ABIOMED INC
Form 10-Q
August 06, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

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 incorporation or organization)	(IRS Employer Identification No.)

22 CHERRY HILL DRIVE

DANVERS, MASSACHUSETTS 01923

(Address of principal executive offices, including zip code)

(978) 646-1400

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 x	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 x

As of July 31, 2014, 40,463,481 shares of the registrant s common stock, $.01 par value, were outstanding.

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ABIOMED, INC. AND SUBSIDIARIES

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PART 1. FINANCIAL INFORMATION

ITEM 1: FINANCIAL STATEMENTS

ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(in thousands, except share and per share data)

	June 30, 2014	March 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,740	$ 20,916
Short-term marketable securities	52,458	55,663
Accounts receivable, net	22,763	24,357
Inventories	13,920	13,948
Prepaid expenses and other current assets	3,334	3,082
Total current assets	127,215	117,966
Long-term marketable securities	33,760	41,761
Property and equipment, net	6,716	6,889
Goodwill	37,694	37,990
Other assets	801	801
Total assets	$ 206,186	$ 205,407
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 6,759	$ 7,746
Accrued expenses	17,015	17,899
Deferred revenue	5,200	4,766
Total current liabilities	28,974	30,411
Long-term deferred tax liability	6,640	6,415
Other long-term liabilities	222	228
Total liabilities	35,836	37,054
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	415	411
Authorized - 100,000,000 shares; Issued - 41,619,312 shares at June 30, 2014 and 41,122,695 shares at March 31, 2014;		
Outstanding - 40,365,369 shares at June 30, 2014 and 39,916,328 shares at March 31, 2014		
Additional paid in capital	441,260	436,136
Accumulated deficit	(252,619)	(250,910)
Treasury stock at cost - 1,253,943 shares at June 30, 2014 and 1,206,367 shares at March 31, 2014	(17,567)	(16,554)
Accumulated other comprehensive loss	(1,139)	(730)
Total stockholders equity	170,350	168,353
Total liabilities and stockholders equity	$ 206,186	$ 205,407

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

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ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,	
	2014	**2013**
Revenue:		
Product revenue	$ 48,660	$ 42,609
Funded research and development	151	61
	48,811	42,670
Costs and expenses:		
Cost of product revenue	9,689	8,723
Research and development	9,062	7,287
Selling, general and administrative	31,598	27,967
	50,349	43,977
Loss from operations	(1,538)	(1,307)
Other income (loss):		
Investment income, net	44	16
Other income (loss), net	11	(21)
	55	(5)
Loss before income tax provision	(1,483)	(1,312)
Income tax provision	226	411
Net loss	$ (1,709)	$ (1,723)
Basic net loss per share	$ (0.04)	$ (0.04)
Basic weighted average shares outstanding	40,062	38,678
Diluted net loss per share	$ (0.04)	$ (0.04)
Diluted weighted average shares outstanding	40,062	38,678

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

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ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME

(Unaudited)

(in thousands, except per share data)

	Three Months Ended June 30,	
	2014	**2013**
Net loss	$ (1,709)	$ (1,723)
Other comprehensive (loss) income:		
Foreign currency translation (losses) gains	(436)	526
Net unrealized gains (losses) on marketable securities	27	(21)
Other comprehensive (loss) income	(409)	505
Comprehensive loss	$ (2,118)	$ (1,218)

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

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ABIOMED, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

(in thousands)

	Three Months Ended June 30,	
	2014	**2013**
Operating activities:		
Net loss	$ (1,709)	$ (1,723)
Adjustments required to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	621	652
Bad debt expense	31	15
Stock-based compensation	4,290	3,921
Write-down of inventory	206	207
Deferred tax provision	225	226
Changes in assets and liabilities:		
Accounts receivable	1,548	1,971
Inventories	(234)	(1,689)
Prepaid expenses and other assets	(255)	292
Accounts payable	(1,049)	(1,302)
Accrued expenses and other long-term liabilities	(919)	(2,397)
Deferred revenue	435	(206)
Net cash provided by (used for) operating activities	3,190	(33)
Investing activities:		
Purchases of marketable securities	(24,524)	(15,401)
Proceeds from the sale and maturity of marketable securities	35,730	17,750
Purchase of other investment		(750)
Purchases of property and equipment	(380)	(711)
Net cash provided by investing activities	10,826	888
Financing activities:		
Proceeds from the exercise of stock options	820	1,931
Payments in lieu of issuance of common stock for minimum payroll taxes	(1,013)	(426)
Net cash (used for) provided by financing activities	(193)	1,505
Effect of exchange rate changes on cash	1	(84)
Net increase in cash and cash equivalents	13,824	2,276
Cash and cash equivalents at beginning of period	20,916	9,451
Cash and cash equivalents at end of period	$ 34,740	$ 11,727

Supplemental disclosures:		
Cash paid for income taxes	$ 172	$ 798
Fixed asset expenditures incurred, not yet paid	215	86

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

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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 leading provider of mechanical circulatory support devices and offers a continuum of care in heart recovery 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, 2014 that has been filed with the Securities and Exchange Commission, or SEC.

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

There have been no changes in the Company s significant accounting policies for the three months ended June 30, 2014 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, 2014 that has been filed with the SEC.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board 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 is effective for the Company in the first quarter of fiscal 2017. Early adoption is not permitted. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

Note 2. Net (Loss) Income Per Share

Basic net (loss) income per share is computed by dividing net (loss) income by the weighted average number of common shares outstanding during the period. Diluted net (loss) income per share is computed by dividing net (loss) 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 awards, 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 (loss) income per share for the three months ended June 30, 2014 and 2013 were as follows (in thousands, except per share data):

	Three Months Ended June 30,	
	2014	2013
Basic Net (Loss) Income Per Share		
Net loss	$ (1,709)	$ (1,723)
Weighted average shares used in computing basic net loss per share	40,062	38,678
Net loss per share - basic	$ (0.04)	$ (0.04)

	Three Months Ended June 30,	
	2014	2013
Diluted Net (Loss) Income Per Share		
Net loss	$ (1,709)	$ (1,723)
Weighted average shares used in computing basic net loss per share	40,062	38,678
Effect of dilutive securities		
Weighted average shares used in computing diluted net loss per share	40,062	38,678
Net loss per share - diluted	$ (0.04)	$ (0.04)

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For the three months ended June 30, 2014, approximately 3,678,000 shares underlying stock options and approximately 1,242,000 restricted shares and restricted stock units were excluded from the calculation of diluted weighted average shares outstanding because the Company incurred a loss in the period and to include them would have been anti-dilutive.

For the three months ended June 30, 2013, approximately 4,326,000 shares underlying stock options and approximately 1,168,000 restricted shares and restricted stock units were excluded from the calculation of diluted weighted average shares outstanding because the Company incurred a loss in the period and to include them would have been anti-dilutive.

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 June 30, 2014 and March 31, 2014 are invested in the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
		(in $000 s)		
At June 30, 2014:				
US Treasury securities	$ 19,486	$	$	$ 19,486
Short-term government-backed securities	32,963	11	(2)	32,972
Long-term government-backed securities	33,758	11	(9)	33,760
	$ 86,207	$ 22	$ (11)	$ 86,218

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
		(in $000 s)		
At March 31, 2014:				
US Treasury securities	$ 31,487	$	$	$ 31,487
Short-term government-backed securities	24,174	6	(4)	24,176
Long-term government-backed securities	41,779	8	(26)	41,761
	$ 97,440	$ 14	$ (30)	$ 97,424

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.

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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 consolidated balance sheet, classified according to the three categories described above:

	Level 1	Level 2	Level 3	Total
		(in $000 s)		
At June 30, 2014:				
U.S. Treasury securities		$ 19,486		$ 19,486
Short-term government-backed securities		32,972		32,972
Long-term government-backed securities		33,760		33,760
		$ 86,218		$ 86,218

	Level 1	Level 2	Level 3	Total
		(in $000 s)		
At March 31, 2014:				
U.S. Treasury securities		$ 31,487		$ 31,487
Short-term government-backed securities		24,176		24,176
Long-term government-backed securities		41,761		41,761
		$ 97,424		$ 97,424

Note 4. Inventories

The components of inventories are as follows:

	June 30, 2014	March 31, 2014
	(in $000 s)	
Raw materials and supplies	$ 6,534	$ 6,414
Work-in-progress	6,295	6,261
Finished goods	1,091	1,273

	$ 13,920	$ 13,948

The Company s inventories relate to its circulatory care product lines, primarily the Impella and AB5000 product platforms. Finished goods and work-in-process inventories consist of direct material, labor and overhead. The Company recorded $0.2 million in each of the three months ended June 30, 2014 and 2013, in write-downs of inventory.

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Note 5. Goodwill

The carrying amount of goodwill at June 30, 2014 and March 31, 2014 was $37.7 million and $38.0 million, respectively, and has been recorded in connection with the Company s acquisition of Impella Cardiosystems AG, or Impella, in 2005. The goodwill activity for the three months ended June 30, 2014 is as follows:

	(in $000 s)
Balance at March 31, 2014	$ 37,990
Exchange rate impact	(296)
Balance at June 30, 2014	$ 37,694

The Company has no accumulated impairment losses on goodwill.

Note 6. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2014	March 31, 2014
	(in $000 s)	
Employee compensation	$ 11,798	$ 11,967
Research and development	1,403	1,587
Sales and income taxes	1,215	1,445
Professional, legal and accounting fees	998	1,304
Warranty	813	794
Other	788	802
	$ 17,015	$ 17,899

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at June 30, 2014 and March 31, 2014.

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Note 7. Stock-Based Compensation

The following table summarizes stock-based compensation expense by financial statement line item in the Company s consolidated statements of operations for the three months ended June 30, 2014 and 2013:

	Three Months Ended June 30,	
	2014	2013
	(in $000 s)	
Cost of product revenue	$ 209	$ 208
Research and development	853	745
Selling, general and administrative	3,228	2,968
	$ 4,290	$ 3,921

The components of stock-based compensation for the three months ended June 30, 2014 and 2013 were as follows:

	Three Months Ended June 30,	
	2014	2013
	(in $000 s)	
Restricted stock units and awards	$ 3,420	$ 2,936
Stock options	799	925
Employee stock purchase plan	71	60
	$ 4,290	$ 3,921

Stock Options

The following table summarizes the stock option activity for the three months ended June 30, 2014:

	Shares Underlying Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at April 1, 2014	3,492	$ 13.27	4.92	
Granted	256	21.55		
Exercised	(67)	9.99		
Cancelled and expired	(3)	17.67		
Outstanding at June 30, 2014	3,678	$ 13.90	5.08	$ 41,412

Exercisable at June 30, 2014	2,938	$ 11.93	4.11	$	38,802
Options vested and expected to vest at June 30, 2014	3,614	$ 13.78	5.01	$	41,108

The aggregate intrinsic value of options exercised was $0.8 million for the three months ended June 30, 2014. The total fair value of options vested during the three months ended June 30, 2014 was $2.2 million.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at June 30, 2014 was approximately $5.9 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 value for options granted during the nine months ended June 30, 2014 and 2013 was $8.78 and $9.68 per share, respectively.

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The fair value of options granted during the three months ended June 30, 2014 and 2013 were calculated using the following weighted average assumptions:

	Three Months Ended June 30,	
	2014	2013
Risk-free interest rate	1.57%	0.85%
Expected option life (years)	4.19	4.26
Expected volatility	49.4%	51.9%

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on the historical volatility of the Company s stock and adjustments for factors not reflected in historical volatility that may be more indicative of future volatility. The Company estimates the expected term of options based on historical exercise experience and estimates of future exercises of unexercised options. An expected dividend yield of zero is used in the option valuation model because the Company does not pay cash dividends and does not expect to pay any cash dividends in the foreseeable future. The Company estimates forfeitures based on an analysis of actual historical forfeitures, adjusted to reflect that historical forfeitures may not be indicative of forfeitures in the future.

Restricted Stock and Restricted Stock Units

In addition to stock option grants, the Company also has the ability to grant restricted stock and restricted stock units. Similar to stock options, these restricted stock and restricted stock unit grants are subject to certain vesting criteria. The following table summarizes the activity for the three months ended June 30, 2014:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value (per share)
Outstanding at April 1, 2014	1,174	$ 21.37
Granted	610	21.55
Vested	(429)	20.51
Forfeited	(113)	23.13
Outstanding at June 30, 2014	1,242	$ 21.59

The remaining unrecognized compensation expense for outstanding restricted stock awards and restricted stock units, including performance-based awards, as of June 30, 2014 was $18.5 million and the weighted-average period over which this cost will be recognized is 2.2 years.

The weighted average grant-date fair value for restricted stock and restricted stock units granted during the three months ended June 30, 2014 and 2013 was $21.55 and $23.15 per share, respectively. The total fair value of restricted stock and restricted stock units vested during the three months ended June 30, 2014 and 2013 was $8.8 million and $5.7 million, respectively.

Performance Based Awards

Included in the restricted stock and restricted stock units activity discussed above are certain awards that vest subject to certain performance-based criteria.

In May 2014, performance-based awards of restricted stock units for the potential issuance of 379,752 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 June 30, 2014, the Company is recognizing compensation expense based on the probable outcome related to the prescribed performance targets on the outstanding awards.

In May 2013, performance-based awards of restricted stock units for the potential issuance of 268,988 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 June 30, 2014, the Company has met the prescribed performance milestones for these awards. These awards are still subject to service requirements for vesting for these employees and the compensation expense is being recognized accordingly.

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In May 2012, performance-based awards of restricted stock units for the potential issuance of 195,188 shares of common stock were issued to certain executive officers and employees of the Company, all of which will vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of June 30, 2014, the Company has met the prescribed performance milestones for these awards. These awards are still subject to service requirements for vesting for these employees and the compensation expense is being recognized accordingly.

In May 2011 and June 2011, performance-based awards of restricted stock units for the potential issuance of 284,000 shares of common stock were issued to certain executive officers and members of the senior management of the Company, which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of June 30, 2014, the Company has met the prescribed milestones for 234,000 shares underlying these awards and recorded all related stock compensation expense. In March 2014, the Company modified the performance condition on the remaining 50,000 restricted stock units. As of June 30, 2014, the Company believes that it is probable that the prescribed performance milestones will be met on these restricted stock units and the compensation expense is being recognized accordingly.

During the three months ended June 30, 2014, the Company has recorded $1.6 million in stock-based compensation expense for equity awards in which the prescribed performance milestones have been achieved or are probable of being achieved. The remaining unrecognized compensation expense related to these equity awards at June 30, 2014 is $9.4 million based on the Company s current assessment of probability of achieving the performance milestones. The weighted-average period over which this cost will be recognized is 2.1 years.

Note 8. Income Taxes

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax basis of assets and liabilities and their financial reporting amounts at each fiscal year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce net deferred tax assets to the amount that is more likely than not to be realized.

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realization of deferred tax assets requires significant management judgment. In determining whether its deferred tax assets are more likely than not realizable, the Company evaluated all available positive and negative evidence, and weighted the evidence based on its objectivity. Evidence the Company considered included, its history of net operating losses incurred for most of its existence, expiration of various federal and state attributes, the uncertainty relative to the Department of Justice and Office of Inspector General investigations of the Company and the Company s Pre-Market Approval, or PMA, application with the U.S. Food and Drug Administration, or FDA, for its Impella products, the Company s expansion into new markets, such as Japan, the government reimbursement environment for the Company s products, the Company s profitability for recent years and uncertainties around the Company s forecasted profit before tax for fiscal 2015. Based on the review of all available evidence, the Company determined that the objectively verifiable negative evidence outweighed the positive evidence and it recorded a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realizable as of June 30, 2014. The Company will continue to assess the level of the valuation allowance required. If sufficient positive evidence exists in future periods to support a release of some or all of the valuation allowance, such a release would likely have a material impact on its results of operations.

As of June 30, 2014, the Company has accumulated a net deferred tax liability of $6.6 million which is the result of the difference in accounting for the Company s goodwill, which is amortizable over 15 years for tax purposes but not amortizable for book purposes. The net deferred tax liability cannot be offset against the Company s deferred tax assets

since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period.

The Company and its subsidiaries are subject to U.S. federal income tax, as well as income tax of multiple state and foreign jurisdictions. The Company has accumulated significant losses since its inception in 1981. All tax years remain subject to examination by major tax jurisdictions, including the federal government and the Commonwealth of Massachusetts. However, because the Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, those years may also be subject to review by relevant taxing authorities if the carryforwards are utilized.

Note 9. Commitments and Contingencies

Commitments

In July 2013, the Company entered into a lease agreement to continue renting its existing space in Aachen, Germany through July 31, 2023. The building serves as the Company s European headquarters and houses most of the manufacturing operations for its Impella product line. The lease payments are approximately 34,500 (euro) (approximately U.S. $47,000 at June 30, 2014 exchange rates) per month.

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In February 2014, the Company entered into a lease agreement to continue renting its existing space in Danvers, Massachusetts through February 28, 2021. Monthly rent is as follows:

The base rent for March 2014 through April 2014 was $66,000 per month; and

The base rent for May 2014 through February 2016 is $74,050 per month; and

The base rent for March 2016 through February 2018 will be $70,750 per month; and

The base rent for March 2018 through February 2021 will be $72,750 per month.

License agreement

In April 2014, the Company entered into an exclusive license agreement with Opsens, Inc. 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 agreed to make additional payments of up to $4.5 million upon the achievement of certain development milestones.

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 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 consolidated financial statements.

On October 26, 2012, the Company was informed that the United States Attorney s Office for the District of Columbia is conducting an investigation that is focused on the Company s marketing and labeling of the Impella 2.5. On October 31, 2012, the Company accepted service of a subpoena related to this investigation seeking documents related to the Impella 2.5. The Company believes that is has substantially complied with the subpoena and has submitted the requested documents to the United States Attorney s Office. On September 13, 2013, the Company entered into a tolling agreement with the United States Attorney s Office, pursuant to which the Company and the United States Attorney s Office mutually agreed to toll the applicable statutes of limitations for all criminal, civil and administrative offenses and violations that could be charged or claimed against the Company as of that date until June 2, 2014. On May 27, 2014, the Company executed an extension of the tolling agreement through February 2, 2015. The investigation is ongoing, however, the Company is unable to predict the ultimate outcome or determine whether a liability has been incurred or make an estimate of the reasonably possible liability, if any, that could result from any unfavorable outcome associated with this inquiry. The Company has incurred significant expenses related to this investigation and expects to continue to incur additional expenses in the future.

On November 16 and 19, 2012, two purported class action complaints were filed against the Company and certain of its officers in the U.S. District Court for the District of Massachusetts by alleged purchasers of its common stock, on behalf of themselves and persons or entities that purchased or acquired securities of the Company between August 5, 2011 and October 31, 2012. The complaints alleged that the defendants violated the federal securities laws in connection with disclosures related to the FDA and the marketing and labeling of the Company s Impella 2.5 product and seek damages in an unspecified amount. The Court consolidated these complaints and a consolidated amended complaint was filed by the plaintiffs on May 20, 2013. On July 8, 2013, the Company filed a motion to dismiss the consolidated class action. Oral arguments on the Company s motion to dismiss were conducted before the presiding district court judge on September 18, 2013. On April 10, 2014, the U.S. District Court entered an order granting our motion and dismissed the consolidated and amended complaint. On May 9, 2014, the plaintiffs filed a notice of appeal, and subsequently filed their appellate brief with the U.S. Court of Appeals for the First Circuit on July 16, 2014. The appeal process remains ongoing.

On February 4, 2013, an alleged stockholder of the Company filed a derivative action on the Company s behalf against each of the Company s directors in the U.S. District Court for the District of Massachusetts. The complaint alleged that the directors breached their fiduciary duties to the Company and its stockholders in connection with disclosures related to the FDA and the marketing and labeling of its Impella 2.5 product and sought damages in an unspecified amount. On March 22, 2013, the Company filed a motion to dismiss the derivative action. On June 21, 2013, the District Court granted the Company s motion to dismiss. The plaintiff appealed the dismissal to the U.S. Court of Appeals for the First Circuit. Oral argument was conducted before the appellate court on February 5, 2014, and the U.S. Court of Appeals for the First Circuit affirmed the District Court s Order of Dismissal in a written opinion issued on June 10, 2014.

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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 expenses and remuneration to healthcare providers for a six month period from July 2012 through December 2012. The Office of Inspector General has informed the Company that the subpoena currently relates to a civil investigation. The Company believes that it has substantially complied with the subpoena and has submitted the requested documents to HHS.

The Company is unable to estimate its potential liability with respect to the Department of Justice investigation, the Office of Inspector General s investigation and the appeal of the dismissal of the purported class action claim. There are numerous factors that make it difficult to meaningfully estimate possible loss or range of loss at this stage of the investigation and lawsuits, including that: the proceedings are in relatively early stages, there are significant factual and legal issues to be resolved, information obtained or rulings made during any lawsuits or investigations could affect the methodology for calculation. In addition, with respect to claims where damages are the requested relief, no amount of loss or damages has been specified. Therefore, the Company is unable at this time to estimate its possible losses and accordingly, 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. Approximately 65% and 74% of the Company s total consolidated assets are located within the U.S. as of June 30, 2014 and March 31, 2014, respectively. The remaining assets are located primarily in Germany and include goodwill of $37.7 million and $35.4 million at June 30, 2014 and March 31, 2014, respectively, associated with the Impella acquisition in May 2005. Total assets outside of the U.S. excluding goodwill amounted to 17% and 8% of total consolidated assets as of June 30, 2014 and March 31, 2014, respectively. International sales (sales outside the U.S. and primarily in Europe) accounted for 11% and 8% of total revenue for the three months ended June 30, 2014 and 2013, respectively.

Note 11. Subsequent Events

Acquisition of ECP Entwickslungsgesellschaft mbH

On July 1, 2014, the Company s wholly-owned German subsidiary, Abiomed Europe GmbH (Abiomed Europe) and the Company, entered into a share purchase agreement with Syscore GmbH, a limited liability company incorporated in Germany (Syscore), providing for the acquisition of all of the issued shares of ECP Entwicklungsgesellschaft GmbH, a limited liability company incorporated in Germany (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 Company acquired ECP for $13.0 million in cash, with additional potential payouts up to a maximum of $15.0 million payable to Syscore based on the achievement of certain technical and commercial milestones. These milestone payments may be made, at the Company s option, by a combination of cash or its common stock. The Company placed $1.3 million of the initial closing payment in escrow for the purpose of partially securing any amounts payable by Syscore as a result of the indemnification provisions in the agreement.

ECP s Acquisition of AIS GmbH Aachen Innovative Solutions

On July 1, 2014, in connection with the Company s acquisition of ECP, ECP acquired all of the issued shares of AIS GmbH Aachen Innovative Solutions (AIS), a limited liability company incorporated in Germany. 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. The purchase price for the acquisition of AIS s shares was $2.8 million in cash and the acquisition closed immediately prior to Abiomed Europe s acquisition of ECP.

The acquisitions will be accounted for as a business combination which requires that the consideration exchanged and net assets acquired be recorded in the Company s financial statements at their respective fair values at the date of acquisition. The Company will include the financial results of ECP and AIS in its consolidated financial statements commencing July 1, 2014. Based upon the timing of the acquisitions subsequent to the Company s first quarter of fiscal 2015, the initial accounting for the business combination is

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incomplete at the time of filing this report. The Company is currently in the process of determining the purchase accounting impact of the acquisitions. As a result, the Company is unable to provide amounts recognized as of the acquisition date for major classes of assets and liabilities acquired and certain required disclosures. If material, the Company will include this in future financial statements.

To date through June 30, 2014, the Company has incurred $0.7 million in transaction costs related to these acquisitions, which have been recorded in general and administrative expenses.

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

Forward Looking Statements

Abiomed s discussion of financial condition and results of operations may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Our actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, including the potential for future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, litigation matters, future capital needs and uncertainty of additional financing and other risks and challenges detailed in our filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this Report. In particular, we encourage you to review the risks and uncertainties discussed under Item 1A of Part I of our Annual Report on Form 10-K, for the year ended March 31, 2014. We undertake no obligation to release publicly the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this Report or to reflect the occurrence of unanticipated events.

Overview

We are a leading provider of 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 and/or performing the pumping function of the heart. Our products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists and 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. We believe heart recovery is the optimal clinical outcome for patients experiencing heart failure because it restores their quality of life. In addition, we believe that for the care of such patients, heart recovery is 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 Impella family of products. Our Impella 2.5 product received 510(k) clearance in June 2008 from the U.S. Food and Drug Administration, or FDA, for partial circulatory support for up to six hours. We received 510(k) clearance in April 2009 for our Impella 5.0 and Impella LD devices for circulatory support for up to six hours. These devices are larger and provide more blood flow to patients than the Impella 2.5. In September 2012, our Impella CP product received 510(k) clearance from the FDA for partial circulatory support for up to six hours. Our Impella 2.5, Impella 5.0, Impella LD and Impella CP products also have CE Mark approval and Health Canada approval which allow us to market these devices in the European Union and Canada.

In November 2012, we announced that the Impella RP received Investigational Device Exemption, or IDE, approval from the FDA for use in RECOVER RIGHT, a pivotal clinical study in the U.S. The RECOVER RIGHT study was designed to enroll up to 30 patients with signs of right side heart failure who require hemodynamic support and are being treated in the cath lab or surgery suite. 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. In April 2013, we enrolled the first patient in RECOVER RIGHT and we completed enrollment for the 30 patients in the Impella RP RECOVER RIGHT study in March 2014. In May 2014, we received approval for implementation of a Continuous Access Protocol, or CAP, from the FDA for the RECOVER RIGHT RP trial. The CAP will allow us to enroll up to 22 additional patients at the 15 U.S. investigational sites for a six month period, from the date of the CAP approval. In April 2014, the Impella RP received CE Marking approval

which allows for commercial sale of Impella RP in the EU and other countries that require a CE Marking approval for commercial sale. This product is not currently available for commercial use outside of Europe.

In December 2012, as part of the FDA s 515 Program Initiative, an FDA panel voted to recommend continuation of Class III status for temporary ventricular support devices within the non-roller type cardiopulmonary bypass blood pumps category, which includes our Impella products. The panel s recommendation of Class III for this category of device is consistent with the current Class III designation for these device types. The FDA accepted the Panel s recommendation recently as reflected in its issuance of a Proposed Order reflecting this categorization. The Proposed Order was open for public comment until April 7, 2014. The FDA process will then be to address the public comments and over an unspecified period of time develop and issue a final order classifying these devices in Class III. We will then be required to file a PMA application for our Impella products within 90 days from the issuance of the Final Order. Under the 515 Program Initiative, we will be permitted to continue to market our Impella products pursuant to the 510(k) clearance for a sufficient period of time to allow for the submission and review of PMA applications relating to our Impella products.

We have been working with the FDA to submit a modular PMA submission for Impella 2.5 in response to the Panel s recommendation of Class III for Impella products. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. The FDA has confirmed that it agrees with our proposed shell for the modular PMA and we submitted all modules required by the FDA as part of the planned modular PMA submission in March 2014. The PMA will be treated as a standard PMA and all modules have now been consolidated for final review by the FDA.

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In November 2011, we announced Symphony, a synchronized minimally invasive implantable cardiac assist device designed to treat chronic patients with moderate heart failure by improving patient hemodynamics and potentially improving their quality of life. The device is designed with the primary goal of stabilizing the progression of heart failure and recovering or remodeling the heart. We are currently conducting first-in-human clinical trials of Symphony outside the U.S. This product is not currently approved by the FDA for sale in the U.S.

On October 26, 2012, we were informed that the United States Attorney s Office for the District of Columbia is conducting an investigation that is focused on our marketing and labeling of the Impella 2.5. On October 31, 2012, we accepted service of a subpoena related to this investigation seeking documents related to the Impella 2.5. We believe we have substantially complied with the subpoena and have submitted the requested documents to the United States Attorney s Office. On September 13, 2013, we entered into a tolling agreement with the United States Attorney s Office, pursuant to which we and the United States Attorney s Office mutually agreed to toll the applicable statutes of limitations for all criminal, civil and administrative offenses and violations that could be charged or claimed against us as of that date until June 2, 2014. On May 27, 2014, we executed an extension of the tolling agreement through February 2, 2015. The investigation is ongoing, however, we are unable to predict the ultimate outcome or determine whether a liability has been incurred or make an estimate of the reasonably possible liability, if any, that could result from any unfavorable outcome associated with this inquiry. We have incurred significant expenses related to this investigation and we expect to continue to incur additional expenses in the future.

On November 16 and 19, 2012, two purported class action complaints were filed against us and certain of our officers in the U.S. District Court for the District of Massachusetts by alleged purchasers of our common stock, on behalf of themselves and persons or entities that purchased or acquired our securities between August 5, 2011 and October 31, 2012. The complaints alleged that the defendants violated the federal securities laws in connection with disclosures related to the FDA and the marketing and labeling of our Impella 2.5 product and seek damages in an unspecified amount. The Court consolidated these complaints and a consolidated amended complaint was filed by the plaintiffs on May 20, 2013. On July 8, 2013, we filed a motion to dismiss the consolidated class action. Oral arguments on our motion to dismiss were conducted before the presiding district court judge on September 18, 2013. On April 10, 2014, the U.S. District Court entered an order granting our motion and dismissed the consolidated and amended complaint. On May 9, 2014, the plaintiffs filed a notice of appeal, and subsequently filed their appellate brief with the U.S. Court of Appeals for the First Circuit on July 16, 2014. The appeal process remains ongoing.

On February 4, 2013, an alleged stockholder of the Company filed a derivative action on our behalf against each of our directors in the U.S. District Court for the District of Massachusetts. The complaint alleged that the directors breached their fiduciary duties to us and our stockholders in connection with disclosures related to the FDA and the marketing and labeling of our Impella 2.5 product and sought damages in an unspecified amount. On March 22, 2013, we filed a motion to dismiss the derivative action. On June 21, 2013, the District Court granted our motion to dismiss. The plaintiff appealed the dismissal to the U.S. Court of Appeals for the First Circuit. Oral argument was conducted before the appellate court on February 5, 2014, and the U.S. Court of Appeals for the First Circuit affirmed the District Court s Order of Dismissal in a written opinion issued on June 10, 2014.

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On July 1, 2014, we acquired all of the issued shares of ECP Entwicklungsgesellschaft GmbH, a German limited liability company, or ECP, 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 and commercial milestones. 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. 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. 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.

Our revenues are primarily generated from our Impella line of products. Revenues from our non-Impella products, largely focused on the heart surgery suite, have been lower over the past several years as we have strategically shifted our sales and marketing efforts towards our Impella products and the cath lab. We expect revenues from our non-Impella products, primarily AB5000, will continue to decrease as we continue to focus on our Impella products.

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For the three months ended June 30, 2014, we recognized a net loss of $1.7 million. We may incur additional losses in the future as we continue to invest in research and development related to our products, conduct clinical studies and registries on our products, expand our commercial infrastructure, incur additional legal fees to comply with the ongoing investigations by the Department of Justice and the Office of the Inspector General and defend ourselves from other legal claims, incur additional costs in preparing our PMA application, absorb activities related to the ECP business we acquired in July 2014, enter into collaborations with other parties and invest in new markets such as Japan.

Impella 2.5

The Impella 2.5 catheter is a percutaneous micro heart pump with an integrated motor and sensors. The device is designed primarily for use by interventional cardiologists to support patients in the cath lab who may require assistance to maintain their circulation. The Impella 2.5 device received 510(k) clearance from the FDA in June 2008 for partial circulatory support for up to six hours, has CE mark approval in Europe for up to five days of use and is approved for use in over 40 countries.

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.

In August 2007, we received approval from the FDA to begin a high-risk percutaneous coronary intervention, or PCI, pivotal clinical trial, known as the Protect II study, for the Impella 2.5. This pivotal study was a superiority study to determine the safety and effectiveness of the Impella 2.5 as compared to medical management with an intra-aortic balloon, or IAB, during high-risk angioplasty procedures. In December 2010, we announced the termination of the Protect II study based on a futility determination at the planned interim analysis regarding the primary end-point, which we view as likely to have resulted from how rotational atherectomy was performed by investigators in the study.

In November 2011, we announced additional analysis of the results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 22% relative reduction in major adverse events compared to an intraortic balloon pump, or IAB, at 90 days per protocol (p=0.023), a 52% relative reduction in repeat revascularization (p=0.024) and a 56% relative reduction in material adverse events post hospital discharge (p=0.002). Furthermore, additional data analysis of the clinical data from the Protect II trial revealed that more aggressive revascularization is beneficial for patients with coronary artery disease and reduced left ventricular function.

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, for the first time, included Impella 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 for use in mechanical circulatory support; a December 2012 update to the ACCF/AHA *Guidelines for the Management of ST-Elevation Myocardial Infarction* (STEMI) included Impella for use in patients requiring urgent coronary artery bypass grafting with STEMI and in treatment of patients with cardiogenic shock complications after STEMI; and a January 2013 update to the International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support included Impella for the first time for patients with multi-organ failure.

We are currently conducting USpella, the first U.S. multicenter observational registry collecting clinical data and outcomes for general use patients supported with Impella 2.5, CP, and 5.0 during procedures. In December 2012, as part of the FDA s 515 Program Initiative, an FDA panel voted to recommend continuation of Class III status for temporary ventricular support devices within the non-roller type cardiopulmonary bypass blood pumps category, which includes our Impella products. The panel s recommendation of Class III for this category of device is consistent with the current Class III designation for these device types. The FDA accepted the Panel s recommendation recently as reflected in its issuance of a Proposed Order reflecting this categorization. If the FDA issues a final order classifying these devices in Class III, we will be required to file a PMA application for our Impella products. We will have 90 days to file the PMA from the issuance of the Final Order. Under the 515 Program Initiative, we will be permitted to continue to market our Impella products pursuant to the 510(k) clearance for a sufficient period of time to allow for the submission and review of PMA applications relating to our Impella products.

Pursuant to discussions with the FDA, we have agreed to submit a modular PMA submission for Impella 2.5. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. In July 2013, we received written notification that the FDA has reviewed our proposed PMA shell for modular review of Impella 2.5. The FDA has confirmed that it agrees with our proposed shell. In March 2014, we submitted all of the modules required by the FDA as part of the planned modular PMA submission. The PMA will be treated as a standard PMA and all modules have now been consolidated for final review by the FDA.

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Impella CP

In September 2012, we announced that the Impella CP received 510(k) clearance from the FDA. The Impella CP provides blood flow of approximately one liter more per minute than the Impella 2.5 and is indicated for up to six hours of partial circulatory support using an extracorporeal bypass control unit. It is also intended to be used to provide partial circulatory support, for up to six hours, during procedures not requiring cardiopulmonary bypass. The Impella CP received CE Mark approval to be marketed in the European Union in April 2012 and Health Canada approval to be marketed in Canada in June 2012. We began selling Impella CP in the U.S. during the second quarter of fiscal 2013.

Impella 5.0 and Impella LD

The Impella 5.0 and Impella LD are percutaneous micro heart pumps with integrated motors and sensors for use primarily in the heart surgery suite. These devices are designed to support patients who require higher levels of circulatory support as compared to the Impella 2.5. The Impella 5.0 and Impella LD devices received 510(k) clearance in April 2009, for circulatory support for up to six hours and have CE Mark approval in Europe for up to ten days duration and are approved for use in over 40 countries.

The Impella 5.0 can be quickly implanted via a small incision in the femoral artery in the groin using a guide wire to reach the left ventricle of the heart where it can then be directly deployed to draw blood out of the ventricle, deliver it to the arterial system and perfuse the heart muscle. This function is intended to reduce ventricular work. The Impella LD is similar to the Impella 5.0 but is implanted directly through an aortic graft. The Impella 5.0 and Impella LD can pump up to five liters of blood per minute, providing full circulatory support.

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 heart failure. In November 2012, we announced that the Impella RP 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 at sites that present with signs of right side heart failure, require hemodynamic support, and are 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 and will be applied towards the submission of a Humanitarian Device Exemption, or HDE. In May 2014, we received approval for implementation of a Continuous Access Protocol, or CAP, from the FDA for the RECOVER RIGHT RP trial. The CAP will allow us to enroll up to 22 additional patients at the 15 U.S. investigational sites for a six month period from the date of the CAP approval.

We expect that the HDE will be approved in late fiscal 2015. 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. Approval of an HDE 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 PMA that are available to treat the targeted population. An approved HDE authorizes sales of the device to any hospital after Institutional Review Board review and approval by the hospital. In April 2014, the Impella RP received CE Marking approval which allows for commercial sales of Impella RP in the EU and other countries that require a CE Marking approval for sales. This product is not currently available for commercial use outside of Europe.

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. 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.

Symphony

In November 2011, we announced Symphony, a synchronized minimally invasive implantable cardiac assist device designed to treat chronic patients with moderate heart failure by improving patient hemodynamics and potentially improving their quality of life. The device is designed with the primary goal of stabilizing the progression of heart failure and recovering or remodeling the heart. To date, we have implanted the device in four patients in first-in-human clinical trials of Symphony outside the U.S. We are evaluating the results of these cases and expect to conduct additional Symphony trials outside of the U.S. in fiscal 2015. Symphony is not currently approved by the FDA for sale in the U.S.

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Critical Accounting Policies

There have been no significant changes in our critical accounting policies during the three months ended June 30, 2014, 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 Ma