement filed on July 15, 2005.\* \*\*
- (10.10) Employment Agreement of Michael R. Minogue dated April 5, 2004 filed as Exhibit 10.10 to our Form 10-Q for the quarter ended June 30, 2004.\* \*\*
- (10.11) Summary of Change to Chief Executive Officer Compensation. as filed as Exhibit 10.11 to our Form 10-Q for the quarter ended June 30, 2006.\* \*\*
- (10.12) Inducement stock option granted to Michael R. Minogue dated April 5, 2004 as filed as Exhibit 10.10 to our Form 10-Q for the quarter ended June 30, 2004.\* \*\*
- (10.13) Registration Rights and Stock Restriction Agreement between Abiomed, Inc. and Stockholders of Impella CardioSystems AG as filed as Exhibit 10.1 to our Form 8-K filed on May 16, 2005.\*
- (10.14) Consulting Agreement between Abiomed, Inc. and Dr. David M. Lederman dated October 17, 2005 as filed as Exhibit 10.1 to our Form 8-K filed on October 21, 2005.\*
- (10.15) Restricted Stock Agreement between Abiomed, Inc. and Michael R. Minogue dated April 28, 2005 as filed as Exhibit 10.15 to our Form 10-Q for the fiscal quarter ended September 30, 2005.\* \*\*
- (10.16) Offer letter with Daniel Sutherby dated December 13, 2005 as filed as Exhibit 10.15 to our Form 10-Q for the fiscal quarter ended December 31, 2005.\* \*\*
- (10.17) Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Directors as filed as Exhibit 10.16 to our Form 10-Q for the fiscal quarter ended December 31, 2005.\* \*\*
- (10.18) Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Employees or Consultants as filed as Exhibit 10.17 to our Form 10-Q for the fiscal quarter ended December 31, 2005.\* \*\*
- (10.19) Summary of Executive Compensation as filed as Exhibit 10.18 to our Form 10-Q for the fiscal quarter ended December 31, 2005.\* \*\*
- (10.20) Summary of Director Compensation as filed as Exhibit 10.19 to our Form 10-Q for the fiscal quarter ended December 31, 2005.\* \*\*





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Item 6. Exhibits (continued)

- (10.21) Form of Employment Agreement, Nondisclosure and Non Competition Agreement as filed as Exhibit 10.20 to our Form 10-K for the fiscal year ended March 31, 2006.\* \*\*
- (10.22) Software License Agreement between Abiomed, Inc. and AnswerThink, Inc. dated November 30, 2005 as filed as Exhibit 10.20 to our Form 10-Q for the fiscal quarter ended December 31, 2005.\*
- (10.23) Consulting Agreement between Abiomed, Inc. and AnswerThink, Inc. dated September 15, 2006.
- (10.24) Distribution Agreement between Abiomed, Inc. and MEDIX Japan, Inc. dated November 4, 2006.
- (11.1) Statement regarding computation of Per Share Earnings see Note 7, Notes to Consolidated Financial Statements.
- (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 financial officer
- (32.1) Section 1350 certification

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\* In accordance with Rule 12b-32 under the Securities Exchange Act of 1934 reference is made to the documents previously filed with the Securities and Exchange Commission, which documents are hereby incorporated by reference.

\*\* Management contract or compensatory plan or arrangement.

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ABIOMED, INC. ABIOMED, INC. AND SUBSIDIARIES

PART II. OTHER INFORMATION

SIGNATURE

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.

Date: February 8, 2007

Abiomed, Inc.

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

Principal Accounting Officer

and Principal Financial Officer