

ABIOMED INC
Form 10-Q
November 04, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-09585

ABIOMED, INC.

(Exact name of registrant as specified in its charter)

DELAWARE 04-2743260
(State or other jurisdiction of (IRS Employer
incorporation or organization) Identification No.)

22 CHERRY HILL DRIVE

DANVERS, MASSACHUSETTS 01923

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(Address of principal executive offices, including zip code)

(978) 646-1400

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

As of October 26, 2016, 43,380,993 shares of the registrant's common stock, \$.01 par value, were outstanding.

ABIOMED, INC. AND SUBSIDIARIES

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NOTE REGARDING COMPANY REFERENCES

Throughout this report on Form 10-Q (the “Report”), “Abiomed, Inc.,” the “Company,” “we,” “us” and “our” refer to ABIOMED, Inc. and its consolidated subsidiaries.

NOTE REGARDING TRADEMARKS

ABIOMED, IMPELLA, IMPELLA CP and IMPELLA RP are trademarks of ABIOMED, Inc., and are registered in the U.S. and certain foreign countries. AB5000, IMPELLA 2.5, IMPELLA 5.0, IMPELLA LD and cVAD REGISTRY are trademarks of ABIOMED, Inc. RECOVER is a trademark of Abiomed Europe GmbH, a subsidiary of ABIOMED, Inc., and is registered in certain foreign countries.

PART 1. FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS
ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except share data)

	September 30, 2016	March 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,709	\$48,231
Short-term marketable securities	178,236	163,822
Accounts receivable, net	46,607	42,821
Inventories	31,491	26,740
Prepaid expenses and other current assets	8,827	6,778
Total current assets	319,870	288,392
Long-term marketable securities	4,004	1,000
Property and equipment, net	50,207	23,184
Goodwill	32,582	33,003
In-process research and development	15,199	15,396
Long-term deferred tax assets, net	48,614	58,534
Other assets	4,422	4,422
Total assets	\$ 474,898	\$423,931
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 14,066	\$9,381
Accrued expenses	28,013	28,382
Deferred revenue	9,103	8,778
Current portion of capital lease obligation	740	—
Total current liabilities	51,922	46,541
Other long-term liabilities	4	220
Contingent consideration	7,749	7,563
Long-term deferred tax liabilities	821	832
Capital lease obligation, net of current portion	15,961	—
Total liabilities	76,457	55,156
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value	—	—
Authorized - 1,000,000 shares; Issued and outstanding - none		
Common stock, \$.01 par value	433	426

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Authorized - 100,000,000 shares; Issued - 44,905,284 shares at September 30, 2016 and 43,973,119 shares at March 31, 2016

Outstanding - 43,333,607 shares at September 30, 2016 and 42,596,228 shares at March 31, 2016

Additional paid in capital	536,859	508,624
Accumulated deficit	(77,290)	(99,075)
Treasury stock at cost - 1,571,677 shares at September 30, 2016 and 1,376,891 shares at March 31, 2016	(46,266)	(26,660)
Accumulated other comprehensive loss	(15,295)	(14,540)
Total stockholders' equity	398,441	368,775
Total liabilities and stockholders' equity	\$ 474,898	\$423,931

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

ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except per share data)

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Product revenue	\$ 102,928	\$ 76,354	\$ 205,917	\$ 149,780
Funded research and development	27	5	33	11
	102,955	76,359	205,950	149,791
Costs and expenses:				
Cost of product revenue	17,309	12,144	32,379	23,012
Research and development	18,052	11,569	33,712	21,779
Selling, general and administrative	53,086	39,829	104,118	77,152
	88,447	63,542	170,209	121,943
Income from operations	14,508	12,817	35,741	27,848
Other income (expense):				
Investment income, net	342	62	611	125
Other (expense) income, net	(114)	87	(191)	140
	228	149	420	265
Income before income taxes	14,736	12,966	36,161	28,113
Income tax provision	5,861	5,231	14,376	11,519
Net income	\$ 8,875	\$ 7,735	\$ 21,785	\$ 16,594
Basic net income per share				
Basic net income per share	\$ 0.21	\$ 0.18	\$ 0.51	\$ 0.40
Basic weighted average shares outstanding	43,129	42,228	42,971	41,963
Diluted net income per share				
Diluted net income per share	\$ 0.20	\$ 0.17	\$ 0.49	\$ 0.37
Diluted weighted average shares outstanding	44,580	44,922	44,493	44,778

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

ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(in thousands)

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2016	2015	2016	2015
Net income	\$8,875	\$7,735	\$21,785	\$16,594
Other comprehensive income (loss):				
Foreign currency translation gains (losses)	812	710	(887)	2,308
Net unrealized gains (losses) on marketable securities	(18)	6	132	16
Other comprehensive income (loss)	794	716	(755)	2,324
Comprehensive income	\$9,669	\$8,451	\$21,030	\$18,918

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

ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	For the Six Months Ended September 30,	
	2016	2015
Operating activities:		
Net income	\$21,785	\$16,594
Adjustments required to reconcile net income to net cash provided by		
operating activities:		
Depreciation expense	2,958	1,352
Bad debt expense	(13)	(18)
Stock-based compensation	18,047	15,592
Write-down of inventory	1,354	952
Excess tax benefit from stock-based awards	(3,631)	(383)
Deferred tax provision	9,777	10,803
Change in fair value of contingent consideration	186	307
Changes in assets and liabilities:		
Accounts receivable	(3,807)	(5,214)
Inventories	(6,284)	(6,855)
Prepaid expenses and other assets	(2,029)	456
Accounts payable	1,906	(1,817)
Accrued expenses and other liabilities	3,157	(2,674)
Deferred revenue	330	(239)
Net cash provided by operating activities	43,736	28,856
Investing activities:		
Purchases of marketable securities	(134,235)	(99,002)
Proceeds from the sale and maturity of marketable securities	116,685	101,453
Purchase of other investment	—	(750)
Purchases of property and equipment	(10,453)	(3,419)
Net cash used for investing activities	(28,003)	(1,718)
Financing activities:		
Proceeds from the exercise of stock options	5,764	7,971
Excess tax benefit from stock-based awards	3,631	383
Taxes paid related to net share settlement of vesting of stock awards	(19,608)	(3,810)
Proceeds from the issuance of stock under employee stock purchase plan	769	451
Principal payments on capital lease obligation	(83)	—
Net cash (used for) provided by financing activities	(9,527)	4,995
Effect of exchange rate changes on cash	272	(113)
Net increase in cash and cash equivalents	6,478	32,020
Cash and cash equivalents at beginning of period	48,231	22,401

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Cash and cash equivalents at end of period	\$54,709	\$54,421
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$560	\$576
Cash paid for interest on capital lease obligation	89	—
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment under capital lease obligation	16,784	—
Property and equipment in accounts payable and accrued expenses	3,810	396

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

ABIOMED, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

(In thousands, except share data)

Note 1. Nature of Business and Basis of Preparation

Abiomed, Inc. (the “Company” or “Abiomed”) is a provider of mechanical circulatory support devices and offers a continuum of care to heart failure patients. The Company develops, manufactures and markets proprietary products that are designed to enable the heart to rest, heal and recover by improving blood flow and/or performing the pumping function of the heart. The Company’s products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists and in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophylactically or emergently before, during or after angioplasty or heart surgery procedures.

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial reporting and in accordance with Article 10 of Regulation S-X. Accordingly, they do not include all of the information and note disclosures required by GAAP for complete financial statements. These statements should be read in conjunction with the consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended March 31, 2016 that has been filed with the Securities and Exchange Commission (the “SEC”).

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which are of a normal recurring nature and are necessary for a fair presentation of results for the interim periods presented. The results of operations for any interim period may not be indicative of results for the full fiscal year or any other subsequent period.

There have been no changes in the Company’s significant accounting policies for the three and six months ended September 30, 2016 as compared to the significant accounting policies described in the Company’s Annual Report on Form 10-K for the fiscal year ended March 31, 2016 that has been filed with the SEC, except as follows:

Leases

Lease agreements are evaluated to determine whether they are capital or operating leases in accordance with ASC 840, Leases. When any one of the four test criteria in ASC 840 is met, the lease then qualifies as a capital lease. Capital leases are capitalized at the lower of the net present value of the total amount payable under the leasing agreement (excluding finance charges) or the fair market value of the leased asset. Capital lease assets are depreciated on a straight-line basis, over a period consistent with the Company’s normal depreciation policy for tangible fixed assets. Interest charges are expensed over the period of the term of the capital lease obligation in relation to the carrying value of the capital lease.

Rent expense for operating leases, which may include free rent or fixed escalation amounts in addition to minimum lease payments, is recognized on a straight-line basis over the duration of each lease term.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, Revenue from Contracts with Customers to provide updated guidance on revenue recognition. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under today’s guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 will become effective for the Company beginning in fiscal 2019 under either full or modified retrospective adoption, with early adoption permitted as of the original effective date of ASU 2014-09. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory, which applies to inventory that is measured using first-in, first-out or average cost methods. Under the updated guidance, an entity should measure inventory that is within scope at the lower of cost and net realizable value, which is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. Subsequent measurement is unchanged for inventory that is measured using last-in, last-out. ASU-2015-11 is effective for annual and interim periods beginning after December 15,

2016, and should be applied prospectively with early adoption permitted at the beginning of an interim or annual reporting period. The Company does not expect the adoption of ASU 2015-11 to have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases. This guidance requires an entity to recognize lease liabilities and a right-of-use asset for all leases on the balance sheet and to disclose key information about the entity's leasing arrangements. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within that reporting period, with earlier adoption permitted. ASU 2016-02 must be adopted using a modified retrospective approach for all leases existing at, or entered into after the date of initial adoption, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of adopting ASU 2016-02 on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, which is intended to simplify several aspects of the accounting for share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2016-09 on its consolidated financial statements.

Note 2. Net Income Per Share

Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted net income per share is computed by dividing net income by the weighted average number of dilutive common shares outstanding during the period. Diluted shares outstanding are calculated by adding to the weighted average shares outstanding any potential dilutive securities outstanding for the period. Potential dilutive securities include stock options, restricted stock units, performance-based stock awards and shares to be purchased under the Company's employee stock purchase plan. In periods when a net loss is reported, all common stock equivalents are excluded from the calculation because they would have an anti-dilutive effect, meaning the loss per share would be reduced. Therefore, in periods when a loss is reported, basic and dilutive loss per share are the same. The Company's basic and diluted net income per share for the three and six months ended September 30, 2016 and 2015 were as follows (in thousands, except per share data):

	For the Three Months Ended September 30, 2016		For the Six Months Ended September 30, 2015	
Basic Net Income Per Share				
Net income	\$ 8,875	\$ 7,735	\$ 21,785	\$ 16,594
Weighted average shares used in computing basic net				
income per share	43,129	42,228	42,971	41,963

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Net income per share - basic	\$ 0.21	\$ 0.18	\$ 0.51	\$ 0.40
	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2016	2015	2016	2015
Diluted Net Income Per Share				
Net income	\$ 8,875	\$ 7,735	\$ 21,785	\$ 16,594
Weighted average shares used in computing basic net				
income per share	43,129	42,228	42,971	41,963
Effect of dilutive securities	1,451	2,694	1,522	2,815
Weighted average shares used in computing diluted				
net income per share	44,580	44,922	44,493	44,778
Net income per share - diluted	\$ 0.20	\$ 0.17	\$ 0.49	\$ 0.37

For the three and six months ended September 30, 2016, approximately 1,500 and 8,800 shares underlying out-of-the-money stock options, respectively, were excluded in the computation of diluted earnings per share because their effect would have been anti-dilutive. Also, approximately 186,000 restricted shares in each of the three and six months ended September 30, 2016, respectively, related to performance-based awards for which milestones have not been met, were not included in the computation of diluted earnings per share.

For the three and six months ended September 30, 2015, approximately 1,000 shares underlying out-of-the-money stock options, respectively, were excluded in the computation of diluted earnings per share because their effect would have been anti-dilutive. Also, approximately 227,000 and 226,000 restricted shares in each of the three and six months ended September 30, 2015, respectively, related to performance-based awards for which milestones had not been met were not included in the computation of diluted earnings per share.

Note 3. Marketable Securities and Fair Value Measurements

Marketable Securities

The Company's marketable securities are classified as available-for-sale securities and, accordingly, are recorded at fair value. The difference between amortized cost and fair value is included in stockholders' equity.

The Company's marketable securities at September 30, 2016 and March 31, 2016 are invested in the following:

	Amortized Cost (in \$000's)	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
September 30, 2016:				
Short-term US Treasury mutual fund securities	\$37,141	\$ 9	\$ (1)	\$37,149
Short-term government-backed securities	90,823	39	(3)	90,859
Short-term corporate debt securities	50,079	165	(16)	50,228
Long-term US Treasury mutual fund securities	2,003	1	-	2,004
Long-term government-backed securities	1,999	1	-	2,000
	\$182,045	\$ 215	\$ (20)	\$182,240

	Amortized Cost (in \$000's)	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
March 31, 2016:				
US Treasury mutual fund securities	\$45,635	\$ 21	\$ —	\$45,656
Short-term government-backed securities	118,125	45	(4)	118,166
Long-term government-backed securities	999	1	-	1,000
	\$164,759	\$ 67	\$ (4)	\$164,822

Fair Value Hierarchy

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

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

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

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

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

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

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

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

	Level 1	Level 2	Level 3	Total
September 30, 2016:	(in \$000's)			
Assets				
Short-term U.S. Treasury mutual fund securities	\$—	\$37,149	\$—	\$37,149
Short-term government-backed securities	—	90,859	—	90,859
Short-term corporate debt securities	—	50,228	—	50,228
Long-term U.S. Treasury mutual fund securities	—	2,004	—	2,004
Long-term government-backed securities	—	2,000	—	2,000
Liabilities				
Contingent consideration	—	—	7,749	7,749

	Level 1	Level 2	Level 3	Total
March 31, 2016:	(in \$000's)			
Assets				
U.S. Treasury mutual fund securities	\$—	\$45,656	\$—	\$45,656
Short-term government-backed securities	—	118,166	—	118,166
Long-term government-backed securities	—	1,000	—	1,000
Liabilities				
Contingent consideration	—	—	7,563	7,563

The Company's investments in U.S. Treasury mutual fund securities, short-term government-backed securities, short-term corporate debt securities and long-term government-backed securities are reported as Level 2 financial assets as they are not exchange-traded instruments.

The Company's financial liabilities consisted of contingent consideration potentially payable related to the acquisition of ECP Entwicklungsgesellschaft mbH ("ECP") and AIS GmbH Aachen Innovative Solutions ("AIS"), in July 2014. This liability is reported as Level 3 as the estimated fair value of the contingent consideration related to the acquisition of the ECP requires significant management judgment or estimation and is calculated using the income approach, using various revenue and cost assumptions and applying a probability to each outcome.

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the contingent consideration for the three and six months ended September 30, 2016 and 2015:

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	For the Three Months Ended September 30, 2016		For the Six Months Ended September 30, 2015	
	2016	2015	2016	2015
	(in \$000's)		(in \$000's)	
Level 3 liabilities, beginning balance	\$7,739	\$6,661	\$7,563	\$6,510
Additions	—	—	—	—
Payments	—	—	—	—
Change in fair value	10	156	186	307
Level 3 liabilities, ending balance	\$7,749	\$6,817	\$7,749	\$6,817

The change in fair value of the contingent consideration was primarily due to the passage of time on the fair value measurement of milestones related to the ECP acquisition. Adjustments associated with the change in fair value of contingent consideration are included in research and development expenses in the Company's condensed consolidated statements of operations.

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements as of September 30, 2016 classified as Level 3:

	Fair Value at September 30, 2016 (in \$000's)	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent consideration	\$ 7,749	Probability weighted income approach	Milestone dates	2018 to 2021
			Discount rate	8% to 12%
			Probability of occurrence	Probability adjusted level
				of 50% for the base case
				scenario and 5% to 20%
				for various upside and
				downside scenarios

Other Investments

The Company periodically makes investments in private medical device companies that focus on heart failure and heart pump technologies. The aggregate carrying amount of the Company's other investments was \$4.4 million at each of September 30, 2016 and March 31, 2016, respectively, and is classified within other assets in the unaudited condensed consolidated balance sheets. These investments are accounted for using the cost method and are measured at fair value only if there are identified events or changes in circumstances that may have a significant adverse effect on the fair value of these investments.

Note 4. Property and Equipment

The components of property and equipment are as follows:

September 30,	March
2016	31, 2016

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Machinery and equipment	27,045	25,211
Capital lease assets	\$ 16,784	\$-
Leasehold improvements	10,863	11,833
Furniture and fixtures	2,117	1,510
Construction in progress	14,145	3,712
Total cost	70,954	42,266
Less accumulated depreciation	(20,747)	(19,082)
	\$ 50,207	\$23,184

In August 2016, the Company entered into a new lease agreement for its existing corporate headquarters in Danvers, Massachusetts (see Note 9). The Company recorded \$16.8 million as a capital lease asset with depreciation expense being recorded on a straight line basis over 15 years.

Note 5. Goodwill and In-Process Research and Development

The carrying amount of goodwill at September 30, 2016 and March 31, 2016 was \$32.6 million and \$33.0 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG ("Impella Cardiosystems"), in May 2005 and ECP and AIS in July 2014. The goodwill activity is as follows:

	(in \$000's)
Balance at March 31, 2016	\$33,003
Foreign currency translation impact	(421)
Balance at September 30, 2016	\$32,582

The Company evaluates goodwill and in-process research and development assets ("IPR&D") assets at least annually at October 31, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. The Company has no accumulated impairment losses on goodwill or IPR&D assets.

The carrying amount of IPR&D assets at September 30, 2016 and March 31, 2016 was \$15.2 million and \$15.4 million, respectively, and has been recorded in conjunction with the Company's acquisition of ECP and AIS, in July 2014. The estimated fair value of IPR&D assets at the acquisition date was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows from the expandable catheter pump technology were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 22.5% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.

The carrying value of the Company's IPR&D assets and the change in the balance for the six months ended September 30, 2016 are as follows:

	(in \$000's)
Balance at March 31, 2016	\$ 15,396
Foreign currency translation impact	(197)
Balance at September 30, 2016	\$ 15,199

Note 6. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2016	March 31, 2016
	(in \$000's)	
Employee compensation	\$ 17,319	\$ 18,359
Research and development	2,946	1,587
Sales and income taxes	2,675	2,527
Professional, legal and accounting fees	1,810	1,764
Marketing	1,092	1,146
Warranty	802	998
Other	1,369	2,001
	\$ 28,013	\$ 28,382

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at September 30, 2016 and March 31, 2016.

Note 7. Stock-Based Compensation

The following table summarizes stock-based compensation expense by financial statement line item in the Company's condensed consolidated statements of operations for the three and six months ended September 30, 2016 and 2015:

	For the Three Months Ended September 30, 2016 2015 (in \$000's)		For the Six Months Ended September 30, 2016 2015 (in \$000's)	
Cost of product revenue	\$221	\$218	\$520	\$455
Research and development	2,638	989	3,893	1,920
Selling, general and administrative	6,791	9,586	13,634	13,217
	\$9,650	\$10,793	\$18,047	\$15,592

Stock Options

The following table summarizes the stock option activity for the six months ended September 30, 2016:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at beginning of period	2,244	\$ 20.55	5.19	
Granted	138	103.32		
Exercised	(434)	13.29		
Cancelled and expired	(12)	53.34		
Outstanding at end of period	1,936	\$ 27.87	5.52	\$ 195,015
Exercisable at end of period	1,448	\$ 17.16	4.56	\$ 161,380
Options vested and expected to vest at end of period	1,893	\$ 27.12	5.45	\$ 192,059

The aggregate intrinsic value of options exercised was \$42.6 million for the six months ended September 30, 2016. The total fair value of options that vested during the six months ended September 30, 2016 was \$3.6 million.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at September 30, 2016 was approximately \$8.9 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 2.6 years.

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model. The weighted average grant-date fair values and weighted average assumptions used in the calculation of fair value of options granted during the three and six months ended September 30, 2016 and 2015 was as follows:

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2016	2015	2016	2015
Weighted average grant-date fair value	\$46.50	\$30.12	\$41.60	\$28.26
Valuation assumptions:				
Risk-free interest rate	1.11 %	1.63 %	1.32 %	1.59 %
Expected option life (years)	4.14	4.13	4.13	4.14
Expected volatility	49.0 %	48.3 %	49.6 %	49.7 %

Restricted Stock Units

The following table summarizes activity of restricted stock units for the six months ended September 30, 2016:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value (per share)
Restricted stock units at beginning of period	1,263	\$ 57.95
Granted	277	\$ 101.13
Vested	(489)	\$ 34.36
Forfeited	(18)	\$ 63.57
Restricted stock units at end of period	1,033	\$ 81.52

The remaining unrecognized compensation expense for outstanding restricted stock units, including performance and market-based awards, as of September 30, 2016 was \$40.7 million and the weighted-average period over which this cost will be recognized is 2.3 years.

Performance-Based Awards

In May 2016, performance-based awards of restricted stock units for the potential issuance of up to 190,890 shares of common stock were issued to certain executive officers and employees, all of which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of September 30, 2016, the Company is recognizing compensation expense based on the probable outcome related to the prescribed performance targets on the outstanding awards.

In June 2011, performance-based awards of restricted stock units for the potential issuance of 100,000 shares of common stock was issued to a certain senior executive officer of the Company that would vest upon achievement of prescribed service milestones by the award recipient and performance milestones by the Company. As of September 30, 2016, the Company has met the prescribed milestones for 100,000 shares of this award and the awards are fully vested.

Note 8. Income Taxes

The income tax provision represents the Company's federal and state income tax obligations as well as foreign tax provisions. The Company's income tax provision was \$5.9 million and \$14.4 million for the three and six months ended September 30, 2016, respectively. The Company's income tax provision was \$5.2 million and \$11.5 million for the three and six months ended September 30, 2015, respectively. The estimated annual effective income tax rate is based upon estimated income before income taxes for the year, the geographical composition of the estimated income before taxes and estimated permanent differences. The estimated annual effective income tax rate can fluctuate and may differ from the actual tax rate recognized in fiscal 2017 for various reasons, including estimates of income before taxes, tax legislation, permanent differences, discrete items, and any adjustments between tax provision calculations and filed tax returns.

The significant differences between the statutory tax rate and effective tax rate for the three and six months ended September 30, 2016 and 2015 were as follows:

	For the Three Months Ended September 30, 2016		For the Six Months Ended September 30, 2015	
Statutory income tax rate	35.0	%	35.0	%
Increase resulting from:				
Credits	(1.3)		(1.2)	
State taxes, net	3.4		3.3	
Permanent differences	2.7		3.0	
Other	-		0.2	
Effective tax rate	39.8	%	40.3	%
			39.8	%
			41.0	%

The Company and its subsidiaries are subject to U.S. federal income tax, as well as income tax in multiple states and other countries, including Germany. All tax years remain subject to examination by the Internal Revenue Service and state and foreign tax authorities. The Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, and those years may also be subject to review by relevant taxing authorities if the carryforwards are utilized. Fiscal years 2012 through 2016 remain open to examination in Germany.

Note 9. Commitments and Contingencies

Leases

The Company's corporate headquarters is located in Danvers, Massachusetts. This facility encompasses most of the Company's U.S. operations, including research and development, manufacturing, sales and marketing and general and administrative departments. On August 12, 2016, the Company entered into a new lease agreement to expand its existing corporate headquarters which covers 163,560 square feet of space. The initial term of the lease agreement commenced on August 12, 2016 and terminates on August 31, 2026. The Company has options to extend the initial term for three separate periods of five years each. In connection with the entry into this new lease agreement, the Company terminated the previously existing lease for the facility dated February 24, 2014, as amended by the First Amendment to Lease dated April 30, 2015 and the Second Amendment to Lease effective January 1, 2016. The Company also terminated the purchase and sale agreement it had entered into to acquire the facility for \$16.5 million in December 2015 when it entered into this new lease agreement in August 2016.

The Danvers, Massachusetts building lease is treated as a capital lease. The payments under the lease are accounted for as interest and principal payments over 15 years.

A summary of future lease commitments related to the capital lease obligation is as follows:

	(in \$000s)
2017, remaining portion	\$ 628
2018	1,311
2019	1,349
2020	1,349
2021	1,373
Thereafter	15,137
Total minimum lease payments	21,147
Less amounts representing interest	(4,446)
Total lease obligations	\$ 16,701
Less current capital lease obligation	(740)
Capital lease obligation, net of current portion	15,961

The lease agreement provides the Company with an exclusive option to purchase the building on or before August 31, 2022, subject to certain conditions set forth therein. In addition, the lease agreement grants the Company a one-time right of first offer to purchase the building from September 1, 2022 until August 31, 2026, if the lessor decides to sell the building or receives an offer to purchase the building from a third-party buyer.

The Company's European headquarters is located in Aachen, Germany and consists of approximately 33,000 square feet of space under an operating lease. In July 2013, the Company entered into a lease agreement to continue renting its existing space in Aachen, Germany through July 31, 2023. In October 2015, the Company entered into an amendment to this lease agreement to lease 9,000 square feet of additional space effective July 1, 2015. The Company also entered into another lease agreement in October 2015 to lease approximately 30,000 square feet of additional space adjacent to its Aachen facility from July 1, 2015 through June 30, 2016. This agreement also provided the Company with options to extend the lease through July 31, 2033. The Company exercised the first option under this agreement to extend the lease through June 30, 2017. The Aachen, Germany building lease is recorded as an operating lease with the related rent expense being recorded on a straight line basis over the lease term. The lease payments under these agreements are approximately 64,500€ (euro) (approximately U.S. \$72,000 at September 30, 2016 exchange rates) per month. The Aachen facility encompasses manufacturing, certain research and development activities and the European sales, marketing and general and administrative functions.

License Agreements

In April 2014, the Company entered into an exclusive license agreement for the rights to certain optical sensor technologies in the field of cardio-circulatory assist devices. The Company made a \$1.5 million upfront payment upon execution of the agreement and could make additional payments of up to \$4.5 million upon the achievement of certain development milestones.

In November 2015, the Company entered into an exclusive license agreement for the rights to certain vascular closure device technologies. The Company made a \$0.5 million upfront payment upon execution of the agreement and a milestone payment of \$0.6 million in December 2015. In July 2016, the Company cancelled this agreement and

provided a \$0.2 million termination fee in the quarter ending September 30, 2016.

Litigation

From time to time, the Company is involved in legal and administrative proceedings and claims of various types. In some actions, the claimants seek damages, as well as other relief, which, if granted, would require significant expenditures. The Company records a liability in its condensed consolidated financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in its condensed consolidated financial statements.

On April 25, 2014, the Company received a subpoena from the Boston regional office of the United States Department of Health and Human Services, or HHS, Office of Inspector General requesting materials relevant to the Company's reimbursement of employee expenses and remuneration to healthcare providers for a six month period from July 2012 through December 2012 in connection with a civil investigation under the False Claims Act (the "FCA Investigation"). The Company submitted the requested documents to HHS and believes that it substantially complied with the subpoena. On November 6, 2014, the Company received notice from the U.S. Department of Justice, U.S. Attorney's Office for the District of Massachusetts, or DOJ, in the form of a Civil Investigative Demand, or CID, requesting additional materials relating to this matter for the time period of January 1, 2012 through December 31, 2013. The Company responded to the CID, and believes that it substantially complied with the requests contained therein. On September 19, 2016, the Company received notice from the DOJ in the form of an additional CID requesting additional document production and information relating to this matter for the time period January 1, 2011 through September 14, 2016. The Company is responding to the CID, and continues to cooperate fully with the U.S. Attorney's Office in its FCA investigation.

Thoratec Corporation, or Thoratec, (acquired by St. Jude Medical, Inc. in October 2015) has challenged a number of Company owned patents in the European Patent Office or EPO, in Germany, and in the United Kingdom in connection with the launch of their HeartMate PHP medical device, or PHP, in Europe. These actions all relate to Thoratec's ability to manufacture and sell their PHP product in Europe. None of these matters impact the Company's ability to manufacture or sell its Impella products.

In October 2012, Thoratec filed a notice of opposition in the EPO to a Company owned European patent covering a 'pigtail' feature. In October 2014, the EPO dismissed Thoratec's opposition, and in December 2014, Thoratec filed a notice of appeal. The appeal is scheduled to be heard at the EPO in January 2017.

In December 2014, Thoratec filed a nullity suit in German Federal Court against a German pigtail patent owned by the Company. The validity hearing for the German pigtail patent is scheduled for November 2016. In August 2015, Thoratec filed a nullity action in German Federal Court against two Company owned patents covering a "magnetic clutch" feature. These magnetic clutch patents were acquired by the Company in July 2014, in connection with its acquisition of ECP and AIS. The validity hearing for the magnetic clutch patents is scheduled for June 2017. In September 2015, the Company filed counterclaims in the magnetic clutch action in Germany asserting that the PHP product infringes the two magnetic clutch patents and the two pigtail patents. The infringement trial is scheduled for January 2017.

In July 2015, Thoratec filed a nullity action in the High Court of Justice of England and Wales against the Company's U.K. "magnetic clutch" patents acquired from ECP and AIS. In October 2015, Thoratec added a non-infringement claim seeking a declaration that their PHP product does not infringe the patents in the United Kingdom. Thoratec's claims in the U.K. were heard at trial in early October 2016. While the English Court found on October 28, 2016, that the PHP would infringe a number of claims contained within the Company's patents, the Court found those claims to be invalid because of obviousness or lack of novelty.

In December 2015, the Company received a letter from Maquet Cardiovascular LLC, or Maquet, a subsidiary of the Getinge Group, and maker of the intra-aortic balloon pump, asserting that the Company's Impella products infringe certain claims having guidewire, lumen and sensor features and which are in two Maquet patents and one pending patent application in the U.S. and elsewhere, and encouraged the Company to discuss taking a license from Maquet. In January 2016, the Company responded to Maquet stating that it believed that the cited claims were invalid and that its Impella products did not infringe the cited patents. In May 2016, Maquet sent an additional letter notifying the Company that the pending patent application had been issued as a U.S. patent and repeated their earlier assertion and encouraged the Company to discuss taking a license from Maquet. The three patents expire September 2020, December 2020 and October 2021. On May 19, 2016, the Company filed suit in U.S. District Court for the

District of Massachusetts, or D. Mass., against Maquet seeking a declaratory judgment that the Company's Impella products do not infringe Maquet's cited patent rights.

On August 24, 2016, Maquet sent another letter to the Company identifying four new continuation patent filings with claims that Maquet alleges are infringed by the Company's Impella products. Those U.S. continuation filings have not issued as patents; three of them have not yet published, the fourth is published but has not begun substantive prosecution. If the patent filings were to issue, they will expire in September 2020. On September 23, 2016, Maquet filed an answer to the Company's suit in D. Mass., including various counterclaims alleging that the Company's Impella 2.5, Impella CP, Impella 5.0, and Impella RP heart pumps infringe certain claims of the three issued U.S. patents. The D. Mass. court has not yet set a schedule for the case.

The Company is unable to estimate a potential liability with respect to the legal matters noted above. There are numerous factors that make it difficult to meaningfully estimate possible loss or range of loss at this stage of the legal proceedings, including that the FCA Investigation and patent disputes with Thoratec and Maquet remain in relatively early stages, there are significant factual and legal issues to be resolved and information obtained or rulings made during any potential lawsuits or investigations could affect the methodology for calculation. Therefore, the Company is unable at this time to estimate a possible loss or range of possible loss, and no adjustment has been made to the financial statements to reflect the outcome of these uncertainties.

Note 10. Segment and Enterprise Wide Disclosures

The Company operates in one business segment—the research, development and sale of medical devices to assist or replace the pumping function of the failing heart. The Company’s chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company’s consolidated operating results. International sales (sales outside the U.S. and primarily in Europe) accounted for 9% of total product revenue during each of the three and six months ended September 30, 2016, respectively, and 7% of total product revenue for each of the three and six months ended September 30, 2015, respectively. The Company’s long-lived assets, which are its property, plant and equipment, are located primarily in the U.S. except for \$7.1 million and \$5.9 million at September 30, 2016 and March 31, 2016, respectively, which are located primarily in Germany.

ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward Looking Statements

This Report contains forward- looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Any statements other than one conveying solely historical facts is a forward-looking statement. These forward-looking statements may be accompanied by words such as “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “target,” “will” and other words and terms of similar meaning. These forward-looking statements address various matters including, among others, future actions related to ongoing investigations and litigation and expenditures related thereto; the development and commercialization of new and existing products and anticipated costs, including research and development, sales and marketing and training costs associated with product development and commercialization; expected capital expenditures for the fiscal year ending March 31, 2017; commercial plans for our products into new markets such as Japan; demand and expected shipments of our products; anticipated shifts in the revenue mix associated with our products; our ability to increase revenue from our Impella® line of products and the sufficiency of revenue to fund future operations; and the impact of market factors such as changes in interest rates, currency exchange rates on our securities and the fair value of our financial instruments. Each forward-looking statement in this Report is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, our inability to predict the outcome of investigations and litigation and associated expenses; possible delays in our research and development programs; our ability to obtain regulatory approvals and market our products, and uncertainties related to regulatory processes; greater government scrutiny and regulation of the medical device industry and our ability to respond to changing laws and regulations affecting our industry, including any reforms to the regulatory approval process administered by the U.S Food and Drug Administration, or FDA, and changing enforcement practices related thereto; the inability to manufacture products in commercial quantities at an acceptable cost; the acceptance by physicians and hospitals of our products; the impact of competitive products and pricing; uncertainties associated with future capital needs and the risks identified under Item 1A of Part I of our Annual Report on Form 10-K, for the year ended March 31, 2016, as well as the other information we file with the Securities and Exchange Commission. Readers are cautioned not to place considerable reliance on any forward-looking statements contained in this Report, which speak only as of the date of this Report. We undertake no obligation to update or revise these forward-looking statements whether as a result of new information, future events or otherwise, unless required by law. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

Overview

We are a leading provider of temporary mechanical circulatory support devices and we offer a continuum of care to heart failure patients. We develop, manufacture and market proprietary products that are designed to enable the heart to rest, heal and recover by improving blood flow to the coronary arteries and end-organs and/or temporarily performing the pumping function of the heart. Our products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists, the electrophysiology lab, the hybrid lab and in the heart surgery suite by heart surgeons. A physician may use our devices for patients who are in need of hemodynamic support prophylactically or emergently before, during or after angioplasty or heart surgery procedures. We believe that heart recovery is the optimal clinical outcome for a patient experiencing heart failure because it enhances the potential for the patient to go home with the patient's own native heart, facilitating restoration of quality of life. In addition, we believe, that for the care of such patients, heart recovery is often the most cost-effective solution for the healthcare system.

Our strategic focus and the driver of the majority of our revenue growth is the market penetration of our family of Impella® products. The Impella product portfolio, which includes the Impella 2.5™, Impella CP®, Impella RP®,

Impella LD™ and Impella 5.0™ devices, has supported thousands of patients in the U.S. We expect that almost all of our product and service revenue in the near future will be from our Impella devices. Revenue from our non-Impella products, largely focused on the heart surgery suite, have been decreasing over the past several years as we have strategically shifted our sales and marketing efforts towards our Impella devices and the cath lab.

In March 2015, we received a Pre-Market Approval, or PMA, from the FDA for use of the Impella 2.5 device during elective and urgent high-risk percutaneous coronary intervention, or PCI, procedures. With this PMA indication, the Impella 2.5 device is the first FDA-approved hemodynamic support device indicated for use during high-risk PCI procedures. In April 2016, the FDA approved a PMA supplement for our Impella 2.5, Impella CP, Impella 5.0 and Impella LD devices to provide treatment for ongoing cardiogenic shock. The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

We expect to continue to make additional PMA supplement submissions for our Impella suite of devices for additional indications.

Our Impella 2.5, Impella 5.0, Impella LD, Impella CP and Impella RP devices also have CE Mark approval and Health Canada approval which allows us to market these devices in the European Union and Canada.

In September 2016, we received Pharmaceuticals and Medical Devices Agency, or PMDA, approval from the Japanese Ministry of Health, Labour & Welfare for our Impella 2.5 and Impella 5.0 heart pumps to provide treatment of drug-resistant acute heart failure in Japan. We are preparing for the market launch in Japan, including working with Japanese government authorities to obtain appropriate reimbursement for these products. We do not expect to have any material revenue in Japan during fiscal 2017.

Effective October 1, 2016, the American Hospital Association, or AHA, published simplified ICD-10 coding guidance for the Impella device. The Centers for Medicare and Medicaid Services, or CMS, has assigned all uses of the Impella product to a dedicated heart assist implant MS-DRG, MS-DRG 215, for percutaneous Heart Assist System Implant, a change from MS-DRG 216 – 221 “Cardiac Valve and Other”. The Impella heart pump is now assigned to a dedicated DRG category for left side, right side and biventricular hemodynamic support.

In October 2016, we received FDA approval of a prospective 50 patient feasibility study to evaluate the use of the Impella CP heart pump for unloading of the left ventricle prior to primary PCI in patients presenting with ST segment elevation myocardial infarction, or STEMI, without cardiogenic shock. This trial will focus on feasibility and safety, and lay the groundwork for a potential future trial, designed to measure the impact that unloading may have on infarct size related to reperfusion injury, an acceleration of myocardial damage at the time of revascularization, in STEMI patients.

Our Products

Impella 2.5™

The Impella 2.5 catheter is a percutaneous micro heart pump with an integrated motor and sensors. The device is designed primarily for use by interventional cardiologists to support patients in the cath lab who may require assistance to maintain circulation. The Impella 2.5 catheter can be quickly inserted via the femoral artery to reach the left ventricle of the heart where it is directly deployed to draw blood out of the ventricle and deliver it to the circulatory system. This function is intended to reduce ventricular work and provide flow to vital organs. The Impella 2.5 is introduced with normal interventional cardiology procedures and can pump up to 2.5 liters of blood per minute.

The Impella 2.5 device received 510(k) clearance from the FDA in June 2008 for partial circulatory support for up to six hours. In March 2015, we received a PMA from the FDA for the use of the Impella 2.5 device during elective and urgent high-risk PCI procedures. With this PMA indication, the Impella 2.5 device became the first FDA approved hemodynamic support device for use during high-risk PCI procedures. Under this first PMA, the Impella 2.5 is a temporary (up to six hours) ventricular support device indicated for use during high-risk PCI performed in elective or urgent hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 device in these patients may prevent hemodynamic instability that may occur during planned temporary coronary occlusions and may reduce periprocedural and post-procedural adverse events. The product labeling allows for the clinical decision to leave the Impella 2.5 device in place beyond the intended duration of up to six hours due to unforeseen circumstances. Pursuant to our PMA approval, we are conducting a single-arm, post-approval study on the Impella 2.5 device, collecting data on high-risk PCI patients. The study is a prospective, multi-center study comprised of 369 patients from up to 70 sites supported with the Impella 2.5 system.

In April 2016, following the Company’s submission of a request that the FDA supplement the March 2015 PMA to include the use of Impella technologies in the treatment of patients experiencing cardiogenic shock, the FDA approved

the use of our Impella 2.5, Impella CP, Impella 5.0 and Impella LD devices to provide treatment for ongoing cardiogenic shock. This PMA supplement covers a set of indications related to the use of the Impella devices in patients suffering cardiogenic shock following acute myocardial infarction or cardiac surgery and for a longer duration of support. The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

The data submitted to the FDA in support of the PMA supplement included an analysis of 415 patients from the RECOVER 1 study and the U.S. Impella registry (cVAD Registry™), as well as a literature review using the Impella devices in 692 patients from 17 clinical studies. A safety analysis reviewed over 24,000 Impella patients who had used an Impella device, as documented in the FDA medical device reporting, or MDR, database, which draws from seven years of experience using the Impella devices in the U.S. We believe this is the most comprehensive review ever submitted to the FDA for circulatory support in the cardiogenic shock population.

Pursuant to the April 2016 PMA, the Impella 2.5, Impella CP, Impella 5.0 and Impella LD catheters, in conjunction with the Automated Impella Controller, or AIC, are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella

2.5 and Impella CP, and ≤ 6 days for the Impella 5.0 and LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures. The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function. Optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without an intraortic balloon pump, or IABP.

A November 2011 update to the American College of Cardiology Foundation (ACCF) /American Heart Association (AHA) Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions Guidelines for Percutaneous Coronary Intervention included Impella devices in both the emergent and prophylactic hemodynamic support settings. In addition, a December 2012 update to the AHA's Recommendations for the Use of Mechanical Circulatory Support: Device Strategies and Patient Selection recommended Impella devices for use in mechanical circulatory support; a December 2012 update to the ACCF / AHA Guidelines for the Management of ST-Elevation Myocardial Infarction, or STEMI, included the Impella 2.5 device for use in patients requiring urgent coronary artery bypass grafting with STEMI and in treatment of patients with cardiogenic shock complications after STEMI. A January 2013 update to the International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support included Impella devices for patients with multi-organ failure. In addition, Impella devices were included in a January 2013 update to the ACCF / AHA Task Force on Practice Guidelines for the Management of ST-Elevation Myocardial Infarction and a September 2014 AHA / the American College of Cardiology Task Force on Practice Guidelines for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes.

The Impella 2.5 device has CE Mark approval in Europe for up to five days of use and is approved for use in up to 40 countries. Impella 2.5 device also has Health Canada approval which allows us to market the device in Canada.

In September 2016, we received PMDA approval from the Japanese Ministry of Health, Labour & Welfare for our Impella 2.5 and Impella 5.0 heart pumps to provide treatment of drug-resistant acute heart failure in Japan. We are preparing for the market launch in Japan, including working with Japanese government authorities to obtain reimbursement for these products. We do not expect to have any material revenue in Japan during fiscal 2017.

Impella CP®

In September 2012, we announced that the Impella CP device received 510(k) clearance from the FDA. The Impella CP device provides blood flow of approximately one liter more per minute than the Impella 2.5 device and is primarily used by either interventional cardiologists to support patients in the cath lab or by surgeons in the heart surgery suite.

As previously discussed, in April 2016, the FDA approved the PMA supplement for certain of our devices, including our Impella CP device to provide treatment for ongoing cardiogenic shock.

In October 2016, we received FDA approval of a prospective 50 patient feasibility study to evaluate the use of the Impella CP heart pump for unloading of the left ventricle prior to primary PCI in patients presenting with ST segment elevation myocardial infarction, or STEMI, without cardiogenic shock. This trial will focus on feasibility and safety, and lay the groundwork for a potential future trial, designed to measure the impact that unloading may have on infarct size related to reperfusion injury, an acceleration of myocardial damage at the time of revascularization, in STEMI patients.

We expect to continue to make additional PMA supplement submissions for our Impella suite of products for additional marketing indications, including to expand the current PMA that we have for the Impella 2.5 device to the Impella CP device for elective and urgent high-risk PCI procedures.

Impella 5.0™ and Impella LD™

The Impella 5.0 device and Impella LD device are percutaneous micro heart pumps with integrated motors and sensors for use primarily in the heart surgery suite. These devices are designed to support patients who require higher levels of circulatory support as compared to the Impella 2.5.

The Impella 5.0 device can be inserted into the left ventricle via femoral cut down or through the axillary artery. The Impella 5.0 device is passed into the ascending aorta, across the valve and into the left ventricle. The Impella LD device is similar to the Impella 5.0 device, but it is implanted directly into the ascending aorta through an aortic graft. Both of these procedures are normally performed with the assistance of heart surgeons in the surgery suite. The Impella 5.0 device and Impella LD device can pump up to five liters of blood per minute, potentially providing full circulatory support.

The Impella 5.0 and Impella LD devices originally received 510(k) clearance in April 2009, for circulatory support for up to six hours. As previously discussed, the FDA approved the PMA supplement certain of our devices, including our Impella 5.0 and Impella LD devices to provide treatment for ongoing cardiogenic shock.

The Impella 5.0 and Impella LD devices have CE Mark approval in Europe for up to ten days' duration and are approved for use in over 40 countries.

In September 2016, we received PMDA approval from the Japanese Ministry of Health, Labor & Welfare for our Impella 2.5 and Impella 5.0 heart pumps to provide treatment of drug-resistant acute heart failure in Japan. We are preparing for the market launch in Japan, including working with Japanese government authorities to obtain reimbursement for these products. We do not expect to have any material revenue in Japan during fiscal 2017.

Impella RP®

The Impella RP is a percutaneous catheter-based axial flow pump that is designed to allow greater than four liters of flow per minute and is intended to provide the flow and pressure needed to compensate for right side heart failure. The Impella RP is the first percutaneous single access heart pump designed for right heart support to receive FDA approval. The Impella RP device is approved to provide support of the right heart during times of acute failure for certain patients who have received a left ventricle assist device or have suffered heart failure due to acute myocardial infarction, or AMI, or a failed heart transplant.

In November 2012, the Impella RP device received U.S. investigational device exemption, or IDE, approval from the FDA for use in RECOVER RIGHT, a pivotal clinical study in the U.S. In March 2014, we completed enrollment of 30 patients that presented signs of right side heart failure, required hemodynamic support, and were capable of being treated in the catheterization lab or cardiac surgery suite. The study collected safety and effectiveness data on the percutaneous use of the Impella RP device and was submitted to the FDA in support of a Humanitarian Device Exemption, or HDE, submission. An HDE is similar to a PMA application but is intended for patient populations of 4,000 or less per year in the U.S. and is subject to certain profit and use restrictions. An HDE approval requires demonstration of the safety and probable benefit of the product, which is a lower standard than is applied to a PMA. In order to receive an HDE, there must be no comparable devices approved under a PMA that are available to treat the targeted population. An approved HDE authorizes sales of the device to any hospital after review and approval by the hospital's Institutional Review Board.

In January 2015, we received FDA approval for the Impella RP device under an HDE. As part of the HDE approval, we are required to conduct two post approval studies for the Impella RP device. One includes an adult patient population of 30 patients and the other includes a pediatric patient population of a maximum of 15 patients. These studies are designed to monitor the post-market safety and probable benefit of the Impella RP device. Both studies will be single-arm multicenter studies that will follow the respective patients at 30 and 180 days post device explant. We have completed 18 patients to date on the adult patient population study, and we expect to complete this study in fiscal 2017. In April 2014, the Impella RP device received CE Mark approval which allows for commercial sales of the Impella RP device in the European Union and other countries that require a CE Mark approval for commercial sales.

AB5000™

We manufacture and sell the AB5000 Circulatory Support System for the temporary support of acute heart failure patients in profound shock, including patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock, or myocarditis. The AB5000 device was approved by the FDA in 2003. We believe the AB5000 is the only commercially available cardiac assist device that is approved by the FDA for all indications where heart

recovery is the desired outcome, including patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. Revenue from the AB5000 device have been declining in recent years, and we expect to only have minimal revenue from the AB5000 in the future as we focus our efforts on the Impella family of devices.

ECP

In July 2014, we acquired all of the issued shares of ECP Entwicklungsgesellschaft mbH, or ECP, a German limited liability company, for \$13.0 million in cash, with additional potential payments up to a maximum of \$15.0 million based on the achievement of certain technical, regulatory and commercial milestones. In connection with our acquisition of ECP, ECP acquired all of the issued shares of AIS GmbH Aachen Innovative Solutions, or AIS, a German limited liability company, for \$2.8 million in cash which was provided by us. AIS, based in Aachen, Germany, holds certain intellectual property useful to ECP's business, and, prior to being acquired by ECP, had licensed such intellectual property to ECP.

ECP, based in Berlin, Germany, is engaged in research, development, prototyping and the pre-serial production of a percutaneous expandable catheter pump which increases blood circulation from the heart with an external drive shaft. The ECP pump is designed for blood flow of >3 liters/minute. It is intended to be delivered on the standard Impella 9 Fr catheter and will include an 18 Fr expandable inflow in the left ventricle with a smooth membrane crossing the left ventricle. The ECP pump is still in early stages of research and development and has not been approved for commercial use or sale.

Critical Accounting Policies and Estimates

There have been no significant changes in our critical accounting policies during the three and six months ended September 30, 2016, as compared to the critical accounting policies disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the fiscal year ended March 31, 2016.

Recent Accounting Pronouncements

Information regarding recent accounting pronouncements is included in "Note 1. Nature of Business and Basis of Preparation" to our condensed consolidated financial statements and are incorporated herein by reference.

Results of Operations

The following table sets forth certain condensed consolidated statements of operations data for the periods indicated as a percentage of total revenue:

	For the Three Months Ended September 30, 2016		For the Six Months Ended September 30, 2015	
Revenue:				
Product revenue	100.0 %	100.0 %	100.0 %	100.0 %
Costs and expenses as a percentage of total revenue:				
Cost of product revenue	16.8	15.9	15.7	15.4
Research and development	17.5	15.1	16.4	14.5
Selling, general and administrative	51.6	52.2	50.5	51.5
Total costs and expenses	85.9	83.2	82.6	81.4
Income from operations	14.1	16.8	17.4	18.6
Income tax provision and other	5.5	6.7	6.8	7.5
Net income as a percentage of total revenue	8.6 %	10.1 %	10.6 %	11.1 %

Three and six months ended September 30, 2016 compared with the three and six months ended September 30, 2015

Revenue

Our revenues are comprised of the following:

	For the Three Months Ended September 30,		For the Six Months Ended September 30,	
	2016	2015	2016	2015
	(in \$000's)		(in \$000's)	
Impella product revenue	\$97,915	\$71,701	\$195,734	\$140,506
Service and other revenue	4,455	3,929	8,944	8,082
Other products	558	724	1,239	1,192
Total product revenue	102,928	76,354	205,917	149,780
Funded research and development	27	5	33	11
Total revenue	\$102,955	\$76,359	\$205,950	\$149,791

Impella product revenue encompasses Impella 2.5, Impella CP, Impella 5.0, Impella LD and Impella RP device sales. Service and other revenue represents revenue earned on service maintenance contracts and preventive maintenance calls. Other product revenue includes AB5000 and product accessory revenue.

Total revenue for the three months ended September 30, 2016 increased \$26.6 million, or 35%, to \$103.0 million from \$76.4 million for three months ended September 30, 2015. Total revenue for the six months ended September 30, 2016 increased \$56.2 million, or 38%, to \$206.0 million from \$149.8 million for the six months ended September 30, 2015. The increase in total revenue was primarily due to higher Impella product revenue from increased utilization in the U.S. Sales of Impella 2.5 devices were higher as a result of PMA approval in March 2015 for elective and high risk PCI procedures and the Impella CP device has continued to experience higher utilization by those interventional cardiologists who prefer higher blood flow. Revenue from our Impella products also increased with our recent PMA approval of these products for cardiogenic shock in April 2016.

Impella product revenue for three months ended September 30, 2016 increased by \$26.2 million, or 37%, to \$97.9 million from \$71.7 million for three months ended September 30, 2015. Impella product revenue for the six months ended September 30, 2016 increased by \$55.2 million, or 39%, to \$195.7 million from \$140.5 million for the six months ended September 30, 2015. Most of the increase in Impella product revenue was from increased device sales in the U.S. of all of our Impella products, as we focus on increasing utilization of our disposable catheter products through continued investment in our field organization and physician training programs. Impella product revenue outside of the U.S. also increased primarily due to increased utilization in Germany as we expand our field organization in that country. We expect product revenue from our Impella line to continue to increase due to our recent PMAs in the U.S. for our Impella devices to provide treatment for ongoing cardiogenic shock, continued utilization for high risk PCI procedures, continued controlled launch of Impella RP devices in the U.S. and expansion efforts in Europe, particularly Germany.

Service and other revenue for three months ended September 30, 2016 increased by \$0.6 million, or 15%, to \$4.5 million from \$3.9 million for three months ended September 30, 2015. Service and other revenue for the six months ended September 30, 2016 increased by \$0.8 million, or 10%, to \$8.9 million from \$8.1 million for the six months ended September 30, 2015. The increase in service revenue was primarily due to an increase in preventative maintenance service contracts. We have expanded the number of Impella AIC consoles to most of our using sites and placed more consoles at existing higher using sites. We expect revenue growth for service revenue to be slower in fiscal 2017 as we have service contracts that normally have three year terms at most of our sites in the U.S.

Other product revenue for three months ended September 30, 2016 decreased by \$0.1 million, or 14%, to \$0.6 million from \$0.7 million for three months ended September 30, 2015. Other product revenue remained flat at \$1.2 million for the six months ended September 30, 2016 and 2015. We expect that AB5000 revenue will be minimal in the future we focus our sales efforts in the surgical suite on our Impella devices and we focus more of our attention on the cath lab.

Costs and Expenses

Cost of Product Revenue

Cost of product revenue for three months ended September 30, 2016 increased by \$5.2 million, or 43%, to \$17.3 million from \$12.1 million for three months ended September 30, 2015. Gross margin was 83% for the three months ended September 30, 2016 and 84% for the three months ended September 30, 2015. Cost of product revenue for the six months ended September 30, 2016 increased \$9.4 million, or 41%, to \$32.4 million from \$23.0 million for the six months ended September 30, 2015. Gross margin was 84% for the six months ended September 30, 2016 and 85% for the six months ended September 30, 2015. The increase in cost of product revenue was related to higher demand for our Impella devices and higher production volume and costs to support growing demand for our Impella devices. The decrease in gross margin was primarily due to larger number of shipments of AICs during the three months ended September 30, 2016.

Research and Development Expenses

Research and development expenses for three months ended September 30, 2016 increased by \$6.5 million, or 56%, to \$18.1 million from \$11.6 million for three months ended September 30, 2015. Research and development expenses for the six months ended September 30, 2016 increased by \$11.9 million, or 55%, to \$33.7 million from \$21.8 million for the six months ended September 30, 2015. The increase in research and development expenses was primarily due to product development initiatives on our existing products and new technologies as we expanded our engineering organization, increased clinical spending primarily related to our cVAD Registry™ and our continued focus on quality initiatives for our Impella devices.

We expect research and development to increase for the remainder of fiscal 2017 as we continue to increase clinical spending related to our cVAD Registry™ and incur additional costs as we continue to focus on engineering initiatives to improve our existing products and develop new technologies.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for three months ended September 30, 2016 increased by \$13.3 million, or 33%, to \$53.1 million from \$39.8 million for three months ended September 30, 2015. Selling, general and administrative expenses for the six months ended September 30, 2016 increased by \$26.9 million, or 35%, to \$104.1 million from \$77.2 million for the six months ended September 30, 2015.

The increase in selling, general and administrative expenses was primarily due to the hiring of additional U.S. field sales and clinical personnel, increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support after receiving PMAs in the U.S. for Impella 2.5, Impella CP, Impella 5.0 and Impella LD devices, higher stock-based compensation expense, higher legal expenses related to the FCA Investigation and patent related matters discussed in “Note 9. Commitments and Contingencies—Litigation,” to our condensed consolidated financial statements and higher professional fees to support the growth of our business.

We expect to continue to increase our expenditures on sales and marketing activities, with particular investments in field sales and clinical personnel with cath lab expertise to drive recovery awareness for acute heart failure patients. We also plan to increase our marketing, service and training investments as a result of recent PMA approvals in the U.S. for our Impella devices and as we expand to new markets outside of the U.S., such as Japan. We also expect to continue to incur significant legal expenses for the foreseeable future related to the FCA Investigation and patent related matters. We expect that this increase in selling, general and administrative expense will be offset somewhat by the moratorium of the medical device tax in the U.S. for the two calendar years beginning in January 2016.

Income Tax Provision

We recorded an income tax provision of \$5.9 million and \$14.4 million for the three and six months ended September 30, 2016, respectively, compared to \$5.2 million and \$11.5 million for the three and six months ended September 30, 2015, respectively. The increase in income tax provision for the three months ended September 30, 2016 was due primarily to an increase in income before taxes for the three months ended September 30, 2016 due to higher Impella product revenue.

Net Income

For three months ended September 30, 2016, we recognized net income of \$8.9 million, or \$0.21 per basic share and \$0.20 per diluted share, compared to \$7.7 million, or \$0.18 per basic share and \$0.17 per diluted share for three months ended September 30, 2015. For the six months ended September 30, 2016, we recognized net income of \$21.8 million, or \$0.51 per basic share and \$0.49 per diluted share, compared to \$16.6 million, or \$0.40 per basic share and \$0.37 per diluted share for the six months ended September 30, 2015. Our net income for fiscal 2017 was driven primarily by higher Impella product revenue due to greater utilization of our Impella devices in the U.S. and Germany.

Liquidity and Capital Resources

At September 30, 2016, our total cash, cash equivalents and marketable securities totaled \$236.9 million, an increase of \$23.8 million compared to \$213.1 million at March 31, 2016. The increase in our cash, cash equivalents and marketable securities was due primarily to positive cash flows from operations in the six months ended September 30, 2016.

Following is a summary of our cash flow activities:

	For the Six Months Ended September 30,	
	2016	2015
Net cash provided by operating activities	\$43,736	\$28,856
Net cash (used for) provided by investing activities	(28,003)	(1,718)
Net cash (used for) provided by financing activities	(9,527)	4,995
Effect of exchange rate changes on cash	272	(113)
Net (decrease) increase in cash and cash equivalents	\$6,478	\$32,020

Cash Provided by Operating Activities

For the six months ended September 30, 2016, cash provided by operating activities consisted of net income of \$21.8 million, adjustments for non-cash items of \$28.7 million and cash used in working capital of \$6.7 million. The increase in net income was

primarily due to higher revenue from increased utilization of our Impella devices. Adjustments for non-cash items consisted primarily of \$18.0 million of stock-based compensation expense, a \$9.8 million change in deferred tax provision, \$3.6 million in excess tax benefits on stock-based awards, \$3.0 million of depreciation expense on property, plant and equipment and \$1.4 million in inventory write-downs. The change in cash from working capital included a \$3.8 million increase in accounts receivable associated with our higher revenue, a \$6.3 million increase in inventory as we build up our inventory safety stock to support growing demand for our Impella devices, \$5.1 million increase in accounts payable and accrued expenses and a \$0.3 million increase in deferred revenue primarily due to an increase in preventative maintenance service contracts.

For the six months ended September 30, 2015, cash provided by operating activities consisted of net income of \$16.6 million, adjustments for non-cash items of \$28.6 million and cash used in working capital of \$16.3 million.

Adjustments for non-cash items primarily consisted of \$15.6 million of stock-based compensation expense and a \$10.8 million change in deferred tax provision. The change in cash from working capital included a \$5.2 million increase in accounts receivable associated with our higher revenue, a \$6.9 million increase in inventory to support growing demand for our Impella products and a \$4.5 million decrease in accounts payable and accrued expenses and a \$0.2 million decrease in deferred revenue.

Cash Used for Investing Activities

For the six months ended September 30, 2016, net cash used for investing activities included \$17.6 million in purchases (net of maturities) of marketable securities and \$10.5 million for the purchase of property and equipment mostly related to expansion of manufacturing capacity and office space in Danvers, Massachusetts and Aachen, Germany.

For the six months ended September 30, 2015, net cash provided by investing activities included \$2.5 million in maturities (net of purchases) of marketable securities offset by \$3.4 million for the purchase of property and equipment mostly related to expansion of manufacturing capacity and office space in Danvers Massachusetts and Aachen, Germany. We also made a \$0.8 million investment in a private medical technology company during the six months ended September 30, 2015.

Capital expenditures for fiscal 2017 are estimated to range from \$45 million to \$60 million, including approximately \$30 million for potential property acquisitions or capital lease assets acquired. We are also expecting to incur significant capital expenditures for manufacturing capacity and office leasehold improvements in both our Danvers, Massachusetts, Aachen, Germany, Berlin, Germany and Tokyo, Japan facilities.

Cash Provided by Financing Activities

For the six months ended September 30, 2016, net cash used for financing activities included \$19.6 million in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards. These amounts were offset by \$5.8 million in proceeds from the exercise of stock options, \$3.6 million in excess tax benefits on stock-based awards and \$0.8 million in proceeds from the issuance of stock under the employee stock purchase plan.

For the six months ended September 30, 2015, net cash provided by financing activities included \$8.0 million in proceeds from the exercise of stock options, \$0.5 million in proceeds from the issuance of stock under the employee stock purchase plan and \$0.4 million in excess tax benefits on stock-based awards. These amounts were partially offset by \$3.8 million in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards.

Operating Capital and Liquidity Requirements

We believe that our revenue from product sales together with existing resources will be sufficient to fund our operations for at least the next twelve months, exclusive of activities involving any future acquisitions of products or companies that complement or augment our existing line of products.

Our primary liquidity requirements are to fund the expansion of our commercial and operational infrastructure in the U.S., increase our manufacturing capacity, incur additional capital expenditures as we expand our office space and manufacturing capacity in Danvers and Aachen, increase our inventory levels in order to meet growing customer demand for our Impella devices, fund new product development initiatives, prepare for commercial launches of Impella devices in new markets in the future, such as Japan, increased clinical spending, costs of legal fees related to the FCA Investigation and ongoing patent litigation and to provide for general working capital needs. To date, we have primarily funded our operations through product sales and the sale of equity securities.

Our liquidity is influenced by our ability to sell our products in a competitive industry and our customers' ability to pay for our products. Factors that may affect liquidity include our ability to penetrate the market for our products, maintain or reduce the length of

the selling cycle for our products, capital expenditure additions, investments in collaborative arrangements with other partners, and our ability to collect cash from customers after our products are sold. We also expect to continue to incur legal expenses for the foreseeable future related to the FCA Investigation and ongoing patent litigation. We continue to review our short-term and long-term cash needs on a regular basis. At September 30, 2016 we had no long-term debt outstanding.

Marketable securities at September 30, 2016 and March 31, 2016 consisted of \$182.2 million and \$164.8 million held in funds that invest in U.S. Treasury, government-backed and corporate debt securities, respectively. We are not a party to any interest rate swaps, currency hedges or derivative contracts of any type and have no exposure to commercial paper or auction rate securities markets.

Cash and cash equivalents held by our foreign subsidiaries totaled \$6.5 million and \$4.5 million at September 30, 2016 and March 31, 2016, respectively. Our operating income outside the U.S. is deemed to be permanently reinvested in foreign jurisdictions. We do not intend or currently foresee a need to repatriate cash and cash equivalents held by our foreign subsidiaries. If these funds are needed in the U.S., we believe that the potential U.S. tax impact to repatriate these funds would not have a material impact on our financial condition.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Primary Market Risk Exposures

Our cash, cash equivalents and marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10% from levels at September 30, 2016, we believe the decline in fair market value of our investment portfolio would be immaterial.

Currency Exchange Rates

We have foreign currency exposure to exchange rate fluctuations and particularly with respect to the euro, British pound sterling and Japanese yen. Therefore, our investment in our subsidiaries is sensitive to fluctuations in currency exchange rates. The effect of a change in currency exchange rates on our net investment in international subsidiaries is reflected in the accumulated other comprehensive (loss) income component of stockholders' equity. If rates of exchange for the euro, British pound and Japanese yen were to have depreciated immediately and uniformly by 10% relative to the U.S. dollar from levels at September 30, 2016, the result would have been a reduction of stockholders' equity of approximately \$6.4 million.

Fair Value of Financial Instruments

At September 30, 2016, our financial instruments consist primarily of cash and cash equivalents, short-term marketable securities, accounts receivable, accounts payable and contingent consideration. The carrying amounts of accounts receivable and accounts payable are considered reasonable estimates of their fair value, due to the short maturity of these instruments. The estimated fair values of the financial instruments have been determined by us using available market information and appropriate valuation techniques. Considerable judgment is required, however, to interpret market data to develop the estimates of fair value. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value amounts. The carrying value of our capital lease obligations approximates fair value based on the borrowing rates currently available to us for loans and capital leases with similar terms.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), as of September 30, 2016. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2016, 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 Securities and Exchange 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 Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Evaluation of Changes in Internal Control over Financial Reporting

During the second quarter of our fiscal year ending March 31, 2017, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

We are from time to time involved in various legal actions, the outcomes of which are not within our complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages, as well as other relief, which, if granted, would require significant expenditures. We record a liability in our condensed consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. We review these estimates each accounting period as additional information is known and adjust the loss provision when appropriate. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in the condensed consolidated financial statements. Material legal proceedings are discussed in “Note 9. Commitments and Contingencies—Litigation” to our condensed consolidated financial statements and are incorporated herein by reference.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this Report, you should carefully consider the factors discussed in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended March 31, 2016, which could materially affect our business, financial condition or future results. As of the date of this Report there has been no material change in any of the risk factors described in our Annual Report on Form 10-K for the fiscal year ended March 31, 2016, except as noted below:

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

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights may be applicable to our business. We may be subject to healthcare fraud and abuse regulation and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- The federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce (i) the referral of an individual, for an item or service, or (ii) the recommending, purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- The federal False Claims Act, which prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, including claims made pursuant to an unlawful kickback, and which may apply to entities like us that promote medical devices, provide medical device management services and may provide coding and billing advice to customers;
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- State law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ in significant ways from state to state and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, the compliance environment is changing, with more states, such as California, Connecticut, Nevada and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, requiring reporting to state governments of gifts, compensation

and other remuneration to physicians. The Physician Payments Sunshine Act, or PPSA, which was signed into law on March 23, 2010, requires U.S. manufacturers of drug, device, biologics, and medical supplies covered under Medicare, Medicaid, or State Children's Health Insurance Program, or SCHIP, to report payments made to physicians and teaching hospitals on an annual basis to the government. These laws all provide for penalties for non-compliance. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different and difficult compliance and reporting requirements, increases the possibility that we may run afoul of one or more laws. The costs to comply with these regulatory requirements are becoming more expensive and will also impact our profitability.

Many of these requirements are new and their application is uncertain, and regulatory guidance is limited. We could face enforcement action, fines and other penalties and could receive adverse publicity, all of which could harm our business, if it is alleged that we have failed to fully comply with such laws and regulations. Similarly, if the physicians or other providers or entities that we do business with are found not to comply with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

On April 25, 2014, the Company received a subpoena from the Boston regional office of the United States Department of Health and Human Services, or HHS, Office of Inspector General requesting materials relevant to the Company's reimbursement of employee expenses and remuneration to healthcare providers for a six month period from July 2012 through December 2012 in connection with a civil investigation under the False Claims Act (the "FCA Investigation"). The Company submitted the requested documents to HHS and believes that it substantially complied with the subpoena. On November 6, 2014, the Company received notice from the U.S. Department of Justice, U.S. Attorney's Office for the District of Massachusetts, or DOJ, in the form of a Civil Investigative Demand, or CID, requesting additional materials relating to this matter for the time period of January 1, 2012 through December 31, 2013. The Company responded to the CID, and believes that it substantially complied with the requests contained therein. On September 19, 2016, the Company received notice from the DOJ in the form of an additional CID requesting additional document production and information relating to this matter for the time period January 1, 2011 through September 14, 2016. The Company is responding to the CID, and continues to cooperate fully with the U.S. Attorney's Office in its FCA investigation.

We own patents, trademarks, trade secrets, copyrights and other intellectual property and know-how that we believe give 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. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, copyright, trade secret and domain name protection laws, as well as confidentiality agreements with our employees and others, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from using our proprietary technologies or from marketing products that are very similar or identical to ours.

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

Our business position also depends in part on our ability to maintain and defend our existing patents and obtain, maintain, and defend additional patents and other intellectual property rights. We intend to seek additional patents, but

our pending and future patent applications may not result in issued patents or be granted on a timely basis. In addition, issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. The scope of our patent claims also may vary between countries, as individual countries have distinctive patent laws. We may be subject to challenges by third parties regarding our intellectual property, including, among others, claims regarding validity, enforceability, scope and effective term. 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. Our competition may also hold or obtain intellectual property rights that would threaten our ability to develop or commercialize our product offerings. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect our business and our prospects.

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

Thoratec Corporation, or Thoratec, (acquired by St. Jude Medical, Inc. in October 2015) has challenged a number of Company owned patents in the European Patent Office or EPO, in Germany, and in the United Kingdom in connection with the launch of their HeartMate PHP medical device, or PHP, in Europe. These actions all relate to Thoratec's ability to manufacture and sell their PHP product in Europe. None of these matters impact the Company's ability to manufacture or sell its Impella products.

In October 2012, Thoratec filed a notice of opposition in the EPO to a Company owned European patent covering a 'pigtail' feature. In October 2014, the EPO dismissed Thoratec's opposition, and in December 2014, Thoratec filed a notice of appeal. The appeal is scheduled to be heard at the EPO in January 2017.

In December 2014, Thoratec filed a nullity suit in German Federal Court against a German pigtail patent owned by the Company. The validity hearing for the German pigtail patent is scheduled for November 2016. In August 2015, Thoratec filed a nullity action in German Federal Court against two Company owned patents covering a "magnetic clutch" feature. These magnetic clutch patents were acquired by the Company in July 2014, in connection with its acquisition of ECP and AIS. The validity hearing for the magnetic clutch patents is scheduled for June 2017. In September 2015, the Company filed counterclaims in the magnetic clutch action in Germany asserting that the PHP product infringes the two magnetic clutch patents and the two pigtail patents. The infringement trial is scheduled for January 2017.

In July 2015, Thoratec filed a nullity action in the High Court of Justice of England and Wales against the Company's U.K. "magnetic clutch" patents acquired from ECP and AIS. In October 2015, Thoratec added a non-infringement claim seeking a declaration that their PHP product does not infringe the patents in the United Kingdom. Thoratec's claims in the U.K. were heard at trial in early October 2016. While the English Court found on October 28, 2016, that the PHP would infringe a number of claims contained within the Company's patents, the Court found those claims to be invalid because of obviousness or lack of novelty.

In December 2015, the Company received a letter from Maquet Cardiovascular LLC, or Maquet, a subsidiary of the Getinge Group, and maker of the intra-aortic balloon pump, asserting that the Company's Impella products infringe certain claims having guidewire, lumen and sensor features and which are in two Maquet patents and one pending patent application in the U.S. and elsewhere, and encouraged the Company to discuss taking a license from Maquet. In January 2016, the Company responded to Maquet stating that it believed that the cited claims were invalid and that its Impella products did not infringe the cited patents. In May 2016, Maquet sent an additional letter notifying the Company that the pending patent application had been issued as a U.S. patent and repeated their earlier assertion and encouraged the Company to discuss taking a license from Maquet. The three patents expire September 2020, December 2020 and October 2021. On May 19, 2016, the Company filed suit in U.S. District Court for the District of Massachusetts, or D. Mass., against Maquet seeking a declaratory judgment that the Company's Impella products do not infringe Maquet's cited patent rights.

On August 24, 2016, Maquet sent another letter to the Company identifying four new continuation patent filings with claims that Maquet alleges are infringed by the Company's Impella products. Those U.S. continuation filings have not issued as patents; three of them have not yet published, the fourth is published but has not begun substantive prosecution. If the patent filings were to issue, they will expire in September 2020. On September 23, 2016, Maquet

filed an answer to the Company's suit in D. Mass., including various counterclaims alleging that the Company's Impella 2.5, Impella CP, Impella 5.0, and Impella RP heart pumps infringe certain claims of the three issued U.S. patents. The D. Mass. court has not yet set a schedule for the case.

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

(a) Not applicable.

(b) Not applicable.

(c) Not applicable.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures
Not applicable.

Item 5. Other Information
None

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Item 6. Exhibits

Exhibit No.	Description	Filed with This Form 10-Q	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
2.1	Agreement on the Sale and Transfer of all shares in ECP Entwicklungsgellschaft mbH			July 7, 2014 (File No. 8-K 001-09585)	2.1
2.2	Agreement on the Sale and Transfer of all shares in AIS GmbH Aachen Innovation Solutions			July 7, 2014 (File No. 8-K 001-09585)	2.2
3.1	Restated Certificate of Incorporation.		S-3	September 29, 1997	3.1
3.2	Restated By-Laws, as amended.			May 27, 2004 (File No. 10-K 001-09585)	3.2
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock.		S-3	September 29, 1997	3.3
3.4	Amendment to the Company's Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000.		8-K	March 21, 2007 (File No. 001-09585)	3.4
10.1	Lease Agreement dated August 12, 2016 between Abiomed, Inc. and Leo C. Thibeault, Jr., Trustee of the Thibeault Nominee Trust	X			
10.2	Change in Control Severance Agreement with Michael J. Tomsicek dated September 27, 2016	X			
31.1	Principal Executive Officer Certification pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Principal Financial Officer Certification pursuant to Securities Exchange Act Rule 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			

32.1 Principal Executive Officer and Principal Financial
Officer Certifications pursuant to 18 U.S.C. Section
1350 as adopted pursuant to Section 906 of the
Sarbanes-Oxley Act of 2002. X

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Exhibit No.	Description	Filed with This Form 10-Q Incorporated by Reference Form Filing Date Exhibit No.
101	The following financial information from the ABIOMED, Inc. Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2016 and March 31, 2016; (ii) Condensed Consolidated Statements of Operations for the three and six months ended September 30, 2016 and 2015; (iii) Condensed Consolidated Statements of Comprehensive Income for the three and six months ended September 30, 2016 and 2015; (iv) Condensed Consolidated Statements of Cash Flows for the six months ended September 30, 2016 and 2015; and (v) Notes to Condensed Consolidated Financial Statements.	X

ABIOMED, INC. AND SUBSIDIARIES

PART II. OTHER INFORMATION

SIGNATURES

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

ABIOMED, Inc.

Date: November 4, 2016 /s/ MICHAEL J. TOMSICEK
Michael J. Tomsicek
Vice President and Chief Financial Officer
(Principal Accounting and Financial Officer)