

ABIOMED INC
Form 10-K
May 28, 2013
[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For fiscal year ended March 31, 2013

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
*(State or Other Jurisdiction of
Incorporation or Organization)*

04-2743260
*(I.R.S. Employer
Identification No.)*

22 Cherry Hill Drive
Danvers, Massachusetts

01923

Edgar Filing: ABIOMED INC - Form 10-K

(Address of Principal Executive Offices)

(978) 646-1400

(Zip Code)

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange
Common Stock, \$.01 par value	on Which Registered
	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Rule 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 ☒

Non-accelerated filer ☐

Accelerated filer ☐

Smaller reporting company ☐

(Do not check if a 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 ☒

The aggregate market value of the registrant's common stock as of September 30, 2012, held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of such date was \$832,362,795. As of May 15, 2013, 38,735,227 shares of the registrant's common stock, \$.01 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for Abiomed, Inc.'s 2012 Annual Meeting of Stockholders, which is scheduled to be filed within 120 days after the end of Abiomed, Inc.'s fiscal year, are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K.

Table of Contents**TABLE OF CONTENTS**

	Page
<u>PART I</u>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	12
Item 1B. <u>Unresolved Staff Comments</u>	26
Item 2. <u>Properties</u>	26
Item 3. <u>Legal Proceedings</u>	26
Item 4. <u>Mine Safety Disclosures</u>	26
<u>PART II</u>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	27
Item 6. <u>Selected Financial Data</u>	29
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	30
Item 7A. <u>Quantitative and Qualitative Disclosure About Market Risk</u>	38
Item 8. <u>Financial Statements and Supplementary Data</u>	39
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	39
Item 9A. <u>Controls and Procedures</u>	39
Item 9B. <u>Other Information</u>	42
<u>PART III</u>	
Item 10. <u>Director, Executive Officers and Corporate Governance</u>	42
Item 11. <u>Executive Compensation</u>	42
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	42
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	42
Item 14. <u>Principal Accountant Fees and Services</u>	42
<u>PART IV</u>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	43

Table of Contents

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the documents incorporated by reference in this report, includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, may and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements in these documents include, but are not necessarily limited to, those relating to:

our ability to obtain and maintain regulatory approval both in the U.S. and abroad for our existing products as well as for new products in development;

the ability of patients and other customers using our products to obtain reimbursement of their medical expenses by government healthcare programs and private insurers including potential changes to current government and private insurers' reimbursements;

other competing therapies that may in the future be available to heart failure patients;

our plans to develop and market new products and improve existing products;

the potential markets that exist or could develop for our products and products under development;

our business strategy;

our revenue growth expectations, our level of operating and capital expenses and our goal of achieving and maintaining profitability; and

the sufficiency of our liquidity and capital resources.

Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the Risk Factors section set forth in Part I, Item 1A and elsewhere in this report. In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this report or in any document incorporated by reference might not occur. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference. We do not undertake any obligation to update or alter any forward-looking statements whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Table of Contents

PART I

ITEM 1. BUSINESS

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, and principally our Impella 2.5 product, which 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, we announced that our Impella CP product received 510(k) clearance from the FDA for partial circulatory support for up to six hours. The Impella CP (previously marketed outside of the U.S. as Impella cVAD) received CE Mark approval to market the device in the European Union and Health Canada approval to market the device in Canada. We initiated a controlled launch with top heart hospitals in the U.S. during the second quarter of fiscal 2013 and we continued to expand the introduction of Impella CP to more hospitals in the U.S. during the second half of fiscal 2013, which we expect to continue over the next 12 months.

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 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 announced the enrollment of the first patient in RECOVER RIGHT and we expect to enroll 30 patients with signs of right side heart failure and are being treated in the cath lab or surgery suite. We are also conducting initial patient use trials of the Impella RP outside of the U.S. This product is not currently available for commercial use.

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. If the FDA accepts the panel's determination and issues a final order classifying these devices in Class III, we will be required to file a Pre-Market Approval, or PMA application for Impella 2.5. 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 intend to submit a modular PMA submission for Impella by the end of fiscal 2014. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. We are working with the FDA to prepare this modular PMA application for our Impella products.

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.

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 recently 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, including BVS and AB5000, will continue to decrease as we continue to focus on our Impella products.

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 the Company's marketing and labeling of the Impella 2.5. On October 31, 2012, we accepted service of a subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5. We are in the process of responding and we intend to cooperate fully with the subpoena.

Table of Contents

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 allege 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 has consolidated these complaints. A consolidated amended complaint was filed by us on May 20, 2013.

Additionally, on February 4, 2013, an alleged holder of our common stock 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 alleges 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 seeks damages in an unspecified amount. We have moved to dismiss the complaint in its entirety, and that motion has been briefed, argued and is under advisement by the Court. Separately, on January 21, 2013 and February 5, 2013, we received demands from purported stockholders to inspect certain of our books and records related to these matters.

In June 2011, we received a warning letter from the FDA and a follow up letter in April 2012 stating that some of our promotional materials had marketed Impella 2.5 for uses that had not been approved by the FDA. We cooperated with the FDA and made changes to our promotional materials in response to those letters. The FDA's Office of Compliance communicated to us in February 2013 that they had completed its review of the corrective actions we took in response to the warning letter and that the concerns cited in that letter appeared to have been addressed.

For the year ended March 31, 2013, we recognized net income of \$15.0 million. With the exception of fiscal 2012 and 2013, we have incurred net losses since our inception. Even though we were profitable in fiscal 2013 and 2012, 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, pay additional excise taxes as a result of the implementation of the medical device tax in the U.S. in January 2013, incur additional legal fees to comply with the subpoena received from the Department of Justice in October 2012 and defend ourselves from other legal claims and invest in new markets such as Japan.

Corporate Background

We are incorporated in Delaware and trade on the NASDAQ Global Select Market under the ticker symbol ABMD.

Our principal executive offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923. Our telephone number is (978) 646-1400. We make available, free of charge on our website located at www.abiomed.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission, or SEC. Our corporate governance guidelines, code of conduct, audit committee, governance and nominating committee and compensation committee charters are also posted on our website. The contents of our website are not incorporated by reference into this report.

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 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.

Table of Contents

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. Currently, there are 41 hospitals in the U.S. and Canada contributing data to the USpella registry.

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. If the FDA accepts the panel's determination and issues a final order classifying these devices in Class III, we will be required to file a PMA application for Impella 2.5. 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 intend to submit a modular PMA submission for Impella by the end of fiscal 2014. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. We are working with the FDA to prepare this modular PMA application for our Impella products.

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 (previously marketed outside of the U.S. as Impella cVAD) received CE Mark approval to market the device in the European Union in April 2012 and Health Canada approval to market the device in Canada in June 2012. We initiated a controlled launch with top heart hospitals in the U.S. during the second quarter of fiscal 2013 and have continued a controlled commercial launch of Impella CP to more hospitals in the U.S., which we expect to continue over the next 12 months.

Impella 5.0 and Impella LD

The Impella 5.0 catheter 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

In November 2012, we announced that the Impella RP received IDE approval from the FDA for use in RECOVER RIGHT, a pivotal clinical study in the U.S. 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. The study will enroll 30 patients that present with signs of right side heart failure, require hemodynamic support, and are being treated in the catheterization lab or cardiac surgery suite. We announced the first enrollment of a patient in RECOVER RIGHT in April 2013 and we estimate the study will take up to 24 months to complete. The study will collect 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. 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. 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. We are currently conducting initial patient use trials outside of the U.S. of the Impella RP. This product is not currently available for commercial use.

Table of Contents

AB5000 and BVS 5000

We manufacture and sell the AB5000 Circulatory Support System and the BVS 5000 Biventricular Support System for the temporary support of acute heart failure patients in profound shock, including patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock, or myocarditis. We believe the AB5000 and BVS 5000 systems are the only commercially available cardiac assist devices that are 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. We are currently only actively selling the BVS 5000 upon request. We have transitioned our sales focus in the surgery market from the BVS 5000 to the AB5000, the Impella 5.0, and the Impella LD.

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. 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.

AbioCor

Our AbioCor implantable replacement heart was the first completely self-contained artificial heart. Designed to sustain the body's circulation, the AbioCor is intended for end-stage biventricular heart failure patients whose other treatment options have been exhausted. We received an HDE supplement approval from the FDA for product enhancement of the AbioCor in January 2008. The HDE allows the AbioCor to be made available to a limited patient population. However, we have no current plans to market AbioCor in the foreseeable future or seek a broader regulatory approval of the AbioCor. In September 2012, the FDA agreed to our request to place the post-approval study of the AbioCor on hold. We have not had any AbioCor sales since fiscal 2009, and we do not expect revenues from sales of the AbioCor for the foreseeable future as our primary strategic focus is centered on heart recovery for acute heart failure patients.

Our Markets

According to the American Heart Association, or AHA, Heart Disease and Stroke Statistics 2011 Update Report, coronary heart disease, or CHD, caused about 1 of every 6 deaths in the U.S. in 2007. Coronary heart disease is a condition of the coronary arteries that causes reduced blood flow and insufficient oxygen delivery to the affected portion of the heart. Coronary heart disease leads to acute myocardial infarction, or AMI, commonly known as a heart attack, which may lead to heart failure, a condition in which the heart is unable to pump enough blood to the body's major organs. CHD mortality in 2007 was approximately 406,000. In 2009, an estimated 785,000 Americans had a first time coronary attack and about 470,000 had a recurrent attack. An estimated additional 195,000 silent first myocardial infarctions occur each year.

A broad spectrum of therapies exists for the treatment of patients in early stages of CHD. Angioplasty procedures and stents are commonly used in the cath lab to restore and increase blood flow to the heart. These treatments are often successful in slowing the progression of heart disease, extending life, and/or improving the quality of life for some period of time. Patients presenting with acute cardiac injuries potentially have recoverable hearts. Treatment for these patients in pre-shock in the cath lab is primarily focused on hemodynamic stabilization. Acute heart failure patients in profound shock typically require treatment in the surgery suite. These are patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock or myocarditis complicated with cardiogenic shock. Chronic heart failure patients have hearts that are unlikely to be recoverable due to left and/or right side heart failure and their conditions cause their hearts to fail over time. Limited therapies exist today for patients with severe, end-stage, or chronic heart failure.

In more severe cases of heart failure, patients are sent directly to the surgery suite for coronary bypass or valve replacement surgery. The most severe acute heart failure patients are in profound cardiogenic shock, including those suffering from myocarditis (a viral attack of the heart), or from those suffering from an impaired ability of the heart to pump blood after a heart attack or heart surgery. According to results of the SHOCK (Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock) trial published in the August 26, 1999 edition of *The New England Journal of Medicine*, approximately 7 to 10% of the patients who are hospitalized for a heart attack suffer from cardiogenic shock and 60 to 80% of those patients die. These patients typically require treatments in the surgery suite involving the use of mechanical circulatory support devices that provide increased blood flow and reduce the stress on the heart. However, many less severe patients in the cath lab could also benefit from circulatory support devices or other clinical treatment, which could potentially prevent them from entering into profound shock.

There are two primary types of devices used in the cath lab and surgery suite in the U.S. for circulatory support for pre-shock and profound shock patients: intra-aortic balloons, or IABs, and ventricular assist devices, or VADs.

Table of Contents

An IAB is an inflatable balloon inserted via a catheter into a patient's circulation and is inflated and deflated in the aorta. This is used as an initial line of therapy in the cath lab or the surgery suite for patients with diminished heart function. There are an estimated 124,000 IAB procedures performed annually in the U.S. However, IABs typically provide only limited enhancement and depend on the patient's own heart to generate the majority of the patient's blood flow. In addition, IABs are often required to be used in conjunction with inotropes or other drugs to stimulate heart muscle ejection. The use of these drugs, however, increases the risk of mortality. Clinical publications have demonstrated that the need for two or more inotropes to improve blood flow results in mortality rates of approximately 80%. In addition, IABs have limited effectiveness in patients that are arrhythmic and/or in cardiogenic shock and published reports have indicated that IABs do not reduce mortality for patients in cardiogenic shock.

VADs are mechanical devices that help the failing heart pump blood or take over the pumping function of the failing heart. Historically, VADs have been highly invasive and require implantation in the surgery suite. The use of surgically placed VADs generally falls into three sub-categories: recovery, bridge-to-transplant and destination therapy.

Recovery VADs are designed to enable the patient's heart to rest and potentially recover so that the patient can return home with his or her own heart. Because recovery is the goal, these devices are designed to minimize damage to heart tissue and are removed once the patient's heart has recovered. If possible, recovery of a patient's heart is generally preferred to transplantation or prolonged device implantation, both of which have significant side effects for the patient and increase the risk of mortality. We believe heart recovery is a preferred clinical outcome for patients, since it also generally lowers the overall relative cost to the healthcare system versus alternative therapies and treatment paths that may require multiple surgeries, lengthy or repeated hospital stays, chronic therapeutic and immunosuppressant drugs and other related healthcare costs.

Bridge-to-transplant VADs are primarily used to support chronic heart failure patients eligible to receive a heart transplant. Destination therapy generally involves the implantation of a mechanical support device as the last clinical alternative for a chronic patient with end-stage heart failure who is not eligible for transplantation.

Our product portfolio is designed to provide a continuum of care in heart recovery to acute heart failure patients from the intensive care unit to the cath lab to the surgery suite to home discharge and to provide an array of choices for clinicians treating acute heart failure patients. Our products provide various levels of blood flow and are capable of supporting a patient for lengths of time ranging from several hours to months to align with the clinical needs of the patient, whether in pre-shock or profound shock. Our primary cath lab products include the Impella® pumps for partial or full circulatory support. Our primary cath lab products are Impella 2.5 and Impella CP. Our primary surgery suite products include our Impella 5.0, Impella LD and our AB5000 VAD. Our surgery suite products are designed to support acute heart failure patients in need of more blood flow. Our VADs are indicated for longer duration of support of up to 30 days for AMI, cardiogenic shock post-AMI, and myocarditis patients.

Research and Product Development

Since our founding in 1981, we have gained substantial expertise in circulatory support while developing our Impella platform, our BVS and AB5000 systems, and our AbioCor. Our current strategy is to develop a complete portfolio of products for partial and full circulatory support to treat acute heart failure patients. We intend to continue to use this experience to develop additional circulatory support products. Our research and development efforts are focused on developing a broader portfolio of products across the continuum of care in heart recovery, primarily focused in the area of circulatory care. In addition, we have a number of new products at various stages of development some of which integrate the Impella technology platform.

As of March 31, 2013, our research and development staff consisted of 92 employees. We expended \$25.6 million, \$27.2 million and \$26.7 million on research and development in fiscal years 2013, 2012 and 2011, respectively. Our research and development expenditures include costs related to clinical trials, including ongoing clinical studies for our Impella products.

Sales, Clinical Support, Marketing and Field Service

As of March 31, 2013, our worldwide sales, clinical support, marketing and field service teams included 183 full-time employees, 166 of whom are in the U.S. and Canada and 17 of whom are in Europe. Over the past five years, we have significantly increased the number of our direct sales and clinical support personnel covering the U.S., Canada, Germany, France, and the U.K.

Our clinical support personnel consist primarily of registered nurses and other personnel with considerable experience in either the surgery suite or the cath lab, and they play a critical role in training current and prospective customers in the use of our products.

International sales (sales outside the U.S., primarily in Europe) accounted for 7%, 8% and 8% of total product revenue during the fiscal years ended March 31, 2013, 2012 and 2011, respectively.

Table of Contents

Manufacturing

We manufacture our products in Danvers, Massachusetts and Aachen, Germany. Our Danvers facility manufactures certain Impella subsystems and accessories, including our Automated Impella Console, or AIC, our console for our Impella products, the AB5000, and Portable Driver. Our Aachen facility manufactures most of our Impella disposable products. In addition, we rely on third-party suppliers to provide us with components used in our existing products and products under development. For example, we outsource some of the manufacturing for components and circuit cards within our consoles.

We believe our existing manufacturing facilities give us the necessary physical capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months based on our current revenue forecast. We expect to increase Impella manufacturing capacity in our Aachen and Danvers facilities in fiscal 2014 to support the growing demand for our Impella products. Our U.S. and German manufacturing facilities are certified by the International Organization for Standardization, or ISO, and operate under the FDA's good manufacturing practice requirements set forth in the current quality system regulation, or QSR.

Intellectual Property

We have developed significant know-how and proprietary technology, upon which our business depends. To protect our know-how and proprietary technology, we rely on trade secret laws, patents, copyrights, trademarks, and confidentiality agreements and contracts. However, these methods afford only limited protection. Others may independently develop substantially equivalent proprietary information or technology, gain access to our trade secrets or disclose or use such secrets or technology without our approval.

A substantial portion of our intellectual property rights relating to the Impella products, AB5000, and other products under development is in the form of trade secrets, rather than patents. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. We cannot assure you that our trade secrets will not become known to or be independently developed by our competitors.

We own or have rights to numerous U.S. and foreign patents. Our U.S. patents have expiration dates ranging from 2014 to 2029 and our foreign patents have expiration dates ranging from 2016 to 2027. We also own or have rights to certain pending U.S. and foreign patent applications. We believe patents will issue pursuant to such applications, but cannot guarantee it. Moreover, neither the timing of any issuance, the scope of protection, nor the actual issue date of these pending applications can be forecasted with precision. Where we have licensed patent rights from third parties, we are generally required to pay royalties.

Our patents may not provide us with competitive advantages. Our pending or future patent applications may not be issued. The patents of others may render our patents obsolete, limit our ability to patent future innovations, or otherwise have an adverse effect on our ability to conduct business. Because foreign patents may afford less protection than U.S. patents, they may not adequately protect our technology.

The medical device industry is characterized by a large number of patents and by frequent and substantial intellectual property litigation. Our products and technologies could infringe on the proprietary rights of third parties. If third parties successfully assert infringement or other claims against us, we may not be able to sell our products or we may have to pay significant damages and ongoing royalties. In addition, patent or intellectual property disputes or litigation may be costly, result in product development delays, or divert the efforts and attention of our management and technical personnel. If any such disputes or litigation arise, we may seek to enter into a royalty or licensing arrangement. However, such an arrangement may not be available on commercially acceptable terms, if at all. We may decide, in the alternative, to litigate the claims or seek to design around the patented or otherwise protected proprietary technology.

The U.S. government may obtain certain rights to use or disclose technical data developed under government contracts that supported the development of some of our products. We retain the right to obtain patents on any inventions developed under those contracts, provided we follow prescribed procedures and are subject to a non-exclusive, non-transferable, royalty-free license to the U.S. government.

Competition

Competition among providers of treatments for the failing heart is intense and subject to rapid technological change and evolving industry requirements and standards. We compete with companies that have substantially greater or broader financial, product development, sales and marketing resources and experience than we do. These competitors may develop superior products or products of similar quality at the same or lower prices. Moreover, improvements in current or new technologies may make them technically equivalent or superior to our products in addition to providing cost or other advantages. Other advances in medical technology, biotechnology and pharmaceuticals may reduce the size of the potential markets for our products or render those products obsolete. Among our medical device competitors are Getinge (Maquet Cardiovascular), Teleflex Inc., Thoratec Corporation, HeartWare International Inc., Jarvik Heart, CircuLite, Inc., Terumo Heart, Inc. and CardiacAssist Inc.

Table of Contents

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

Third-Party Reimbursement

Our products and services are generally purchased by healthcare institutions that rely on third-party payers to cover and reimburse the costs of related patient care. In the U.S., as well as in many foreign countries, government-funded or private insurance programs pay the cost of a significant portion of a patient's medical expenses. No uniform policy of coverage or reimbursement for medical technology exists among all these payers. Therefore, coverage and reimbursement can differ significantly from payer to payer.

Third-party payers may include government healthcare programs such as Medicare or Medicaid, private insurers or managed care organizations. The Centers for Medicare & Medicaid Services, or CMS, is responsible for administering the Medicare program and, along with its contractors, establishes coverage and reimbursement policies for the Medicare program. Medicare's coverage and reimbursement policies are particularly significant to our business because a large percentage of the population for which our products are intended includes elderly individuals who are Medicare beneficiaries. In addition, private payers often follow the coverage and reimbursement policies of Medicare. We cannot assure that government or private third-party payers will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

Medicare payment may be made, in appropriate cases, for procedures performed in the in-patient hospital setting using our technology. Medicare generally reimburses healthcare institutions in which the procedures are performed based upon prospectively determined amounts. For hospital in-patient stays, the prospective payment generally is determined by the patient's condition and other patient data and procedures performed during the in-patient stay, using a classification system known as diagnosis-related groups, or DRGs. Prospective rates are adjusted for, among other things, regional differences, co-morbidity and complications. Hospitals performing in-patient procedures using our devices generally do not receive separate Medicare reimbursement for the specific costs of purchasing or implanting our products. Rather, reimbursement for these costs is bundled with the DRG-based payments made to hospitals for the procedures during which our devices are implanted, removed, repaired or replaced. Because prospective payments are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, hospitals have incentives to lower their in-patient operating costs by utilizing products, devices and supplies that will reduce the length of in-patient stays, decrease labor or otherwise lower their costs.

Coverage and reimbursements for procedures to implant, remove, replace or repair our products are generally established in the U.S. market. For instance, Medicare covers the use of VADs when used for support of blood circulation post-cardiotomy, as a temporary life-support system until a human heart becomes available for transplant, or as therapy for patients who require permanent mechanical cardiac support. Coverage and reimbursements for procedures to implant the Impella 2.5, CP, 5.0, or LD are also established for in-hospital use by Medicare including ICD-9 for procedures and DRG coding. Actual coverage and payment may vary by local Medicare fiscal intermediary or third-party insurer.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services when they perform surgeries to implant, remove, replace or repair our devices or when they perform percutaneous insertion and removal of Impella. Physicians generally bill for such services using a coding system known as Current Procedural Terminology, or CPT, codes. Physician services performed in connection with the implantation, removal, replacement or repair of our approved products are billed using a variety of CPT codes. Generally, Medicare payment levels for physician services are based on the Medicare Physician Fee Schedule and are revised annually by CMS.

We also announced in March 2013 recent coverage decisions by third party insurers, including Humana and United Healthcare, to include Impella policies in their commercial and/or Medicare plans. We expect to continue to work with third party insurers in the U.S. in the next 12 months to expand the number of insurers to include Impella in their plans.

In general, third-party reimbursement programs in the U.S. and abroad, whether government-funded or commercially insured, are developing a variety of increasingly sophisticated methods of controlling healthcare costs, including prospective reimbursement and capitation programs, group purchasing, reducing benefit coverage, requiring second opinions prior to major surgery, negotiating reductions to charges on patient bills, promoting healthier lifestyle initiatives and exploring more cost-effective methods of delivering healthcare. These types of cost-containment programs, as well as legislative or regulatory changes to reimbursement policies, could limit the amount which healthcare providers may be willing to pay for our medical devices.

Table of Contents

Government Regulation

The healthcare industry, and thus our business, is subject to extensive federal, state, local and foreign regulation. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In addition, these laws and their interpretations are subject to change.

Premarket Regulation

In the U.S., the FDA strictly regulates medical devices under the authority of the Federal Food, Drug and Cosmetic Act, or FDCA, and its regulations. The FDA classifies U.S. medical devices into one of three classes (Class I, II or III) based on the statutory framework described in the FDCA. Class III devices, which are typically life-sustaining, life-supporting or implantable devices, or new devices that have been found not to be substantially equivalent to legally marketed devices, must generally receive a PMA by the FDA to ensure their safety and effectiveness.

When clinical trials of a device are required in order to obtain FDA approval, the sponsor of the trial is required to file an investigational device exemption, or IDE, application before commencing clinical trials. The FDA reviews and must approve an IDE before a study may begin in the U.S. In addition, the study must be approved by an Institutional Review Board, or IRB, for each clinical site.

The FDA and the IRB at each institution at which a clinical trial is being performed or ourselves, may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. All clinical studies of investigational devices must be conducted in compliance with FDA requirements. Following the completion of a study, the data from the study must be collected, analyzed and presented in an appropriate submission to the FDA, either through a 510(k) premarket notification or a PMA.

During the 510(k) process, the FDA reviews a premarket notification and determines whether or not a proposed device is substantially equivalent to predicate devices. If the intended use and technological characteristics are comparable to a predicate device, the device may be cleared for marketing. If the device has the same intended use as a predicate device and different technological characteristics, but data is submitted to the FDA showing that the device is at least as safe and effective as the legally marketed device, it may also be cleared for marketing. The FDA's 510(k) clearance pathway usually takes three to 12 months, but it can often last longer and clearance is never assured. In reviewing a premarket notification, the FDA may request additional information, including clinical data. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the agency can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA can also require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Additionally, the manufacturer may be subject to significant regulatory fines or penalties.

Certain Class III devices that were on the market before May 28, 1976, known as pre-amendment Class III devices, and devices that are determined to be substantially equivalent to them, can be brought to market through the 510(k) process until the FDA, by regulation, calls for PMA applications for these devices. In addition, the Safe Medical Devices Act of 1990, as amended by the Food and Drug Administration Safety and Innovation Act (FDAISIA) of 2012, requires the FDA either down-classify pre-amendment Class III devices to Class I or Class II or to publish an administrative order retaining the devices in Class III. Manufacturers of pre-amendment Class III devices that the FDA retains in Class III must submit a PMA application within 90 days after the FDA publishes a final order requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Failure to meet the deadline can lead the FDA to prevent continued marketing of the device during the PMA application review period. The Impella 2.5, Impella CP, Impella 5.0 and Impella LD received clearance based on a pre-amendment Class III device. If the FDA publishes a final order that calls for a PMA, a PMA must be submitted for the device even if the device has already received 510(k) clearance; however, if the FDA down-classifies a pre-amendment Class III device to Class I or Class II, a PMA application will not be required.

The PMA approval pathway requires reasonable assurance of the safety and effectiveness of the device to the FDA's satisfaction. The PMA approval pathway is much more costly, lengthy and uncertain than the 510(k) path. In the PMA process, the FDA examines detailed data to assess the safety and effectiveness of the device. This information includes design, development, manufacture, labeling, advertising, preclinical testing and clinical study data. Prior to approving a PMA, the FDA may conduct an inspection of the manufacturing facilities and the clinical sites where the supporting study was conducted. The facility inspection evaluates the company's compliance with the Quality System Regulation, or QSR. An inspection of clinical sites evaluates compliance with the IDE requirements. Typically, the FDA will convene an advisory panel meeting to seek review of the data presented in the PMA. The panel's recommendation is given substantial weight, but is not binding on the agency. By regulation, the FDA has 180 days to review a PMA application not requiring an advisory panel meeting, and 320 days to review a PMA application that does require an advisory panel meeting. While the FDA has approved PMA applications within the allotted time period, reviews can occur over a significantly protracted period, usually 18 to 36 months but sometimes longer, and a number of devices have never been approved for marketing.

Table of Contents

If the FDA's evaluation is favorable, the PMA is approved and the device may be marketed in the U.S. The FDA may approve the PMA with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling and promotion, and post-market collection of clinical data. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. Even if a device receives 510(k) clearance or PMA approval, the FDA may include significant limitations on the indicated uses for which a device may be marketed. FDA enforcement policy prohibits the promotion of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial marketing.

In 2009, the FDA implemented the 515 Program Initiative to facilitate the potential reclassification of twenty-six medical devices which are currently classified as Class III devices. Class I and II devices are generally considered to be lower risk than Class III devices and require clearance through the FDA's 510(k) premarket notification process. Class III devices, however, are typically higher risk and first-of-a-kind and require approval through a PMA which is a much more costly and uncertain process to approval than the 510(k) premarket notification process. Under the 515 Program Initiative, the FDA is reviewing Class III device types to determine whether any of them should be reclassified as Class I or II devices or if they should remain classified as Class III devices and be subject to approval through the PMA process.

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. If the FDA accepts the panel's determination and issues a final order classifying these devices in Class III, we will be required to file a PMA application for Impella 2.5. 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 intend to submit a modular PMA submission for Impella by the end of fiscal 2014. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. We are working with the FDA to prepare this modular PMA application for our Impella products.

In addition, certain devices can be distributed under an HDE, rather than a PMA. In order for a device to be eligible for an HDE, a qualifying target patient population of less than 4,000 patients per year for which there is no other comparable device available to treat the condition must be approved by the FDA. The FDA's approval of an HDE to treat that qualifying patient population then requires demonstration that the device is safe for its intended application, that it is potentially effective, and that the probable benefits outweigh the associated risks. Within the regulations for an HDE, if a device becomes available through the PMA process that addresses the same patient population as the HDE device, the HDE device may need to be withdrawn from the U.S. market.

Our AB5000 and BVS 5000 systems are approved by the FDA for use in patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. The intent of therapy is to provide circulatory support, restore normal hemodynamics, reduce ventricular work, and allow the heart time to recover adequate mechanical function. In 1992, the FDA approved our PMA for the BVS 5000. In 1997, the FDA approved the use of the BVS 5000 for additional indications, expanding its use to the treatment of all patients with potentially reversible heart failure. In April 2003, the AB5000 Circulatory Support System Console and in September 2003, the AB5000 VAD were approved under PMA supplements. We received FDA clearance for our IAB in December 2006. Our iPulse console was approved by the FDA under a PMA supplement in December 2007. Our Impella 2.5 device received 510(k) clearance in June 2008 for partial circulatory support for up to six hours. We received FDA 510(k) clearance of our Impella 5.0 and Impella LD devices in April 2009 for circulatory support for up to six hours. Our AB Portable Driver received FDA approval under a PMA supplement in March 2009. All of these products have CE marks allowing distribution within the European Union. In September 2012, we announced that the Impella CP received 510(k) clearance from the FDA for up to six hours of partial circulatory support using an extracorporeal bypass control unit. The Impella CP (previously marketed outside of the U.S. as Impella cVAD) received CE Mark approval to market the device in the European Union in April 2012 and Health Canada approval to market the device in Canada in June 2012.

Postmarket Regulation

The medical devices that we manufacture and distribute pursuant to FDA clearances or approvals are subject to continuing regulation by the FDA and other regulatory authorities. The FDA reviews design, manufacturing, and distribution practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. Among other FDA requirements, we must comply with the FDA's good manufacturing practice regulations. These regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. We must also comply with Medical Devices Reporting, or MDR, which requires us to report to the FDA any incident in any of our products that may have caused or contributed to a death or serious injury, or required an unnecessary intervention for a patient, or in which any of our products malfunctioned and, if such malfunction were to recur, would be likely to cause or contribute to a death or serious injury. Labeling, advertising, and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the

Table of Contents

Federal Trade Commission. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses. We are subject to routine inspection by the FDA and other regulatory authorities for compliance with Quality System Regulation, or QSR, and MDR requirements, as well as other applicable regulations. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, and require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal fines and penalties against our officers, employees, or us. The FDA may also recommend prosecution to the U.S. Department of Justice.

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

In June 2011, we received a warning letter from the FDA stating that some of our promotional materials marketed the Impella 2.5 for uses that had not been approved by the FDA. We cooperated with the FDA and made changes to our promotional materials in response to the warning letter. However, in April 2012, we received a follow up letter from the FDA stating that some of our promotional materials continued to market the Impella 2.5 in ways that are not compliant with FDA regulations. In February 2013, we received a close-out letter from the FDA with respect to this matter, which noted that the FDA's Office of Compliance had completed its review of the corrective actions we took in response to the warning letter and that the concerns cited in that letter appeared to have been addressed.

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 the Company's marketing and labeling of the Impella 2.5. On October 31, 2012, we accepted service of a subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5. We are in the process of responding to the subpoena and intend to cooperate fully with the subpoena.

The FDA often requires post market surveillance, or PMS, for significant risk devices, such as VADs, that require ongoing collection of clinical data during commercialization that must be gathered, analyzed and submitted to the FDA periodically for up to several years. The PMS data collection requirements are often burdensome and expensive and have an effect on the PMA approval status. The failure to comply with the FDA's regulations can result in enforcement action, including seizure of products, injunction, prosecution, civil fines and penalties, recall and/or suspension of FDA approval. The export of devices such as ours is also subject to regulation in certain instances.

The FDA, in cooperation with U.S. Customs and Border Protection, or CBP, administers controls over the import and export of medical devices into and out of the U.S. The CBP imposes its own regulatory requirements on the import of medical devices, including inspection and possible sanctions for noncompliance. The FDA also administers certain controls over the export of medical devices from the U.S. International sales of our medical devices that have not received FDA approval are therefore subject to FDA export requirements.

Fraud and Abuse Laws

Our business is regulated by laws pertaining to healthcare fraud and abuse including anti-kickback laws and false claims laws. Violations of these laws are punishable by significant criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, such as Medicare and Medicaid. Because of the far-reaching nature of these laws, we may be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws, or the adoption of new laws or regulations, could adversely affect our arrangements with customers and physicians. In addition, any violation of these laws or regulations could have a material adverse effect on our financial condition and results of operations.

Anti-Kickback Statute

Subject to a number of statutory exceptions, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the furnishing, recommending, or arranging for, a good or service for which payment may be made under a federal health care program such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments, and providing anything of value at less than fair market value. The Office of the Inspector General of the U.S. Department of Health and Human Services, or the OIG, and the Department of Justice are responsible for enforcing the federal Anti-Kickback Statute and the OIG is primarily responsible for identifying fraud and abuse activities affecting government healthcare programs.

Penalties for violating the federal Anti-Kickback Statute include substantial criminal fines and/or imprisonment, substantial civil fines and possible exclusion from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted

Table of Contents

prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs and do not include comparable exceptions to those provided by the federal Anti-Kickback Statute.

The OIG has issued safe harbor regulations that identify activities and business relationships that are deemed safe from prosecution under the federal Anti-Kickback Statute. There are safe harbors for various types of arrangements, including certain investment interests, leases, personal service arrangements, and management contracts. The failure of a particular activity to comply with all requirements of an applicable safe harbor regulation does not mean that the activity violates the federal Anti-Kickback Statute or that prosecution will be pursued. However, activities and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG.

In recent years, the federal government and several states have enacted legislation requiring biotechnology, pharmaceutical and medical device companies to establish marketing compliance programs and file periodic reports on sales, marketing, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available 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 to have not complied with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

Federal False Claims Act

The federal False Claims Act prohibits knowingly filing or causing the filing of a false claim or the knowing use of false statements to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim. Private individuals can file suits under the False Claims Act on behalf of the government. These lawsuits are known as *qui tam* actions, and the individuals bringing such suits, sometimes known as *relators* or, more commonly, *whistleblowers*, may share in any amounts paid by the entity to the government in fines or settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act. *Qui tam* actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

HIPAA

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government-sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment.

HIPAA also protects the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses. HIPAA restricts the use and disclosure of patient health information, including patient records. Although we believe that HIPAA does not apply to us directly, most of our customers have significant obligations under HIPAA, and we intend to cooperate with our customers and others to ensure compliance with HIPAA with respect to patient information that comes into our possession. Failure to comply with HIPAA obligations can result in civil fines and/or criminal penalties. Some states have also enacted rigorous laws or regulations protecting the security and privacy of patient information. If we fail to comply with these laws and regulations, we could face additional sanctions.

Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act

In March 2010, Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or together, the Affordable Care Act. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes. Specifically, the law requires the medical device industry to subsidize health care reform in the form of a 2.3% excise tax on United States sales of most medical devices beginning in 2013. We began paying the medical device excise tax in January 2013. We expect that the excise tax will increase our operating expenses in the future. Because many other parts of the Affordable Care Act remain subject to implementation, the long-term impact to us is uncertain. The new law or any future legislation could reduce medical procedure volumes, lower reimbursement for our products, and impact the demand for our products or the prices at which we sell our products.

Table of Contents

The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, or PPSA, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services, or CMS, for subsequent public disclosure. The PPSA requires manufacturers to begin collecting data required beginning in August 2013 with the first report required for the period from August 1 through December 31, 2013 to be reported to CMS in early 2014. We have started our preparations to collect the data to comply with the PPSA. Similar reporting requirements have also been enacted in several states, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. Particularly, some states such as Massachusetts, Minnesota and Vermont, impose an outright ban on certain gifts to physicians. Failure to report appropriate data may result in civil or criminal fines and/or penalties.

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota, requiring reporting to state governments of gifts, compensation and other remuneration to physicians. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and reporting requirements, increases the possibility that a company may run afoul of one or more laws.

International Regulation

We are also subject to regulation in each of the foreign countries in which we sell our products. Many of the regulations applicable to our products in these countries are similar to those of the FDA. The European Union requires that our medical devices comply with the Medical Device Directive or the Active Implantable Medical Device Directive, which includes quality system and CE certification requirements. To obtain a CE Mark in the European Union, defined products must meet minimum standards of safety and quality (i.e., the essential requirements) and then undergo an appropriate conformity assessment procedure. A Notified Body assesses the quality management systems of the manufacturer and the product conformity to the essential and other requirements within the Medical Device Directive. In the European Union, we are also required to maintain certain ISO certifications in order to sell our products. Our Impella 2.5, Impella 5.0, Impella LD, Impella CP, AB5000, BVS 5000, IAB, iPulse console and Portable Driver are all CE marked and available for sale in the European Union. We are also subject to regulations and periodic review from various regulatory bodies in Canada, Japan and other countries where we sell our products. Lack of regulatory compliance in any of these jurisdictions could limit our ability to distribute products in these countries.

Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Many of our customer relationships outside of the United States are, either directly or indirectly, with governmental entities and are therefore subject to various anti-bribery laws. Although our corporate policies mandate compliance with these anti-bribery laws, we operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our business, results of operations and financial condition.

Employees

As of March 31, 2013, we had 467 full-time employees, including:

92 in product engineering, research and development, and regulatory;

183 in sales, clinical support, marketing, field service and related support;

143 in manufacturing; and

49 in general and administration.

We routinely enter into contractual agreements with our employees, which typically include confidentiality and non-competition commitments. Our employees are not represented by unions. We consider our employee relations to be good. If we were unable to attract and retain qualified personnel in the future, our operations could be negatively impacted.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider these risks as well as the other information we include or incorporate by reference in this report, including our consolidated financial

Table of Contents

statements and the related notes. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties of which we are unaware or that we deem immaterial may also adversely affect our business. If any of these risks materializes, the trading price of our common stock could fall and you might lose all or part of your investment.

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

Risks Related to Our Business

We have incurred losses in previous periods and may incur losses in future periods.

For the years ended March 31, 2013 and 2012, we recognized net income of approximately \$15.0 million and \$1.5 million, respectively. For the year ended March 31, 2011, we incurred a net loss of approximately \$11.8 million. The profitability we achieved in the years ended March 31, 2013 and 2012 may not be indicative of our ability to sustain profitability and we may incur losses from operations in future periods. We historically have incurred net losses from our operations. Any losses incurred in the future may result primarily from, among other things, the expansion of our global distribution network, investments in new markets such as Japan, ongoing product development, and legal and other expenses related to our compliance with the subpoena received from the Department of Justice in October 2012 and our defense of other legal claims. Additionally, due to the introduction of the U.S. medical device tax, in January 2013 we began incurring a 2.3% excise tax on the sales of certain of our products regardless of whether we are profitable or not. These expenditures may include costs associated with hiring additional personnel, performing clinical trials, continuing our research and development relating to our products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing activities. The amount of these expenditures is difficult to forecast accurately and cost overruns may occur. We also expect that we will make significant expenditures to market and manufacture in commercial quantities our approved circulatory care products, and any other new products for which we may incur additional expense to obtain regulatory approvals or clearances in the future.

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

Medical devices such as ours are extensively regulated by the FDA in the U.S. and by other federal, state, local and foreign authorities. Governmental regulations relate to the testing, development, manufacturing, labeling, design, sale, promotion, distribution, importing, exporting and shipping of our products. In the U.S., before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we must generally first receive either a premarket approval, or PMA, or 510(k) clearance from the FDA. Both of these processes can be expensive and lengthy and entail significant expenses. The FDA's 510(k) clearance process usually takes between three to twelve months, but it can often last longer. The process of obtaining a PMA approval is much more costly and uncertain than the 510(k) clearance process. It generally takes between one to three years, or even longer, from the time the PMA application is submitted to the FDA. In January 2011, the FDA announced plans to make changes to its 510(k) clearance process. Although the effect of these changes is still unknown, these changes may further delay the time it takes us to prepare applications for 510(k) clearance or the length of time required to receive 510(k) clearance. We cannot assure you that any regulatory clearances or approvals, either foreign or domestic, will be granted on a timely basis, if at all. If we are unable to obtain regulatory approvals or clearances for use of our products under development, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of these products could be limited. The FDA may also limit the claims that we can make about our products.

If we do not receive FDA approval or clearance for one or more of our products, we will be unable to market and sell those products in the U.S. which would have a material adverse effect on our operations and prospects.

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

As a result of determinations made under the FDA's 515 Program Initiative, we will not be permitted to rely on the 510(k) pre-market notification process to market our Impella products.

The FDA implemented the 515 Program Initiative in 2009 to facilitate the potential reclassification of twenty-six medical devices which are currently classified as Class III devices. Class I and II devices are generally considered to be lower risk than Class III devices and require clearance through the FDA's 510(k) premarket notification process. Class III devices, however, are typically higher risk and first-of-a-kind and require approval through a PMA which is a much more costly and uncertain process to approval than the 510(k) premarket notification process. Under the 515 Program Initiative, the FDA is reviewing Class III device types to determine whether any of them should be reclassified as Class I or II devices or if they should remain classified as Class III devices and be subject to approval through the PMA process.

Table of Contents

In December 2012, as part of the 515 Program Initiative, an FDA panel voted to recommend continuation of Class III status for the 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. If the FDA accepts the panel's determination and issues a final order classifying these devices in Class III, we will have 90 days from the date of the issuance of that order to file a PMA application for Impella 2.5 for the product to remain on the market. 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.

Although the effect of the FDA panel's decision is still unknown, these changes will make it more difficult for us to obtain regulatory clearances and approvals for our products and even if we are successful, the time and costs required for us to obtain those clearances and approvals will be substantially increased. If we are unable to obtain regulatory approvals or clearances for use of our products, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of these products could be limited, which could materially and adversely affect our revenues.

If the FDA or another regulatory or enforcement agency determines that we have promoted off-label use of our products, we may be subject to various penalties, including civil or criminal penalties. We have received an administrative subpoena from the Department of Justice (DOJ) which is conducting an investigation that is focused on our marketing and labeling of the Impella 2.5

The FDA, the DOJ and other regulatory or enforcement agencies actively enforce regulations prohibiting promotion of off-label use and the promotion of products for which marketing clearance has not been obtained. If such agency determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products, such agency could disagree and conclude that we have engaged in off-label promotion. In June 2011 we received a warning letter from the FDA stating that some of our promotional materials marketed the Impella 2.5 for uses that had not been approved by the FDA. We cooperated with the FDA and made changes to our promotional materials in response to the warning letter. However, in April 2012, we received a follow up letter from the FDA stating that some of our promotional materials continued to market the Impella 2.5 in ways that are not compliant with FDA regulations. In February 2013, we received a close-out letter from the FDA with respect to this matter, which noted that the FDA's Office of Compliance had completed its review of the corrective actions we took in response to the warning letter and that the concerns cited in that letter appeared to have been addressed. The close-out letter, however, provides no assurance that there may not be other occurrences that may be subject to regulatory or enforcement action.

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 the Company's marketing and labeling of the Impella 2.5. We accepted service of a subpoena related to this investigation on October 31, 2012. The subpoena seeks documents related to the Impella 2.5. We are in the process of responding to the subpoena and intend to cooperate fully with the subpoena. We may not be able to resolve these matters, or any similar matters that may come up in the future, without incurring penalties or facing significant consequences. Even if we are successful in resolving this matter without incurring penalties, responding to the subpoena has resulted and in the future will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations.

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

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

We have been named as a party to purported stockholder class actions and a derivative action, and we may be named in additional litigation, all of which may require significant management time and attention, and result in significant legal expenses and may result in an unfavorable outcome, which could have a material adverse effect on our business, operating results and financial condition.

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 allege 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 has consolidated these complaints. A consolidated amended complaint was filed by the plaintiffs on May 20, 2013.

Table of Contents

Additionally, on February 4, 2013, an alleged holder of our common stock 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 alleges 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 seeks damages in an unspecified amount. We have moved to dismiss the complaint in its entirety, and that motion has been briefed, argued and is under advisement by the Court. Separately, on January 21, 2013 and February 5, 2013, we received demands from purported stockholders to inspect certain of our books and records related to these matters.

We intend to defend these lawsuits vigorously. We cannot assure you, however, that we will be successful. We may have to pay damage awards, indemnify our officers and directors from damage awards that may be entered against them or otherwise may enter into settlement arrangements in connection with such claims. Any such payments or settlement arrangements in these current litigations or any future litigation could have material adverse effects on our business, operating results or financial condition. Even if the plaintiffs' claims are not successful, defending these litigations could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations.

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

In order to obtain PMA approval and in some cases, 510(k) clearance, we may be required to conduct well-controlled clinical trials designed to test the safety and effectiveness of the product. In order to conduct clinical studies, we must generally receive an investigational device exemption, or IDE, for each device from the FDA. An IDE allows us to use an investigational device in a clinical trial to collect data on safety and effectiveness that will support an application for premarket approval or 510(k) clearance from the FDA. We have received IDE approval and are conducting clinical trials for our Impella RP and Portable Driver medical devices. In December 2010, we announced the termination of our Protect II study based on a futility determination at the planned interim analysis regarding the primary end-point, which we view as likely to be due to unanticipated confounding variables related to the use of rotational atherectomy in the study.

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

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

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

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

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

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

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

510(k) clearance of our devices may have the effect of slowing down the progress of related clinical trials since physicians can use our cleared devices commercially outside of the trials;

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

governmental regulations or administrative actions may change and impose new requirements, particularly on reimbursement.

The results of pre-clinical studies do not necessarily predict future clinical trial results and previous clinical trial results may not be repeated in subsequent clinical trials. We may suffer delays, cost overruns and terminate manufacturing of certain of our products despite achieving promising results in pre-clinical testing or

Edgar Filing: ABIOMED INC - Form 10-K

early clinical testing. In addition, the data obtained from clinical trials may be inadequate to support approval or clearance of a submission. The FDA may disagree with our interpretation of the data from our clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate the safety and effectiveness of the product candidate. The FDA may also require us to conduct additional pre-clinical studies or clinical trials which could further delay approval of our products. If we are unable to receive FDA approval of an IDE to conduct clinical trials or the trials are halted by the FDA or others or if we are unsuccessful in receiving FDA approval of a product candidate, we would not be able to sell or promote the product candidate in the U.S., which could seriously harm our business. Moreover, we face similar risks in each jurisdiction in which we sell or propose to sell our products.

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

Table of Contents

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

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

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

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

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

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

Sales of medical devices largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of government reimbursement or third-party insurers' payments for patient care, the market for our products will be limited. Medical products and devices incorporating new technologies are closely examined by governments and private insurers to determine whether the products and devices will be covered by reimbursement, and if so, the level of reimbursement which may apply.

We cannot be sure that additional third-party payers will cover and/or adequately reimburse sales of our products or other products under development, to enable us to sell them at profitable prices.

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

Changes in health care reimbursement systems in the U.S. and abroad could reduce our revenues and profitability.

In March 2010, the federal government enacted healthcare reform legislation. The legislation has changed the manner in which healthcare services are provided and paid for in the U.S. These changes may impact reimbursement for health care services, including

Table of Contents

reimbursement to hospitals and physicians. States may also enact further legislation that impacts Medicaid payments to hospitals and physicians. In addition, the Centers for Medicare & Medicaid Services, the federal agency responsible for administering the Medicare program, has established new payment levels for hospitals and physicians in line with the new legislation, which can increase or decrease payment to such entities. The healthcare reform legislation and any future legislative and regulatory initiatives could adversely affect demand for our products and have a material adverse impact on our revenues. Our business and results of operations could therefore be adversely affected by the current healthcare reform legislation as well as future healthcare reform.

Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers' spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we succeed in bringing our new products to market, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at profitable prices.

Excise tax on medical device sales will cause our costs to increase.

Beginning in January 2013, sales of medical devices are taxed at a rate of 2.3%. We began paying this tax in the fourth quarter of fiscal 2013. The imposition of this tax may require us to identify ways to reduce spending in other areas, such as research and development of our products, to offset the increased expense. We do not expect to be able to pass along the cost of the tax to our customers or to be able to offset the cost of the tax through higher sales volumes resulting from the expansion of health insurance. This tax increases our cost of doing business and hinders profitability.

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, soliciting, receiving or providing remuneration, directly or indirectly, to induce (i) the referral of an individual, for an item or service, or (ii) the 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;

Federal false claims laws which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, 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 federal 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 payor, 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 and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota, 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 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 on an annual basis to the U.S. Department of Health and Human Services, or HHS. Companies are required to start collecting this data on August 1, 2013 and will be required to report this information to HHS in early 2014. These laws all provide for penalties for non-compliance. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and reporting requirements, increases the possibility that a company may run afoul of one or more laws.

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.

Table of Contents

We depend on Impella products for a significant portion of our revenues.

We derive, and expect to continue to derive, a significant portion of our revenues from sales of our Impella products. While we cannot fully predict what level of revenues our Impella products will generate, we anticipate that Impella product sales will continue to account for a significant portion of our revenues in the foreseeable future. Implementation of our strategy depends on continued sales of our Impella products. Our ability to generate sales of our Impella products may be impaired by the factors described below:

our failure to obtain approvals from the FDA and foreign regulatory authorities or to comply with government regulations, or the withdrawal of market clearance or the taking of other enforcement actions;

lack of acceptance or continued acceptance by physicians;

our reliance on specialized suppliers for certain components and materials;

manufacturing or quality control problems;

our inability to protect our proprietary technologies or an infringement of others' patents;

the loss of a distributor or distributor failure to perform;

our failure to compete successfully against our existing or potential competitors;

additional risks associated with selling in international markets;

long and variable sales and deployment cycles;

failure by third-party payors to provide appropriate levels of reimbursement;

our failure to comply with federal and state regulations; and

product liability claims.

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

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

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

Edgar Filing: ABIOMED INC - Form 10-K

approval processes, obtain and protect reimbursement, maintain cost effectiveness for our products, and supply commercial quantities of the product to the market.

Advances in medical technology, biotechnology and pharmaceuticals may reduce the size of the potential markets for our products or render those products obsolete. We are aware of other heart replacement device research efforts in the U.S., Canada, Europe and Japan. In addition, there are a number of companies; including Getinge, Thoratec Corporation, CardiacAssist, Levitronix, Jarvik Heart, HeartWare, MicroMed Technology, EvaHeart, Terumo Heart and several early-stage companies, that are developing heart assist products, including implantable left ventricular assist devices and miniaturized rotary ventricular assist devices.

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

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

developing our global sales and marketing infrastructure and capabilities;

expanding manufacturing capacity, maintaining quality and increasing production;

increasing our foreign regulatory compliance capabilities;

Table of Contents

implementing appropriate operational, financial and IT systems and internal controls;

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

training, managing and supervising our personnel worldwide.

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

The demand for many of our products and products under development is unproven, and we may be unable to successfully commercialize our products.

Our products and products under development may not enjoy commercial acceptance or success, which could adversely affect our business and operational results. We need to create markets for our Impella micro heart pumps, AB5000, and other existing products, as well as other new or future products, including achieving market acceptance among physicians, medical centers, patients and third-party payers. In particular, we need to gain acceptance of our Impella products among interventional cardiologists, who have not previously been users of our other devices. The obstacles we will face in trying to create successful commercial markets for our products include:

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

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

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

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

the cost of our products; and

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

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

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

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

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

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

Edgar Filing: ABIOMED INC - Form 10-K

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

Table of Contents

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

To be successful, we believe we will need to increase our manufacturing capacity. We do not have experience in manufacturing our Impella products in the commercial quantities that might be required to meet potential demand, nor do we have experience manufacturing our other products in large quantities. We may encounter difficulties in scaling up manufacturing of our products, including problems related to product yields, quality control and assurance, component and service availability, dependable sources of supply, adequacy of control policies and procedures and lack of skilled personnel. If we cannot hire, train and retain enough experienced and capable scientific and technical workers, we may not be able to manufacture sufficient quantities of our current or future products on-time and at an acceptable cost, which could limit market acceptance of our products or otherwise damage our business. In order for our manufacturing to meet the expected demand for our Impella products, we have been implementing process improvements on the Impella production line at our manufacturing facility in Aachen, Germany to increase the output that we can produce at the facility. In addition to programs designed to further increase yield and capacity levels, we have expanded manufacturing employment in Aachen and Danvers and relocated selected Impella sub-assembly production to our manufacturing facility in Danvers, Massachusetts. We continue to work on initiatives to expand our Impella manufacturing capacity in both Aachen and Danvers. If we are unable to implement these process improvements on a timely basis, it could inhibit our revenue growth.

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

We currently manufacture our Impella heart pumps at our facility in Aachen, Germany and we manufacture our other products and certain Impella subassemblies at our facility in Danvers, Massachusetts. Events such as fire, flood, loss of electricity or other disasters could prevent us from manufacturing our products in compliance with applicable FDA and other regulatory requirements, which could result in significant delays before we restore production or commence production at another site. These delays may result in lost sales. Our insurance may not be adequate to cover our losses resulting from disasters or other business interruptions. Any significant disruption in the manufacturing of our products could seriously harm our business and results of operations.

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

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

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

We depend heavily on the contributions of the principal members of our business, financial, technical, sales and support, regulatory and clinical, operating and administrative management and staff, many of whom would be difficult to replace. Our key personnel include our senior officers, many of whom have very specialized scientific, medical or operational knowledge. The loss of the service of any of the key members of our senior management team may significantly delay or prevent our achievement of our business objectives. Our ability to attract and retain qualified personnel, consultants and advisors is critical to our success. For example, many of the members of our clinical staff are registered nurses with experience in the surgery suite or cath lab, of which only a limited number of whom seek employment with a company like ours. Competition for skilled and experienced management, scientific, clinical and sales personnel in the medical devices industry is intense. We face competition for skilled and experienced management, scientific, clinical and sales personnel from numerous medical device and life sciences companies, universities, governmental entities and other research institutions. If we lose the services of any of the principal members of our management and staff, or if we are unable to attract and retain qualified personnel in the future, especially scientific and sales personnel, our business could be adversely affected.

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

We rely on third-party suppliers to provide us with some components used in our existing products and products under development. For example, we outsource the manufacturing of most of our consoles other than final assembly and testing. Relying on third-party suppliers makes us vulnerable to component part failures/obsolescence and to interruptions in supply, either of which could impair our ability to conduct clinical tests or to ship our products to our customers on a timely basis. Using third-party vendors makes it difficult and sometimes impossible for us to test fully certain components, such as components on circuit boards, maintain quality control, manage inventory and

Table of Contents

production schedules and control production costs. Manufacturers of our product components may be required to comply with the FDA or other regulatory manufacturing regulations and to satisfy regulatory inspections in connection with the manufacture of the components. Any failure by a supplier to comply with applicable requirements could lead to a disruption in supply. Vendor lead times to supply us with ordered components vary significantly and often can exceed six months or more. Both now and as we expand our manufacturing capacity, we cannot be sure that our suppliers will furnish us required components when we need them. These factors could make it more difficult for us to manufacture our products effectively and efficiently and could adversely impact our results of operations.

Some of our suppliers may be the only source for a particular component, which makes us vulnerable to significant cost increases. We have many foreign suppliers for some of our parts in which we are subject to currency exchange rate volatility. Vendors that are the sole source of certain products may decide to limit or eliminate sales of certain components to the medical industry due to product liability or other concerns and we might not be able to find a suitable replacement for those products. Our inventory may run out before we find alternative suppliers and we might be forced to purchase substantial inventory, if available, to last until we qualify an alternate supplier. If we cannot obtain a necessary component, we may need to find, test and obtain regulatory approval or clearance for a replacement component, produce the component ourselves or redesign the related product, which would cause significant delay and could increase our manufacturing costs. Any of these events could adversely impact our results of operations.

General economic and political conditions could have a material adverse effect on our business.

External factors can affect our profitability and financial condition. Such external factors include general domestic and global economic conditions, such as interest rates, tax rates and factors affecting global economic stability, and the political environment regarding healthcare in general. While the economic environment has shown some signs of improvement, the strength and timing of any economic recovery remains uncertain, and we cannot predict to what extent the global economic slowdown may negatively impact our business. For example, an increase in interest rates could result in an increase in our borrowing costs and could otherwise restrict our ability to access the capital markets. Negative conditions in the credit and capital markets could impair our ability to access the financial markets for working capital or other funds, and could negatively impact our ability to borrow. Such conditions could result in decreased liquidity and impairments in the carrying value of our investments, and could adversely affect our results of operations and financial condition. These and other conditions could also adversely affect our customers, and may impact their ability or decision to purchase our products or make payments on a timely basis.

We do business with foreign governments outside the United States. A number of these countries, including certain European countries, have experienced deterioration in credit and economic conditions. These conditions have resulted in, and may continue to result in, a reduction in the number of procedures that use our products and an increase in the average length of time that it takes to collect accounts receivable outstanding in these countries. In addition, we have been and may continue to be impacted by declines in sovereign credit ratings or sovereign defaults in these countries.

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

We are seeking to expand our international sales of our products by recruiting direct sales and support teams outside the U.S. Our international operations in Germany, France, Canada, Japan and the United Kingdom will be subject to a number of risks, which may vary from the risks we experience in the U.S., including:

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

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

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

longer sales cycles;

limited protection of intellectual property rights;

difficulty in collecting accounts receivable;

different income tax and sales tax environments;

difficulty in supporting patients using our products;

fluctuations in the values of foreign currencies; and

political and economic instability.

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

Table of Contents

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

We rely on distributors to market and sell our products in certain parts of Europe, Asia, South America, the Middle East and Australia. Many of these distributors have the exclusive right to distribute our products in their territory. We may hire distributors to market our products in additional international markets. Our success in these markets will depend almost entirely upon the efforts of our distributors, over whom we have little or no control. If a distributor does not market and sell our products aggressively, we could lose sales and impair our ability to compete in that market. We are also subject to credit risk associated with shipments to our distributors and this could negatively impact our financial condition and liquidity in the future.

Many of our customer relationships outside of the United States are, either directly or indirectly, with governmental entities, and we could be adversely affected by violations of the United States Foreign Corrupt Practices Act and similar worldwide anti-bribery laws outside the United States.

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Many of our customer relationships outside of the United States are, either directly or indirectly, with governmental entities and are therefore subject to such anti-bribery laws. Although our corporate policies mandate compliance with these anti-bribery laws, we operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our business, results of operations and financial condition.

Our operating results may fluctuate unpredictably.

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

the timing of customer orders and deliveries;

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

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

costs we incur developing and testing our Impella heart pumps and other products;

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

costs we incur in connection with the class action suits and derivative action that has been filed against us;

costs we incur in connection with the investigation being conducted by the United States Attorney's Office for the District of Columbia;

additional taxes, such as the Medical Device tax;

economic conditions in the healthcare industry; and

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

Edgar Filing: ABIOMED INC - Form 10-K

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

We may be unable to obtain any benefit from our net operating loss carryforwards and research and development credit carryforwards.

At March 31, 2013, we had federal and state net operating loss, or NOL, carryforwards of approximately \$188.9 million and \$105.9 million, respectively, which expire in varying years from fiscal 2014 through fiscal 2033. During the year ended March 31, 2013, state NOL carryforwards of approximately \$21.2 million expired. Additionally, at March 31, 2013, we had federal and state research and development credit carryforwards of approximately \$11.6 million and \$5.5 million, respectively, which expire in varying years from fiscal 2014 through fiscal 2033.

Table of Contents

Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset our deferred tax assets. Additionally, the future utilization of our NOL and research and development credit carryforwards to offset future taxable income may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to ownership changes that have occurred previously or that could occur in the future. Ownership changes, as defined in Section 382 of the Internal Revenue Code, can limit the amount of NOLs and research and development credit carry forwards that a company can use each year to offset future taxable income and taxes payable. We completed a Section 382 study and analysis in fiscal 2008 to determine whether changes in the composition of our stockholders, including our acquisition of Impella and our public offering, resulted in an ownership change for purposes of Section 382. We believe that all of our federal and state NOLs are available for carryforward to future tax periods, subject to the statutory maximum carryforward limitation of any annual NOL. Any future potential limitation to all or a portion of the NOL or research and development credit carryforwards, before they can be utilized, would reduce our gross deferred tax assets. We plan to monitor subsequent ownership changes, which could impose limitations in the future. In addition, foreign jurisdictions have rules that may limit our ability to utilize net operating loss carryforwards against taxable income in those jurisdictions.

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

The development, manufacture and sale of any medical device in the U.S. and abroad is very expensive. We cannot be sure that we will have the necessary funds to develop and commercialize our new products, or that additional funds will be available on commercially acceptable terms, if at all. If we are unable to obtain the necessary funding to develop and commercialize our products, our business may be adversely affected. We believe we have sufficient liquidity to finance our operations for the next fiscal year. We also may evaluate from time to time other financing alternatives as necessary to fund operations.

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

Our intellectual property rights are and will continue to be a critical component of our success. A substantial portion of our intellectual property rights relating to the Impella products, AB5000, BVS 5000, 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 be approved, may not give us a competitive advantage, could be challenged by others, or if issued, could be deemed invalid or unenforceable. Patent prosecution, related proceedings, and litigation in the U.S. and in other countries may be expensive, time consuming and ultimately unsuccessful. In addition, patents issued by foreign countries may afford less protection than is available under U.S. patent law and may not adequately protect our proprietary information. Our competitors may independently develop proprietary technologies and processes that are the same as or substantially equivalent to ours or design around our patents. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect our business and our prospects.

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

Product liability claims could damage our reputation and adversely affect our financial results.

The clinical use of medical products, even after regulatory approval, poses an inherent risk of product liability claims. We maintain limited product liability insurance coverage, subject to certain deductibles and exclusions. We cannot be sure that product liability insurance will be available in the future or will be available on acceptable terms or at reasonable costs, or that such insurance will provide us with

Table of Contents

adequate coverage against potential liabilities. Claims against us, regardless of their merit or potential outcome, may also hurt our ability to obtain physician endorsement of our products or expand our business. As we continue to introduce more products, we face an increased risk that a product liability claim will be brought against us.

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

The risk of product liability claims is heightened when we sell products that are intended to support a patient until the end of life. The finite life of our products, as well as complications associated with their use, could give rise to product liability claims whether or not the products have extended or improved the quality of a patient's life. If we have to pay product liability claims in excess of our insurance coverage, our financial condition will be adversely affected.

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

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

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

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

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced. We may be required to capitalize a significant amount of intangibles, including goodwill, which may lead to significant amortization or write-off charges. These amortization charges and write-offs could decrease our future earnings or increase our future losses.

Fluctuations in foreign currency exchange rates could result in declines in our reported sales and results of operations.

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

Risks Related to Our Common Stock

The market price of our common stock is volatile.

The market price of our common stock has fluctuated widely and may continue to do so. For example, from April 1, 2012 to March 31, 2013, the price of our stock ranged from a low of \$11.80 per share to a high of \$26.17 per share. Many factors could cause the market price of our common stock to rise and fall. Some of these factors are:

variations in our quarterly results of operations;

the status of regulatory approvals for our products;

the introduction of new products by us or our competitors;

Table of Contents

acquisitions or strategic alliances involving us or our competitors;

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

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

the hiring or departure of key personnel;

results of clinical trials of our products;

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

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

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

The sale of additional shares of our common stock, or the exercise of outstanding options to purchase our common stock, would dilute our stockholders ownership interest.

We have issued a substantial number of options to acquire our common stock and we expect to continue to issue options to our employees and others. If all outstanding stock options were exercised, our stockholders would suffer dilution of their ownership interest. In addition, we have issued from time to time, additional shares of our common stock in connection with acquisitions, public offerings, and other activities. Future issuances of our common stock would also result in a dilution of our stockholders' ownership interest.

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

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

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

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

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

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

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

Edgar Filing: ABIOMED INC - Form 10-K

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

Table of Contents

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters is located at 22 Cherry Hill Drive in Danvers, Massachusetts and consists of approximately 80,000 square feet of space under an operating lease that expires on February 28, 2016.

In addition, we have certain rights to terminate the lease early, subject to the payment of a specified termination fee based on the timing of the termination, as further outlined in the lease amendment. This facility encompasses most of our U.S. operations, including research and development, manufacturing, sales and marketing and general and administrative departments.

Our European headquarters are located in Aachen, Germany in a leased facility of approximately 33,000 square feet. The existing lease for this space expired on December 31, 2012. We entered into an arrangement with our landlord to continue renting our existing space in Aachen at the same monthly rental rate until June 30, 2013 while we negotiate a longer term lease agreement. The building houses most of the manufacturing operations for our Impella product line as well as certain research and development functions and the sales, marketing and general and administrative functions for most of our product lines sold in Europe and the Middle East.

We lease a small office in Paris, France, which focuses on the sales and marketing of our product lines sold in France.

ITEM 3. LEGAL PROCEEDINGS

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

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 the Company's marketing and labeling of the Impella 2.5. On October 31, 2012, we accepted service of a subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5. We are in the process of responding and we intend to cooperate fully with the subpoena.

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 allege 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 has consolidated these complaints. A consolidated amended complaint was filed by the plaintiffs on May 20, 2013.

Additionally, on February 4, 2013, an alleged holder of our common stock 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 alleges 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 seeks damages in an unspecified amount. We have moved to dismiss the complaint in its entirety, and that motion has been briefed, argued and is under advisement by the Court. Separately, on January 21, 2013 and February 5, 2013, we received demands from purported stockholders to inspect certain of our books and records related to these matters.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Price**

Our common stock is traded on the Nasdaq Global Market under the symbol ABMD. The following table sets forth the range of high and low sales prices per share of common stock, as reported by the Nasdaq Global Market for our two most recent fiscal years:

	High	Low
Fiscal Year Ended March 31, 2012		
First Quarter	\$ 19.19	\$ 14.04
Second Quarter	17.37	10.05
Third Quarter	21.50	9.98
Fourth Quarter	24.74	17.09
	High	Low
Fiscal Year Ended March 31, 2013		
First Quarter	\$ 26.17	\$ 18.74
Second Quarter	24.93	19.49
Third Quarter	21.29	11.80
Fourth Quarter	18.92	11.96

Number of Stockholders

As of May 15, 2013, we had approximately 608 holders of record of our common stock and there were approximately 9,158 beneficial holders of our common stock. Many beneficial holders hold their stock through depositories, banks and brokers included as a single holder in the single street name of each respective depository, bank, or broker.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We anticipate that we will retain all of our future earnings, if any, to support operations and to finance the growth and development of our business. Our payment of any future dividends will be at the discretion of our board of directors and will depend upon our financial condition, operating results, cash needs and growth plans.

Issuer Purchases of Equity Securities

In November 2012, our Board of Directors authorized a stock repurchase program for up to \$15.0 million of our common stock. We financed the stock repurchase program with available cash. During the year ended March 31, 2013, we repurchased 1,123,587 shares for \$15.0 million in open-market purchases at an average cost of \$13.39 per share, including commission expense. We completed the purchase of common stock under this stock repurchase program in January 2013.

The following table provides information about our repurchases of shares of our common stock during the fiscal quarter ended March 31, 2013. During that period, we did not act in concert with any affiliate or any other person to acquire any of our common stock and, accordingly, we do not believe that purchases by any such affiliate or other person (if any) are reportable in the following table.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
January 1-31, 2013	323,587(1)	\$ 13.57(1)	323,587(1)	

Edgar Filing: ABIOMED INC - Form 10-K

February 1-28, 2013

March 1-31, 2013

- (1) In January 2013, we completed our stock repurchase program by repurchasing 323,587 shares in open-market transactions for an aggregate cost of \$4.4 million, including commission expense.

Table of Contents**Performance Graph**

The following graph compares the yearly change in the cumulative total stockholder return for our last five full fiscal years, based upon the market price of our common stock, with the cumulative total return on a Nasdaq Composite Index (U.S. Companies) and a peer group, the Nasdaq Medical Equipment-SIC Code 3840-3849 Index, which is comprised of medical equipment companies, for that period. The performance graph assumes the investment of \$100 on March 31, 2008 in our Common Stock, the Nasdaq Composite Index (U.S. Companies) and the peer group index, and the reinvestment of any and all dividends.

Cumulative Total Return (\$)

	3/31/2008	3/31/2009	3/31/2010	3/31/2011	3/31/2012	3/31/2013
ABIOMED, Inc	100	37.29	78.54	110.58	168.87	142.09
Nasdaq Composite Index	100	67.07	105.22	122.02	135.65	143.37
Nasdaq Medical Equipment SIC Code 3840-3849	100	53.98	91.47	100.00	91.82	89.36

This graph is not soliciting material under Regulation 14A or 14C of the rules promulgated under the Securities Exchange Act of 1934, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any of our filings under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Transfer Agent

American Stock Transfer & Trust Company, 59 Maiden Lane, New York, NY 10038, is our stock Transfer Agent.

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA****SELECTED CONSOLIDATED FINANCIAL DATA**

(In thousands, except per share data)

	2013	Fiscal Years Ended March 31,			2009
		2012	2011	2010	
			(in \$000 s)		
Statement of Operations Data:					
Revenue:					
Products	\$ 157,614	\$ 125,286	\$ 99,837	\$ 84,765	\$ 72,512
Funded research and development	510	1,089	1,314	948	698
	158,124	126,375	101,151	85,713	73,210
Costs and expenses:					
Cost of product revenue	31,596	24,507	21,977	22,529	20,437
Research and development	25,647	27,159	26,677	25,954	25,328
Selling, general and administrative	84,227	71,711	62,287	60,837	55,357
Amortization of intangible assets	111	1,478	1,395	1,469	1,606
	141,581	124,855	112,336	110,789	102,728
Income (loss) from operations	16,543	1,520	(11,185)	(25,076)	(29,518)
Other income (expense):					
Investment (expense) income, net	(7)	(3)	9	373	(1,404)
Gain on sale of WorldHeart stock			456	6,389	313
Gain on settlement of investment		1,017			
Other income (expense), net	326	9	(143)	(39)	(236)
	319	1,023	322	6,723	(1,327)
Income (loss) before income tax provision	16,862	2,543	(10,863)	(18,353)	(30,845)
Income tax provision	1,848	1,048	892	671	752
Net income (loss)	\$ 15,014	\$ 1,495	\$ (11,755)	\$ (19,024)	\$ (31,597)
Basic net income (loss) per share	\$ 0.38	\$ 0.04	\$ (0.32)	\$ (0.52)	\$ (0.91)
Basic weighted average shares outstanding	39,113	38,374	37,167	36,875	34,882
Diluted net income (loss) per share	\$ 0.37	\$ 0.04	\$ (0.32)	\$ (0.52)	\$ (0.91)
Diluted weighted average shares outstanding	41,052	40,172	37,167	36,875	34,882
Balance Sheet Data:					
Cash, cash equivalents, and short and long term marketable securities	\$ 88,113	\$ 77,223	\$ 60,312	\$ 58,265	\$ 60,900
Working capital	89,549	88,124	62,394	64,604	70,910
Total assets	169,999	153,911	131,588	129,570	135,958
Stockholder's equity	137,080	126,297	104,743	107,956	115,983

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

All statements, trend analysis and other information contained in the following discussion relative to markets for our products and trends in revenue, gross margin and anticipated expense levels, as well as other statements, including words such as may, anticipate, believe, plan, estimate, expect, and intend and other similar expressions constitute forward-looking statements. These forward-looking statements are subject to business and economic risks and uncertainties and our actual results of operations may differ materially from those contained in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under Item 1A Risk Factors as well as other risks and uncertainties referenced in this report.

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, and principally our Impella 2.5 product, which 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, we announced that our Impella CP product received 510(k) clearance from the FDA for circulatory support for up to six hours. The Impella CP (previously marketed outside of the U.S. as Impella cVAD) received CE Mark approval to market the device in the European Union and Health Canada approval to market the device in Canada. We initiated a controlled launch with top heart hospitals in the U.S. during the second quarter of fiscal 2013 and have continued a controlled commercial launch of Impella CP to more hospitals in the U.S., which we expect to continue over the next 12 months.

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 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 announced the enrollment of the first patient in RECOVER RIGHT and we expect to enroll 30 patients with signs of right side heart failure and are being treated in the cath lab or surgery suite. We are also conducting initial patient use trials of the Impella RP outside of the U.S. This product is not currently available for commercial use.

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. If the FDA accepts the panel's determination and issues a final order classifying these devices in Class III, we will be required to file a PMA application for Impella 2.5. 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 intend to submit a modular PMA submission for Impella by the end of fiscal 2014. A modular PMA allows for a parallel submission of preclinical and manufacturing data for review while still preparing the clinical module. We are working with the FDA to prepare this modular PMA application for our Impella products.

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 the Company's marketing and labeling of the Impella 2.5. On October 31, 2012, we accepted service of a subpoena related to this investigation. The subpoena seeks documents related to the Impella 2.5. We are in the process of responding and we intend to cooperate fully with the subpoena.

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 allege that the defendants violated the

Table of Contents

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 has consolidated these complaints. A consolidated amended complaint was filed by the plaintiffs on May 20, 2013.

Additionally, on February 4, 2013, an alleged holder of our common stock 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 alleges 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 seeks damages in an unspecified amount. We have moved to dismiss the complaint in its entirety, and that motion has been briefed, argued and is under advisement by the Court. Separately, on January 21, 2013 and February 5, 2013, we received demands from purported stockholders to inspect certain of our books and records related to these matters.

In November 2012, we announced that the Impella RP received Investigational Device Exemption, or IDE, approval from the FDA for use in a pivotal clinical study in the U.S. 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. During the fourth quarter of fiscal 2013, we announced the enrollment of the first patient in RECOVER RIGHT, an Investigational Device Exemption (IDE) study of Impella RP (Right Peripheral). We are also conducting initial patient use trials of the Impella RP outside of the U.S. This product is not currently available for commercial use.

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 recently 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, including BVS and AB5000, will continue to decrease as we continue to focus on our Impella products.

For the year ended March 31, 2013, we recognized net income of \$15.0 million. With the exception of fiscal 2012 and 2013, we have incurred net losses since our inception. Even though we were profitable in fiscal 2013, 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, pay additional excise taxes as a result of the implementation of the medical device tax in the U.S. in January 2013, incur additional legal fees to comply with the subpoena received from the Department of Justice in October 2012, defend ourselves from other legal claims and invest in new markets such as Japan.

Critical Accounting Policies and Estimates

Significant Estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements. The preparation of financial statements in conformity with generally accepted accounting principles of the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. We base our estimates on historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, collectability of receivables, realizability of inventory, goodwill and intangible assets, valuation of long-lived assets, accrued expenses, warranty provisions, stock-based compensation, income taxes including the valuation allowance for deferred tax assets, contingencies and litigation. Provisions for depreciation are based on their estimated useful lives using the straight-line method. Some of these estimates can be subjective and complex and, consequently, actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We recognize revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectibility is reasonably assured.

Revenue from product sales to customers is recognized when delivery has occurred. All costs related to product sales are recognized at time of delivery. We do not provide for rights of return to customers on our product sales and therefore do not record a provision for returns.

Maintenance and service support contract revenues are included in product revenue and are recognized ratably over the term of the service contracts based upon the elapsed term of the service contract. Revenue is recognized as it is earned in limited instances where we rent console medical devices to customers on a month-to-month basis or for a longer specified period of time.

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

Table of Contents

Goodwill

Goodwill is recorded when consideration for an acquisition exceeds the fair value of the net tangible and intangible assets acquired. Goodwill is not amortized, instead we evaluate goodwill for impairment 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 goodwill impairment test involves a two-step process. The first step is a comparison of the reporting unit's fair value to its carrying value. If the reporting unit's fair value exceeds its carrying value, no further procedures are required. However, if the reporting unit's fair value is less than its carrying value, an impairment of goodwill may exist, requiring a second step to measure the amount of impairment loss. If the implied fair value of goodwill is less than the recorded goodwill, an impairment charge is recorded for the difference.

We estimate the fair value of our single reporting unit using a combination of the income approach and the market approach. The income approach incorporates the use of a discounted cash flow method in which the estimated future cash flows and terminal values for the reporting unit is discounted to a present value using an appropriate discount rate. Cash flow projections are based on management's estimates of economic and market conditions which drive key assumptions of revenue growth rates, operating margins, capital expenditures and working capital requirements. The discount rate is based on the specific risk characteristics of the reporting unit and its underlying forecast. The market approach estimates fair value by comparing publicly traded companies with similar operating and investment characteristics as the reporting unit. The fair values determined by the market approach and income approach, are weighted to determine the fair value for the reporting unit based primarily on the similarity of the operating and investment characteristics of the reporting unit to the comparable publicly traded companies used in the market approach. In order to assess the reasonableness of the calculated reporting unit's fair value, we also compare the reporting unit's fair value to our market capitalization (per share stock price times number of common shares outstanding) and calculate an implied control premium (the excess of the reporting unit's fair value over the market capitalization).

We performed our annual impairment review for fiscal 2013 as of October 31, 2012 and determined that no write-down for impairment of goodwill was required as the fair value of the reporting unit substantially exceeded the carrying value. The carrying amount of goodwill at March 31, 2013 was \$35.4 million.

Stock-Based Compensation

We record stock-based compensation in our statements of operations based on the fair value method. This expense is determined after consideration of several significant judgments and estimates, including the probable outcome for awards with a performance condition or conditions. The fair value of stock option grants is estimated using the Black-Scholes option pricing model, which requires management to make certain assumptions with respect to selected model inputs. 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 historical volatility of our stock. In addition, an expected dividend yield of zero is used in the option valuation model because we do not pay dividends and do not expect to pay any dividends in the foreseeable future. We estimate the expected term of options based on historical exercise experience and estimates of future exercises of unexercised options. Forfeitures are estimated based on an analysis of actual option forfeitures, adjusted to the extent historic forfeitures may not be indicative of forfeitures in the future.

For awards with service conditions only, we recognize compensation cost on a straight-line basis over the requisite service period. For awards with service and performance conditions, we recognize compensation costs using the graded vesting method over the requisite service period. Accruals of compensation cost for awards with performance conditions are based on the probable outcome of the performance conditions. The cumulative effects of changes in the probability outcomes are recorded in the period in which the changes occur.

Income Taxes

Our provision for income taxes is composed of a current and a deferred portion. The current income tax provision is calculated as the estimated taxes payable or refundable on tax returns for the current year. The deferred income tax provision is calculated for the estimated future tax effects attributable to temporary differences and net operating loss carryforwards using expected tax rates in effect in the years during which the differences are expected to reverse.

We regularly assess our ability to realize our deferred tax assets. Assessing the realization of deferred tax assets requires significant management judgment. In determining whether our deferred tax assets are more likely than not realizable, we evaluated all available positive and negative evidence, and weighted the evidence based on its objectivity. Evidence we considered included, net operating losses incurred from our inception to March 31, 2011, expiration of various federal and state attributes, the uncertainty relative to the Department of Justice investigation and our planned PMA application for our Impella products, profits before tax for fiscal 2012 and 2013 and forecasted profit before tax for fiscal 2014. Based on our review of all available evidence, we determined that the objectively verifiable negative evidence outweighed the positive evidence and we recorded a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realizable as of March 31, 2013.

Accounting for income taxes requires a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if, based on the technical merits, it is more likely than not that the position will be sustained upon audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. We re-evaluate these uncertain tax positions on a quarterly basis. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax laws, effectively settled issues under audit and new audit activity. Any changes in these factors could result in the recognition of a tax benefit or an additional charge to the tax provision. We accrue for the effects of uncertain tax positions and the related potential penalties and interest.

Table of Contents**Results of Operations**

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

	Year Ended March 31,		
	2013	2012	2011
Revenues:			
Product	99.7%	99.1%	98.7%
Funded research and development	0.3	0.9	1.3
Total revenues	100.0	100.0	100.0
Costs and expenses:			
Cost of product revenue	20.0	19.4	21.7
Research and development	16.2	21.5	26.4
Selling, general and administrative	53.3	56.7	61.6
Amortization of intangible assets	0.1	1.2	1.4
Total costs and expenses	89.5	98.8	111.1
Income (loss) from operations	10.5	1.2	(11.1)
Other income (expense):			
Gain on settlement of investment		0.8	0.5
Other expense, net	0.2		(0.1)
	0.2	0.8	0.4
Income (loss) before income tax provision	10.7	2.0	(10.7)
Income tax provision	1.2	0.8	0.9
Net income (loss)	9.5%	1.2%	(11.6)%

Fiscal Years Ended March 31, 2013 and March 31, 2012 (fiscal 2013 and fiscal 2012)

Revenue

Our revenues are comprised of the following:

	Year Ended March 31,	
	2013	2012
	(in \$000 s)	
Impella product revenue	\$ 140,325	\$ 106,925
Other products	8,134	11,088
Service and other revenue	9,155	7,273
Total product revenues	157,614	125,286
Funded research and development	510	1,089
Total revenues	\$ 158,124	\$ 126,375

Edgar Filing: ABIOMED INC - Form 10-K

Impella product revenue encompasses Impella 2.5, Impella CP, Impella 5.0, and Impella LD product sales. Other product revenue includes AB5000, BVS5000 and cannulae product sales. Service and other revenue represents revenue earned on preventative maintenance service contracts and maintenance calls.

Total revenues for fiscal 2013 increased by \$31.7 million, or 25%, to \$158.1 million from \$126.4 million for fiscal 2012. The increase in total revenue was primarily due to higher Impella revenue due to greater utilization in the U.S., which was attributable in part to the launch of Impella CP in fiscal 2013.

Table of Contents

Impella product revenues for fiscal 2013 increased by \$33.4 million, or 31%, to \$140.3 million from \$106.9 million for fiscal 2012. Most of our increase in Impella revenue was from disposable catheter sales in the U.S., as we focus on increasing utilization of our disposable catheter products through continued investment in our field organization and physician training program. In the second half of fiscal 2013, we began our initial launch of Impella CP in the U.S. We plan to continue our controlled commercial launch of Impella CP during fiscal 2014 and we expect Impella CP and Impella 2.5 revenues to increase as we add new customer sites and increase utilization at existing customer sites.

Other product revenues for fiscal 2013 decreased by \$3.0 million, or 27%, to \$8.1 million from \$11.1 million for fiscal 2012. The decrease in other revenue was due to a decline in BVS 5000 and AB5000 disposable sales. We are currently only actively selling the BVS 5000 upon request and expect that AB5000 revenue will continue to decline in fiscal 2014 as we focus our sales efforts in the surgical suite on Impella 5.0 and LD.

Service and other revenue for fiscal 2013 increased by \$1.9 million, or 26%, to \$9.2 million from \$7.3 million for fiscal 2012. The increase in service revenue was primarily due to an increase in preventative maintenance service contracts, as we expand the use of our Impella AIC consoles.

Cost of Product Revenue

Cost of product revenue for fiscal 2013 increased by \$7.1 million, or 29%, to \$31.6 million from \$24.5 million for fiscal 2012. Gross margin for fiscal 2013 was 80% compared to 81% for fiscal 2012. The increase in cost of product revenues was related to increased Impella demand and higher production volume and costs to support the higher demand for Impella products. The decrease in gross margin was related primarily to increased investment in expanding manufacturing capacity to support future demand for Impella products, start up costs related to the initial production of Impella CP and increased shipments of AIC consoles.

Research and Development Expenses

Research and development expenses for fiscal 2013 decreased by \$1.6 million, or 6%, to \$25.6 million from \$27.2 million in fiscal 2012. The decrease in research and development expenses was due to a decrease in clinical trial expenditures as we completed the Protect II trial for the Impella 2.5 and spending on Impella CP product development activities decreased in fiscal 2013 after the Impella CP was approved in the U.S. in September 2012, and was partially offset by an increase in spending on product development initiatives associated with Impella RP and Symphony. We expect research and development expenses to increase in fiscal 2014 as we continue to focus on new product development initiatives associated with Impella RP and Symphony. We will also have additional research and development costs as we prepare our PMA application for our existing Impella products available for sale in the U.S. and expenses related to obtaining regulatory approval for our Impella products in Japan.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for fiscal 2013 increased by \$12.5 million, or 17%, to \$84.2 million from \$71.7 million in fiscal 2012. The increase in selling, general and administrative expenses was primarily due to increased personnel expenses related to increased U.S. field sales and clinical headcount, increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support and increases in legal expenses. During fiscal 2013, we incurred legal expenses of approximately \$3.1 million in connection with complying with the subpoena received from the Department of Justice in October 2012 and defense of other legal claims. We also incurred \$0.7 million of expenses in fiscal 2013 for payment of the medical device tax after its implementation in the U.S. in January 2013.

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. We also plan to increase our marketing, service, and training investments to support the efforts of the sales and field clinical teams to drive recovery awareness for acute heart failure patients. We also will have additional expenses with the implementation of the medical device tax. We expect to continue to incur significant legal expenses related to the Department of Justice investigation, our defense of purported class actions and a derivative action and our response to information requests for the foreseeable future.

Amortization of Intangible Assets

Amortization of intangible assets for fiscal 2013 decreased by \$1.4 million, or 93%, to \$0.1 million from \$1.5 million for fiscal 2012. Amortization primarily relates to specifically identified assets from the Impella acquisition in May 2005. We fully amortized the remaining net book value of our intangible assets during the year ended March 31, 2013.

Income Tax Provision

During fiscal 2013 and 2012, we recorded provisions for income taxes of \$1.8 million and \$1.0 million, respectively. The income tax provision is primarily due to \$1.1 million of income taxes in Germany that we do not expect will be offset by our net operating loss

Table of Contents

carryforwards in Germany. Accordingly, we expect to have a tax liability in Germany that we will pay in cash. We have also recorded provisions of \$0.8 million for income taxes related to our deferred tax liability on our goodwill and alternative minimum tax in the U.S. If we continue to be profitable, we expect that income tax expense will increase in the future.

Net Income

During fiscal 2013, we recognized net income of \$15.0 million, or \$0.38 per basic share and \$0.37 per diluted share compared to net income of \$1.5 million, or \$0.04 per basic and diluted share, for the prior fiscal year. The increase in net income in fiscal 2013 compared to fiscal 2012 was due primarily to increased Impella sales due to greater demand in the U.S. Even though we were profitable in fiscal 2013 and 2012, we may incur 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, pay additional excise taxes as a result of the implementation of the medical device tax in the U.S. in January 2013, incur additional legal fees to comply with the subpoena received from the Department of Justice in October 2012 and defend ourselves from other legal claims and invest in new markets such as Japan.

Fiscal Years Ended March 31, 2012 and March 31, 2011 (fiscal 2012 and fiscal 2011)**Revenue**

Our revenues are comprised of the following:

	Year Ended March 31,	
	2012	2011
	(in \$000 s)	
Impella products	\$ 106,925	\$ 78,230
Other products	11,088	15,751
Service and other revenue	7,273	5,856
 Total product revenues	 125,286	 99,837
Funded research and development	1,089	1,314
 Total revenues	 \$ 126,375	 \$ 101,151

Total revenues for fiscal 2012 increased by \$25.2 million, or 25%, to \$126.4 million from \$101.2 million for fiscal 2011. The increase in total revenue was primarily due to higher Impella revenue due to greater utilization in the U.S.

Impella product revenues for fiscal 2012 increased by \$28.7 million, or 37%, to \$106.9 million from \$78.2 million for fiscal 2011. Most of our Impella revenue was from disposable product sales of Impella 2.5 in the U.S., as we focused on controlled rollouts for new sites and increasing utilization of these products through continued investment in our sales force and physician training.

Other product revenues for fiscal 2012 decreased by \$4.7 million or 30%, to \$11.1 million from \$15.8 million for fiscal 2011. The decrease in other revenue was due to a decline in BVS and AB5000 disposable sales.

Service and other revenue for fiscal 2012 increased by \$1.4 million, or 24%, to \$7.3 million from \$5.9 million for fiscal 2011. The increase in service revenue was primarily due to an increase in service contracts, primarily for Impella consoles.

Cost of Product Revenue

Cost of product revenue for fiscal 2012 increased by \$2.5 million or 12%, to \$24.5 million from \$22.0 million for fiscal 2011. Gross margin for fiscal 2012 was 81% compared to 78% for fiscal 2011. The increase in gross margin was primarily due to higher reorders of Impella product disposable pumps and improved manufacturing efficiency.

Research and Development Expenses

Edgar Filing: ABIOMED INC - Form 10-K

Research and development expenses for fiscal 2012 increased by \$0.5 million, or 2%, to \$27.2 million from \$26.7 million in fiscal 2011. The increase in research and development expenses was due to an increase in spending on product development initiatives associated with

Table of Contents

Impella RP, Impella cVAD and Symphony, and was partially offset by a decrease in clinical trial expenditures as we completed our work associated with the Protect II trial for the Impella 2.5. Research and development expenses for fiscal 2012 and 2011 included \$4.9 million and \$8.8 million, respectively, in clinical trial costs primarily associated with our Impella 2.5 U.S. trials.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for fiscal 2012 increased by \$9.4 million, or 15%, to \$71.7 million from \$62.3 million in fiscal 2011. The increase in selling, general and administrative expenses was primarily due to an increased field headcount as we concentrated our commercial efforts in the U.S. and increased spending on marketing initiatives as we continued to educate physicians on the benefits of hemodynamic support.

Amortization of Intangibles

Amortization of intangible assets for fiscal 2012 decreased by \$0.1 million, or 6%, to \$1.5 million from \$1.4 million for fiscal 2011. Amortization primarily relates to specifically identified assets from the Impella acquisition.

Gain on Sale of WorldHeart Stock

In December 2007, we made a \$5.0 million investment in WorldHeart, a developer of an implantable mechanical circulatory support system for chronic heart failure patients. We recorded an impairment charge of \$5.0 million in fiscal 2008, reducing the carrying value of the investment to zero. In July 2008, the note receivable and warrant were converted into common stock of WorldHeart. In fiscal 2010 we sold 2,543,496 shares of WorldHeart common stock, which resulted in a gain of \$6.4 million. In fiscal 2011 we sold our remaining 188,170 shares of WorldHeart common stock, which resulted in a gain of \$0.5 million.

Gain on Settlement of Investment

In December 2011, we received \$1.0 million in proceeds in conjunction with a settlement agreement on an investment.

Income Tax Provision

During fiscal 2012 and 2011, we recorded a provision for income taxes of \$1.0 million and \$0.9 million, respectively. The income tax provision is primarily due to income taxes in Germany that we do not expect will be offset by our net operating loss carryforwards in Germany and therefore we expect to have a tax liability that we will pay in cash. We have also recorded provisions for income taxes related to our deferred tax liability on our goodwill and alternative minimum tax in the U.S.

Net Income (Loss)

During fiscal 2012, we incurred net income of \$1.5 million, or \$0.04 per basic and diluted share compared to a net loss of \$11.8 million, or \$0.32 per share, for the prior fiscal year. The increase in the net income in fiscal 2012 compared to the net loss in fiscal 2011 was due primarily to increased Impella sales due to greater demand in the U.S.

Liquidity and Capital Resources

At March 31, 2013, our cash, cash equivalents, and short and long-term marketable securities totaled \$88.1 million, an increase of \$10.9 million compared to \$77.2 million in cash, cash equivalents and short-term marketable securities at March 31, 2012. 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 infrastructure in the U.S., increase our Impella manufacturing capacity, increase our inventory levels in order to meet increasing customer demand for Impella in the U.S., fund new product development, pay for fees related to the Department of Justice investigation, our defense of purported class actions and a derivative action, and our response to information requests and provide for general working capital needs. Through March 31, 2013, we have funded our operations principally from product sales and through the sale of equity securities. We also generate cash through funded research and development revenue.

In November 2012, our Board of Directors authorized a stock repurchase program for up to \$15.0 million of our common stock. We financed the stock repurchase program with our available cash. During the year ended March 31, 2013, we repurchased 1,123,587 shares for

Table of Contents

\$15.0 million in open market purchases at an average cost of \$13.39 per share, including commission expense. We completed the purchase of common stock under this stock repurchase program in January 2013.

Marketable securities at March 31, 2013 consisted of \$78.7 million held in funds that invest in U.S. Treasury and government-backed securities. 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.

During the year ended March 31, 2013, net cash provided by operating activities was \$26.4 million, compared to \$3.6 million during the same period in the prior year. The increase in cash provided by operations was primarily attributable to the improvement in net income of \$13.5 million reflected in our net income of \$15.0 million for the year ended March 31, 2013 compared to \$1.5 million in fiscal 2012, supplemented by a \$2.7 million increase in cash provided by accounts receivable due to increases in revenue and timing of receivable collections and a \$0.9 million decrease in cash used for accounts payable, which were offset by a \$4.4 million increase in cash used for accrued expenses primarily related increases in inventory costs and higher personnel expenses as a result of increased headcount and increases in legal expenses, and a \$0.9 million increase in cash used for inventories as we have increased inventory safety stock levels in fiscal 2013 to support continued growing customer demand for Impella. In addition, net cash provided by operating activities was impacted by changes in non-cash adjustments of a \$1.7 million increase in stock-based compensation, partially offset by a \$1.6 million decrease in depreciation and amortization expense and a \$0.6 million decrease in write-downs of inventory.

During the year ended March 31, 2013, net cash used for investing activities was \$10.3 million, compared to \$17.5 million during the same period in the prior year. The decrease in cash used for investing activities was primarily attributable to a \$34.3 million increase in proceeds from the sale and maturity of marketable securities, partially offset by a \$24.9 million increase in purchases of marketable securities. We also had a \$1.1 million increase in cash used for capital expenditures and a \$1.0 million decrease in proceeds upon settlement of an investment in fiscal 2012.

During the year ended March 31, 2013, net cash used for financing activities was \$11.8 million, compared to net cash provided by financing activities of \$14.7 million during the same period in the prior year. The increase in cash used for financing activities was primarily attributable to a \$15.0 million increase in cash used for the repurchase of common stock under our share repurchase program, an \$11.3 million decrease in proceeds from the exercise of stock options because fewer stock options were exercised in that period as compared to the prior year, and a \$0.2 million increase in payments in lieu of issuance of common stock for minimum payroll taxes upon vesting of certain equity awards.

Capital expenditures for fiscal 2014 are estimated to range from \$3.0 to \$4.0 million, and are expected to relate primarily to capital expenditures for manufacturing capacity increases for Impella, leasehold improvements and software development projects.

Cash and cash equivalents held by our foreign subsidiaries totaled \$2.8 million and \$3.0 million at March 31, 2013 and 2012, 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 would be required to accrue and pay U.S. taxes to repatriate these funds.

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, and collect cash from clients after our products are sold. We also expect to continue to incur legal expenses related to the Department of Justice investigation, our defense of purported class actions and a derivative action and our response to requests for information for the foreseeable future. We continue to review our long-term cash needs on a regular basis. At March 31, 2013, we had no long-term debt outstanding.

Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations at March 31, 2013 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

	Payments Due By Fiscal Year (in \$000 s)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Contractual Obligations					
Operating lease commitments	\$ 3,002	\$ 1,157	\$ 1,685	\$ 64	\$ 96
Contractual obligations(1)	4,744	840	1,204	1,700	1,000
Total obligations	\$ 7,746	\$ 1,997	\$ 2,889	\$ 1,764	\$ 1,096

Edgar Filing: ABIOMED INC - Form 10-K

- (1) Contractual obligations represent future cash commitments and expected liabilities under agreements with third parties, primarily for research and development activities, such as clinical trials and material purchases for new product testing.

Table of Contents

We had no long-term debt, capital leases or other material commitments for open purchase orders and clinical trial agreements at March 31, 2013 other than those shown in the table above.

Our operating lease for our facility in Danvers, Massachusetts expires on February 28, 2016. Monthly rent is as follows:

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

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

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

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

We rent our European headquarters in Aachen, Germany. The lease payments are approximately 36,000 (Euro) (approximately U.S. \$50,000 at March 31, 2013 exchange rates) per month. The existing lease for this space expired on December 31, 2012. We entered into an arrangement with our landlord to continue renting our existing space in Aachen at the same monthly rental rate until June 30, 2013 while we negotiate a longer term lease agreement.

We are also party to a license agreement related to certain circulatory care device patents and know-how. Under this agreement, we would be obligated to pay up to \$3.0 million in cash or stock, if certain development and regulatory milestones are achieved. This amount has not been included in the contractual obligations table above due to the uncertainty related to the successful achievement of these milestones.

We apply the disclosure provisions of *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others*, to our agreements that contain guarantee or indemnification clauses. These disclosure provisions require that guarantors disclose certain types of guarantees, even if the likelihood of requiring the guarantor's performance is remote. The following is a description of arrangements in which we are a guarantor.

We enter into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements at March 31, 2013.

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

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

Patent indemnifications In many sales transactions, we indemnify customers against possible claims of patent infringement caused by our products. The indemnifications contained within sales contracts usually do not include limits on the claims. We have never incurred any material costs to defend lawsuits or settle patent infringement claims related to sales transactions.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Primary Market Risk Exposures

Our cash, cash equivalents and short-term marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. Marketable securities at March 31, 2013 consisted of \$78.7 million held in funds that invest in U.S. Treasury and government-backed securities. If market interest rates were to increase immediately and uniformly by 10 percent from levels at March 31, 2013, we believe the decline in fair market value of our investment portfolio would be immaterial.

Table of Contents

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 March 31, 2013, the result would have been a reduction of stockholders' equity of approximately \$3.7 million.

Fair Value of Financial Instruments

Our financial instruments consist primarily of cash and cash equivalents, and short-term marketable securities, accounts receivable, and accounts payable. The estimated fair values of the financial instruments have been determined by us using available market information and appropriate valuation techniques. Considerable judgment is required, however, to interpret market data to develop the estimates of fair value. Accordingly, the estimates presented are not necessarily indicative of the amounts that we could realize in a current market exchange. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value amounts.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements and Supplementary Data are provided under Part IV, Item 15 of this Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of March 31, 2013. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2013, these disclosure controls and procedures were effective to provide reasonable assurance that material information required to be disclosed by us, including our consolidated subsidiaries, in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Evaluation of Changes in Internal Control over Financial Reporting

During the fourth quarter of our fiscal year ended March 31, 2013, 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.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we assessed the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment under the framework in *Internal Control - Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of March 31, 2013.

Important Considerations

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our

Table of Contents

internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Table of Contents

Deloitte & Touche LLP, an independent registered public accounting firm that audited our financial statements for the year ended March 31, 2013, included in this annual report, has issued an attestation report on the effectiveness of our internal control over financial reporting. This report is set forth below:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

ABIOMED, Inc.

Danvers, Massachusetts

We have audited the internal control over financial reporting of ABIOMED, Inc. and subsidiaries (the Company) as of March 31, 2013, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2013, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended March 31, 2013 of the Company and our report dated May 28, 2013 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

May 28, 2013

Table of Contents

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTOR, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Item 10 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year captioned:

Proposal No. 1: Election of Directors,

Executive Officers and Directors,

Audit Committee Report,

Corporate Governance, and

Section 16(a) Beneficial Ownership Reporting Compliance.

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions. A paper copy of our code of ethics may be obtained free of charge by writing to us care of our Compliance Officer at our principal executive office located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, or by email at IR@abiomed.com.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year end captioned:

Executive Compensation

Compensation Discussion and Analysis,

Compensation Committee Interlocks and Insider Participation, and

Compensation Committee Report.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCK HOLDER MATTERS

The information required by Item 12 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year end captioned:

Securities Beneficially Owned by Certain Persons

Equity Compensation Plans

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by Item 13 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year end captioned:

Executive Compensation,

Proposal No. 1: Election of Directors, and

Certain Relationships and Related-Person Transactions.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year end captioned:

Audit and Other Fees.

Table of Contents**PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this report:

(1) The financial statements from our Annual Report for our fiscal year ending March 31, 2013 are attached hereto.

<u>Report of Independent Registered Public Accounting Firm</u>	Page F-2
<u>Consolidated Balance Sheets as of March 31, 2013 and 2012</u>	F-3
<u>Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2013, 2012 and 2011</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended March 2013, 2012, and 2011</u>	F-5
<u>Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2013, 2012, and 2011</u>	F-6
<u>Consolidated Statements of Comprehensive Income (Loss) for the Fiscal Years Ended March 31, 2013, 2012, and 2011</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8
(2) Consolidated financial statement schedule	

Schedule II: Valuation and Qualifying Accounts

(3) Exhibits**EXHIBIT INDEX**

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
2.1	Share Purchase Agreement for the acquisition of Impella Cardio Systems AG, dated April 26, 2005.		8-K	May 16, 2005	2.1
3.1	Restated Certificate of Incorporation.		S-3	September 29, 1997	3.1
3.2	Restated By-Laws, as amended.		10-K	May 27, 2004	3.2
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock filed as Exhibit 3.3 to the 1997 Registration Statement.*		S-3	September 29, 1997	3.3
3.4	Amendment to the Company's Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000.		8-K	March 21, 2007	3.4
4.1	Specimen Certificate of common stock.		S-1	June 5, 1987	4.1
10.1*	Form of Indemnification Agreement for Directors and Officers.		S-1	June 5, 1987	10.13
10.2*	1992 Combination Stock Option Plan.		10-Q	October 27, 1995	10.2
10.3*	Amendment to 1992 Combination Stock Option Plan.		10-Q	October 14, 1997	10.2
10.4*	1988 Employee Stock Purchase Plan, as amended.		10-Q	February 8, 2005	10.11
10.5*	1989 Non-Qualified Stock Option Plan for Non-Employee Directors.		10-Q	October 27, 1995	10.1
10.6*	1998 Equity Incentive Plan.		10-Q/A	January 8, 1999	10
10.7*	2000 Stock Incentive Plan Agreement, as amended.		Sch. 14A	July 15, 2005	Appendix A
10.8*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Directors.		10-Q	February 9, 2006	10.16
10.9*			10-Q	February 9, 2006	10.17

Edgar Filing: ABIOMED INC - Form 10-K

Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Employees or Consultants.				
10.10*	Second Amended and Restated 2008 Stock Incentive Plan.	Sch. 14A	June 29, 2012	Appendix A
10.11*	Form of Non-Statutory Stock Option Agreement for Employees and Consultants under 2008 Stock Incentive Plan.	8-K	August 18, 2008	10.1

Table of Contents

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
10.12*	Form of Non-Statutory Stock Option Agreement for Non-Employee Directors under 2008 Stock Incentive Plan.		8-K	August 18, 2008	10.2
10.13*	Form of Restricted Stock Agreement under 2008 Stock Incentive Plan.		8-K	August 18, 2008	10.3
10.14*	Form of Change of Control Agreement.		8-K	August 18, 2008	10.4
10.15*	Employment Agreement of Michael R. Minogue dated April 5, 2004 (including Change in Control Agreement).		10-Q	August 9, 2004	10.10
10.16*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008.		10-Q	February 9, 2009	10.1
10.17*	Amendment to Change in Control Agreement with Michael R. Minogue dated December 31, 2008.		10-Q	February 9, 2009	10.1
10.18*	Inducement stock option granted to Michael R. Minogue dated April 5, 2004.		10-Q	August 9, 2004	10.11
10.19*	Restricted Stock Agreement between Abiomed, Inc. and Michael R. Minogue.		10-Q	October 9, 2005	10.15
10.20*	Offer Letter with Robert L. Bowen dated December 15, 2008.		8-K	December 22, 2008	99.2
10.21*	Offer letter with David Weber dated April 23, 2007		10-Q	August 9, 2007	10.1
10.22*	Summary of Executive Compensation.	X			
10.23*	Summary of Director Compensation.	X			
10.24*	Form of Employment, Nondisclosure and Non Competition Agreement.		10-K	June 14, 2006	10.20
10.25	Facility Lease dated January 8, 1999 for the premises at 22 Cherry Hill Drive.		10-Q	February 12, 1999	10
10.26	First Amendment to Lease Agreement dated June 27, 2008 between Abiomed, Inc. and Leo C. Thibeault, Jr., Trustee of The Thibeault Nominee Trust.		8-K	July 2, 2008	10.1
10.27*	Form of Performance Share Award (Performance and Time Based RSU).		10-Q	August 5, 2011	10.1
10.28*	Form of Performance Share Award (Time Based RSU).		10-Q	August 5, 2011	10.2
11.1	Statement regarding computation of Per Share Earnings (see Note 2, Notes to Consolidated Financial Statements).	X			
21.1	Subsidiaries of the Registrant.	X			
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm.	X			
31.1	Rule 13a 14(a)/15d 14(a) certification of principal executive officer.	X			
31.2	Rule 13a 14(a)/15d 14(a) certification of principal accounting officer.	X			
32.1	Section 1350 certification.	X			
101	The following financial information from the ABIOMED, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2013, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of March 31, 2013 and 2012; (ii) Consolidated Statements of Operations for the fiscal years ended March 31, 2013, 2012 and 2011; (iii) Consolidated Statements of Comprehensive Income (Loss) for the fiscal years ended March 31, 2013, 2012 and 2011; (iv) Consolidated Statements of Stockholders' Equity for the fiscal years ended March 2013, 2012 and 2011; (v) Consolidated Statements of Cash Flows for the fiscal years ended March 31, 2013, 2012 and 2011; and (vi) Notes to Consolidated Financial Statements.**	X			

* Management contract or compensatory plan.

** The information contained in this exhibit shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Act of 1934, whether made before or after the date hereof and regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Table of Contents**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.

Dated: May 28, 2013

By

/s/ ROBERT L. BOWEN
Robert L. Bowen
Vice President, Chief Financial Officer
(Principal Financial Officer and

Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ MICHAEL R. MINOGUE Michael R. Minogue	President, Chief Executive Officer, President and Chairman (Principal Executive Officer)	May 28, 2013
/s/ ROBERT L. BOWEN Robert L. Bowen	Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 28, 2013
/s/ W. GERALD AUSTEN W. Gerald Austen	Director	May 28, 2013
/s/ LOUIS E. LATAIF Louis E. Lataif	Director	May 28, 2013
/s/ DOROTHY E. PUHY Dorothy E. Puhly	Director	May 28, 2013
/s/ MARTIN P. SUTTER Martin P. Sutter	Director	May 28, 2013
/s/ HENRI A. TERMEER Henri A. Termeer	Director	May 28, 2013
/s/ PAUL THOMAS Paul Thomas	Director	May 28, 2013

Table of Contents

ABIOMED, INC.

Consolidated Financial Statements

Index

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of March 31, 2013 and 2012</u>	F-3
<u>Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2013, 2012, and 2011</u>	F-4
<u>Consolidated Statements of Comprehensive Income (Loss) for the Fiscal Years Ended March 31, 2013, 2012, and 2011</u>	F-5
<u>Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended March 2013, 2012, and 2011</u>	F-6
<u>Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2013, 2012, and 2011</u>	F-7
<u>Notes to Consolidated Financial Statements</u>	F-8

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

ABIOMED, Inc.

Danvers, Massachusetts

We have audited the accompanying consolidated balance sheets of ABIOMED, Inc. and subsidiaries (the Company) as of March 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended March 31, 2013. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of ABIOMED, Inc. and subsidiaries as of March 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2013, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of March 31, 2013, based on the criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated May 28, 2013 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

May 28, 2013

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Consolidated Balance Sheets**

(dollars in thousands)

	March 31,	
	2013	2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 9,451	\$ 5,990
Short-term marketable securities	67,256	71,233
Accounts receivable, net	22,946	20,458
Inventories	14,930	11,142
Prepaid expenses and other current assets	2,022	1,716
Total current assets	116,605	110,539
Long-term marketable securities	11,406	
Property and equipment, net	6,549	6,378
Goodwill	35,410	36,846
Other	29	148
Total assets	\$ 169,999	\$ 153,911
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 7,696	\$ 6,910
Accrued expenses	15,162	12,480
Deferred revenue	4,198	3,025
Total current liabilities	27,056	22,415
Long-term deferred tax liability	5,554	4,799
Other long-term liabilities	309	400
Total liabilities	32,919	27,614
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value		
Authorized 1,000,000 shares; Issued and outstanding none		
Common stock, \$.01 par value	397	393
Authorized 100,000,000 shares; Issued 39,788,383 shares at March 31, 2013 and 39,323,708 shares at March 31, 2012;		
Outstanding 38,601,384 shares at March 31, 2013 and 39,272,754 shares at March 31, 2012		
Additional paid in capital	414,810	401,771
Accumulated deficit	(258,261)	(273,275)
Treasury stock at cost 1,186,999 shares at March 31, 2013 and 50,954 shares at March 31, 2012	(16,129)	(827)
Accumulated other comprehensive loss	(3,737)	(1,765)
Total stockholders' equity	137,080	126,297
Total liabilities and stockholders' equity	\$ 169,999	\$ 153,911

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Consolidated Statements of Operations****(in thousands, except per share data)**

	Fiscal Years Ended March 31,		
	2013	2012	2011
Revenue:			
Product revenue	\$ 157,614	\$ 125,286	\$ 99,837
Funded research and development	510	1,089	1,314
	158,124	126,375	101,151
Costs and expenses:			
Cost of product revenue	31,596	24,507	21,977
Research and development	25,647	27,159	26,677
Selling, general and administrative	84,227	71,711	62,287
Amortization of intangible assets	111	1,478	1,395
	141,581	124,855	112,336
Income (loss) from operations	16,543	1,520	(11,185)
Other income:			
Investment (expense) income, net	(7)	(3)	9
Gain on sale of WorldHeart stock			456
Gain on settlement of investment		1,017	
Other income (expense), net	326	9	(143)
	319	1,023	322
Income (loss) before income tax provision	16,862	2,543	(10,863)
Income tax provision	1,848	1,048	892
Net income (loss)	\$ 15,014	\$ 1,495	\$ (11,755)
Basic net income (loss) per share	\$ 0.38	\$ 0.04	\$ (0.32)
Basic weighted average shares outstanding	39,113	38,374	37,167
Diluted net income (loss) per share	\$ 0.37	\$ 0.04	\$ (0.32)
Diluted weighted average shares outstanding	41,052	40,172	37,167

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents

ABIOMED, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income (Loss)

(in thousands)

	Fiscal Years Ended March 31,		
	2013	2012	2011
Net income (loss)	\$ 15,014	\$ 1,495	\$ (11,755)
Other comprehensive (loss) income:			
Foreign currency translation (losses) gains	(1,974)	(2,510)	1,747
Net unrealized gains on marketable securities	2		
Other comprehensive (loss) income	(1,972)	(2,510)	1,747
Comprehensive income (loss)	\$ 13,042	\$ (1,015)	\$ (10,008)

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Consolidated Statements of Stockholders' Equity**

(dollars in thousands)

	Common Stock		Treasury Stock		Additional	Accumulated	Accumulated	Total
	Number of	Par	Number of	Amount	Paid in	Deficit	Other	Stockholders
	shares	value	shares		Capital		(Loss) Income	Equity
Balance, April 1, 2010	37,433,064	\$ 375	50,954	\$ (827)	\$ 372,425	\$ (263,015)	\$ (1,002)	\$ 107,956
Restricted stock issued	356,000	4			(4)			-
Stock options exercised	126,460	1			1,060			1,061
Stock issued under employee stock purchase plan	36,207				313			313
Stock issued to directors	3,096							-
Cancellation of restricted stock	(249,062)	(3)			3			-
Stock compensation expense					5,421			5,421
Other comprehensive income							1,747	1,747
Net loss						(11,755)		(11,755)
Balance, March 31, 2011	37,705,765	377	50,954	(827)	379,218	(274,770)	745	104,743
Stock options exercised	1,516,038	15			14,242			14,257
Stock issued under employee stock purchase plan	45,445	1			422			423
Stock issued to directors	5,506				116			116
Stock compensation expense					7,773			7,773
Other comprehensive loss							(2,510)	(2,510)
Net income						1,495		1,495
Balance, March 31, 2012	39,272,754	393	50,954	(827)	401,771	(273,275)	(1,765)	126,297
Restricted stock issued	91,503	1			(1)			-
Stock options exercised	337,212	3			2,933			2,936
Stock issued under employee stock purchase plan	33,132				555			555
Stock issued to directors	2,828				51			51
Repurchase of common stock	(1,123,587)		1,123,587	(15,045)				(15,045)
Return of common stock to pay withholding taxes on restricted stock	(12,458)		12,458	(257)				(257)
Stock compensation expense					9,501			9,501
Other comprehensive loss							(1,972)	(1,972)
Net income						15,014		15,014
Balance, March 31, 2013	38,601,384	\$ 397	1,186,999	\$ (16,129)	\$ 414,810	\$ (258,261)	\$ (3,737)	\$ 137,080

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows****(in thousands)**

	Fiscal Years Ended March 31,		
	2013	2012	2011
Operating activities:			
Net income (loss)	\$ 15,014	\$ 1,495	\$ (11,755)
Adjustments required to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	2,723	4,336	3,948
Bad debt expense	33	117	139
Stock-based compensation	9,501	7,773	5,421
Write-down of inventory	1,172	1,833	2,781
Loss on disposal of fixed assets	10	53	29
Deferred tax provision	755	789	970
Gain on sale of WorldHeart common stock			(456)
Gain on settlement of investment		(1,017)	
Changes in assets and liabilities:			
Accounts receivable	(2,586)	(5,284)	(1,923)
Inventories	(5,315)	(6,229)	(1,508)
Prepaid expenses and other assets	(326)	(239)	161
Accounts payable	1,183	287	2,480
Accrued expenses and other long-term liabilities	3,057	(1,330)	605
Deferred revenue	1,178	1,050	682
Net cash provided by operating activities	26,399	3,634	1,574
Investing activities:			
Purchases of marketable securities	(49,429)	(24,502)	(8,004)
Proceeds from the sale and maturity of marketable securities	42,000	7,750	7,000
Proceeds from the sale of WorldHeart common stock			456
Proceeds from settlement of investment		1,017	
Purchases of property and equipment	(2,836)	(1,745)	(1,804)
Net cash used for investing activities	(10,265)	(17,480)	(2,352)
Financing activities:			
Proceeds from the exercise of stock options	2,936	14,257	1,061
Repurchase of common stock	(15,045)		
Payments in lieu of issuance of common stock for minimum payroll taxes	(257)		
Proceeds from the issuance of stock under employee stock purchase plan	555	423	313
Net cash (used for) provided by financing activities	(11,811)	14,680	1,374
Effect of exchange rate changes on cash	(862)	(675)	447
Net increase in cash and cash equivalents	3,461	159	1,043
Cash and cash equivalents at beginning of year	5,990	5,831	4,788
Cash and cash equivalents at end of year	\$ 9,451	\$ 5,990	\$ 5,831
Supplemental disclosures:			
Fixed asset expenditures incurred, not yet paid	\$ 250	\$ 535	\$ 48

The accompanying notes are an integral part of the consolidated financial statements.

Table of Contents

ABIOMED, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(Dollars in thousands, except per share data)

Note 1. Nature of Operations

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.

Note 2. Summary of Significant Accounting Policies

The accompanying consolidated financial statements reflect the application of certain significant accounting policies described below.

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles of the United States of America, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. The Company bases its estimates on historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, collectability of receivables, realizability of inventory, goodwill and intangible assets, valuation of goodwill and long-lived assets, accrued expenses, stock-based compensation, income taxes including the valuation allowance for deferred tax assets, contingencies and litigation. Provisions for depreciation are based on their estimated useful lives using the straight-line method. Some of these estimates can be subjective and complex and, consequently, actual results may differ from these estimates under different assumptions or conditions.

Cash Equivalents and Marketable Securities

The Company classifies any marketable security with a maturity date of 90 days or less at the time of purchase as a cash equivalent. Cash equivalents are carried on the balance sheet at fair market value.

The Company classifies any security with a maturity date of greater than 90 days at the time of purchase as marketable securities and classifies marketable securities with a maturity date of greater than one year from the balance sheet date as long-term marketable securities. Securities that the Company has the positive intent and ability to hold to maturity are reported at amortized cost and classified as held-to-maturity securities. If the Company does not have the intent and ability to hold a security to maturity, it reports the investment as available-for-sale securities. The Company reports available-for-sale securities at fair value, and includes unrealized gains and, to the extent deemed temporary, losses in stockholder's equity. If any adjustment to fair value reflects a decline in the value of the investment, the Company considers available evidence to evaluate whether the decline is other than temporary and, if so, marks the security to market through a charge to unrealized loss on short-term marketable securities in the consolidated statements of operations.

Major Customers and Concentrations of Credit Risk

Abiomed primarily sells its products to hospitals and distributors. No customer accounted for more than 10% of total product revenues in fiscal year 2013, 2012, or 2011. No customer had an accounts receivable balance greater than 10% of total accounts receivable at March 31, 2013 and 2012.

Credit is extended based on an evaluation of a customer's financial condition and generally collateral is not required. To date, credit losses have not been significant and the Company maintains an allowance for doubtful accounts based on its assessment of the collectability of accounts receivable. Receivables are geographically dispersed, primarily throughout the U.S., as well as in Europe and other foreign countries where formal distributor agreements exist.

Table of Contents

ABIOMED, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

Note 2. Summary of Significant Accounting Policies (Continued)

Financial instruments which potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, short and long-term marketable securities and accounts receivable. Management mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity and have a high credit quality.

Inventories

Inventories are stated at the lower of cost or market. Cost is based on the first in, first out method. The Company regularly reviews inventory quantities on hand and writes down to its net realizable value any inventory that it believes to be impaired. Management considers forecasted demand in relation to the inventory on hand, competitiveness of product offerings, market conditions and product life cycles when determining excess and obsolescence and net realizable value adjustments. Once inventory is written down and a new cost basis is established, it is not written back up if demand increases.

Property and Equipment

Property and equipment is recorded at cost less accumulated depreciation. Depreciation is computed using the straight line method based on estimated useful lives of two to ten years for machinery and equipment, three to seven years for computer software, and four to ten years for furniture and fixtures. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful lives of the related assets. Expenditures for maintenance and repairs are expensed as incurred. Upon retirement or other disposition of assets, the costs and related accumulated depreciation are eliminated from the accounts and the resulting gain or loss is reflected in operating expenses.

Property and equipment is reviewed for impairment losses whenever events or changes in circumstances indicate the carrying amount may not be recoverable. An impairment loss would be recognized based on the amount by which the carrying value of the asset or asset group exceeds its fair value. Fair value is determined primarily using the estimated future cash flows associated with the asset or asset group under review discounted at a rate commensurate with the risk involved and other valuation techniques.

Goodwill

Goodwill is recorded when consideration for an acquisition exceeds the fair value of the net tangible and intangible assets acquired. Goodwill is not amortized, instead the Company evaluates goodwill for impairment 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 goodwill impairment test involves a two-step process. The first step is a comparison of the reporting unit's fair value to its carrying value. If the reporting unit's fair value exceeds its carrying value, no further procedures are required. However, if the reporting unit's fair value is less than its carrying value, an impairment of goodwill may exist, requiring a second step to measure the amount of impairment loss. If the implied fair value of goodwill is less than the recorded goodwill, an impairment charge is recorded for the difference.

The Company estimates the fair value of its single reporting unit using a combination of the income approach and the market approach. The income approach incorporates the use of a discounted cash flow method in which the estimated future cash flows and terminal values for the reporting unit is discounted to a present value using an appropriate discount rate. Cash flow projections are based on management's estimates of economic and market conditions which drive key assumptions of revenue growth rates, operating margins, capital expenditures and working capital requirements. The discount rate is based on the specific risk characteristics of the reporting unit and its underlying forecast. The market approach estimates fair value by comparing publicly traded companies with similar operating and investment characteristics as the reporting unit. The fair values determined by the market approach and income approach, are weighted to determine the fair value for the reporting unit based primarily on the similarity of the operating and investment characteristics of the reporting unit to the comparable publicly traded companies used in the market approach. In order to assess the reasonableness of the calculated reporting unit's fair value, the Company also compares the reporting unit's fair value to its market capitalization (per share stock price times number of common shares outstanding) and calculate an implied control premium (the excess of the reporting unit's fair value over the market capitalization).

The Company performed its annual impairment review for fiscal 2013 as of October 31, 2012 and determined that no write-down for impairment of goodwill was required as the fair value of the reporting unit substantially exceeded the carrying value. The carrying amount of goodwill at March 31, 2013 was \$35.4 million.

Table of Contents

ABIOMED, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

Note 2. Summary of Significant Accounting Policies (Continued)

Financial Instruments

The Company's financial instruments are comprised of cash and cash equivalents, marketable securities, accounts receivable and accounts payable, the carrying amounts of which approximate fair market value as they are highly liquid and primarily short term in nature.

Accrued Expenses

As part of the process of preparing its financial statements, the Company is required to estimate accrued expenses. This process involves identifying services that third parties have performed and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in its financial statements. Examples of estimated accrued expenses include contract service fees, such as amounts due to clinical research organizations, professional service fees, such as attorneys and accountants, and investigators in conjunction with clinical trials and third party expenses relating to marketing efforts associated with commercialization of the Company's product and product candidates. In the event that the Company does not identify certain costs that have been incurred or it under or over-estimates the level of services or the costs of such services, reported expenses for a reporting period could be overstated or understated. The date on which certain services commence, the level of services performed on or before a given date and the cost of services is often subject to the Company's judgment. The Company makes these judgments and estimates based upon known facts and circumstances.

Revenue Recognition

The Company recognizes revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectibility is reasonably assured.

Revenue from product sales to customers is recognized when delivery has occurred. All costs related to product sales are recognized at time of delivery. The Company does not provide for rights of return to customers on product sales and therefore does not record a provision for returns.

Maintenance and service support contract revenues are included in product sales and are recognized ratably over the term of the service contracts. Revenue is recognized as earned in limited instances where the Company rents its console medical devices on a month-to-month basis or for a longer specified period of time to customers.

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

Product Warranty

The Company generally provides a one-year warranty for certain products sold in which estimated contractual warranty obligations are recorded as an expense at the time of shipment and are included in accrued expenses in the accompanying consolidated balance sheets. The Company's products are subject to regulatory and quality standards. Future warranty costs are estimated based on historical product performance rates and related costs to repair given products. The accounting estimate related to product warranty involves judgment in determining future estimated warranty costs. Should actual performance rates or repair costs differ from estimates, revisions to the estimated warranty liability would be required.

Translation of Foreign Currencies

All assets and liabilities of the Company's non-U.S. subsidiaries are translated at year-end exchange rates and revenues and expenses are translated at average exchange rates for the year. The functional currencies of our non-U.S. subsidiaries are the euro, British pound and Japanese yen. Resulting translation adjustments are reflected in the accumulated other comprehensive (loss) income component of stockholders' equity. Currency transaction gains and losses are included as other income (expense), net in the statements of operations.

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 2. Summary of Significant Accounting Policies (Continued)****Net Income (Loss) Per Share**

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the fiscal year. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of dilutive common shares outstanding during the fiscal year. Diluted shares outstanding is calculated by adding to the weighted average shares outstanding any potential dilutive securities outstanding for the fiscal year. Potential dilutive securities include stock options, restricted stock awards, restricted stock units, performance-based awards and shares to be purchased under the employee stock purchase plan. In fiscal years 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.

	2013	March 31, 2012	2011
Basic Net Income (Loss) Per Share			
Net income (loss)	\$ 15,014	\$ 1,495	\$ (11,755)
Weighted average shares used in computing basic net income (loss) per share	39,113	38,374	37,167
Net income (loss) per share basic	\$ 0.38	\$ 0.04	\$ (0.32)

	2013	March 31, 2012	2011
Diluted Net Income (Loss) Per Share			
Net income (loss)	\$ 15,014	\$ 1,495	\$ (11,755)
Weighted average shares used in computing basic net income (loss) per share	39,113	38,374	37,167
Effect of dilutive securities	1,939	1,798	
Weighted average shares used in computing diluted net income (loss) per share	41,052	40,172	37,167
Net income (loss) per share diluted	\$ 0.37	\$ 0.04	\$ (0.32)

For the fiscal years ended March 31, 2013 and 2012, approximately 438,000 and 410,000 shares of common stock underlying outstanding securities primarily related to out-of-the-money stock options and performance-based awards where milestones were not met were not included in the computation of diluted earnings per share because their inclusion would be anti-dilutive. For the fiscal year ended March 31, 2011, approximately 5,945,000 shares of common stock underlying stock options and approximately 407,000 restricted shares are excluded from the calculation of diluted weighted average shares outstanding because the Company incurred a loss in that fiscal year, and to include them would have been anti-dilutive.

Stock-Based Compensation

The Company's stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, and includes an estimate of awards that will be forfeited.

The fair value of stock option grants is estimated using the Black-Scholes option pricing model. Use of the valuation model requires management to make certain assumptions with respect to selected model inputs. 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 historical volatility of the Company's stock. The Company

Edgar Filing: ABIOMED INC - Form 10-K

estimates the expected term of options based on historical exercise experience and estimates of future exercises of unexercised options. In addition, an expected dividend yield of zero is used in the option valuation model because the Company does not pay dividends and does not expect to pay any cash dividends in the foreseeable future. Forfeitures are estimated based on an analysis of actual option forfeitures, adjusted to the extent historical forfeitures may not be indicative of forfeitures in the future.

F-11

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 2. Summary of Significant Accounting Policies (Continued)**

For awards with service conditions only, the Company recognizes compensation cost on a straight-line basis over the requisite service period. For awards with service and performance conditions, the Company recognizes compensation costs using the graded vesting method over the requisite service period. Accruals of compensation cost for an award with performance conditions are based on the probable outcome of the performance conditions. The cumulative effects of changes in the probability outcomes are recorded in the period in which the changes occur.

Income Taxes

The Company's provision for income taxes is comprised of a current and a deferred portion. The current income tax provision is calculated as the estimated taxes payable or refundable on tax returns for the current year. The deferred income tax provision is calculated for the estimated future income tax effects attributable to temporary differences and carryforwards using expected tax rates in effect in the years during which the differences are expected to reverse.

Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases 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 recognizes and measures uncertain tax positions using a two-step approach. The first step is to evaluate the tax position for recognition by determining if, based on the technical merits, it is more likely than not that the position will be sustained upon audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit at the largest amount that is more than 50% likely of being realized upon ultimate settlement. The Company reevaluates these uncertain tax positions on a quarterly basis. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, changes in tax laws, effectively settled issues under audit and new audit activity. Any changes in these factors could result in the recognition of a tax benefit or an additional charge to the tax provision. The Company accrues for the effects of uncertain tax positions and the related potential penalties and interest.

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 March 31, 2013 and 2012 are classified on the balance sheet as follows (in thousands):

	March 31,	
	2013	2012
	(in \$000 s)	
Short-term marketable securities	\$ 67,256	\$ 71,233
Long-term marketable securities	11,406	
	\$ 78,662	\$ 71,233

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 3. Marketable Securities and Fair Value Measurements (Continued)**

The Company's marketable securities at March 31, 2013 and 2012 are invested in the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in \$000 s)			
At March 31, 2013:				
US Treasury securities	\$ 59,002	\$	\$	\$ 59,002
Short-term government-backed securities	8,126	1		8,127
Long-term government-backed securities	11,405	3	(2)	11,406
Accrued interest	127			127
	\$ 78,660	\$ 4	\$ (2)	\$ 78,662

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in \$000 s)			
At March 31, 2012:				
US Treasury securities	\$ 71,233	\$	\$	\$ 71,233

Fair Value Hierarchy

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

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

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

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

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

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

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

The following table presents the Company's fair value hierarchy for its financial instruments measured at fair value as of March 31, 2013 and 2012:

Edgar Filing: ABIOMED INC - Form 10-K

	Level 1	Level 2	Level 3	Total
At March 31, 2013:				
U.S. Treasury securities	\$	\$ 59,020	\$	\$ 59,020
Short-term government-backed securities		8,236		8,236
Long-term government-backed securities		11,406		11,406
	\$	\$ 78,662	\$	\$ 78,662

F-13

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 3. Marketable Securities and Fair Value Measurements (Continued)**

	Level 1	Level 2	Level 3	Total
	(in \$000 s)			
At March 31, 2012:				
U.S. Treasury securities	\$	\$ 71,233	\$	\$ 71,233

During fiscal 2013, the Company reevaluated the methodologies used by third-party brokers in determining the estimated fair value of its investments in U.S. Treasury securities. After this analysis, the Company determined that the fair value of U.S. Treasuries should be reported as Level 2. In prior years, U.S. Treasury securities were incorrectly classified as Level 1. The Company has corrected the prior year presentation of these amounts, which conforms with the current year presentation. These corrections in the disclosed classification had no effect on the reported fair values of these instruments.

Note 4. Accounts Receivable

The components of accounts receivable are as follows:

	March 31,	March 31,
	2013	2012
	(in \$000 s)	
Trade receivables	\$ 23,082	\$ 20,688
Allowance for doubtful accounts	(136)	(230)
	\$ 22,946	\$ 20,458

Note 5. Inventories

The components of inventories are as follows:

	March 31,	March 31,
	2013	2012
	(in \$000 s)	
Raw materials and supplies	\$ 6,267	\$ 3,586
Work-in-progress	5,296	4,098
Finished goods	3,367	3,458
	\$ 14,930	\$ 11,142

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. During the years ended March 31, 2013, 2012, and 2011, the Company recorded \$1.2 million, \$1.8 million and \$2.8 million, respectively, in write-downs of inventory.

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 6. Property and Equipment**

The components of property and equipment are as follows:

	March 31, 2013	March 31, 2012
	(in \$000 s)	
Machinery and equipment	\$ 14,392	\$ 13,860
Furniture and fixtures	969	498
Leasehold improvements	1,843	1,147
Construction in progress	1,541	768
Total cost	18,745	16,273
Less accumulated depreciation	(12,196)	(9,895)
	\$ 6,549	\$ 6,378

Depreciation expense related to property and equipment was \$2.5 million, \$2.3 million and \$1.9 million for the years ending March 31, 2013, 2012, and 2011, respectively.

Note 7. Goodwill

The carrying amount of goodwill at March 31, 2013 and 2012 was \$35.4 million and \$36.8 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG, or Impella, in 2005. The goodwill activity is as follows:

	(in \$000 s)
Balance at March 31, 2011	\$ 38,946
Exchange rate impact	(2,100)
Balance at March 31, 2012	\$ 36,846
Exchange rate impact	(1,436)
Balance at March 31, 2013	\$ 35,410

The Company has no accumulated impairment losses.

Note 8. Stockholders' Equity**Stock Repurchase Program**

In November 2012, the Company's Board of Directors authorized a stock repurchase program for up to \$15.0 million of its common stock. The Company financed the stock repurchase program with its available cash. During the year ended March 31, 2013, the Company repurchased 1,123,587 shares for \$15.0 million in open market purchases at an average cost of \$13.39 per share, including commission expense. The Company has completed the purchase of common stock under this stock repurchase program in January 2013.

Note 9. Stock Award Plans and Stock-Based Compensation

Stock Award Plans

The Company grants stock options and restricted stock awards to employees and others. All outstanding stock options of the Company as of March 31, 2013 were granted with an exercise price equal to the fair market value on the date of grant. Outstanding stock options, if not exercised, expire 10 years from the date of grant.

The Company's 2008 Stock Incentive Plan (the "Plan") authorizes the grant of a variety of equity awards to the Company's officers, directors, employees, consultants and advisers, including awards of unrestricted and restricted stock, restricted stock units, incentive and nonqualified

F-15

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 9. Stock Award Plans and Stock-Based Compensation (Continued)**

stock options to purchase shares of common stock, performance share awards and stock appreciation rights. The Plan provides that options may only be granted at the current market value on the date of grant. Each share of stock issued pursuant to a stock option or stock appreciation right counts as one share against the maximum number of shares issuable under the Plan, while each share of stock issued pursuant to any other type of award counts as 1.58 shares against the maximum number of shares issuable under the Plan for grants made on or after August 11, 2010 (and as 1.5 shares for grants made prior to that date). The Company's policy for issuing shares upon exercise of stock options or the vesting of its restricted stock awards and restricted stock units is to issue shares of common stock at the time of exercise or conversion. At March 31, 2013, a total of approximately 2,405,300 shares were available for future issuance under the Plan.

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 fiscal years ended March 31, 2013, 2012 and 2011 (in thousands):

	2013	March 31, 2012 (in \$000 s)	2011
Cost of product revenue	\$ 450	\$ 282	\$ 214
Research and development	1,843	1,719	1,001
Selling, general and administrative	7,208	5,772	4,206
	\$ 9,501	\$ 7,773	\$ 5,421

The components of stock-based compensation for the fiscal years ended March 31, 2013, 2012 and 2011 were as follows (in thousands):

	2013	March 31, 2012 (in \$000 s)	2011
Restricted stock units	\$ 5,970	\$ 2,808	\$
Stock options	2,680	2,722	3,837
Restricted stock	653	2,095	1,480
Employee stock purchase plan	198	148	104
	\$ 9,501	\$ 7,773	\$ 5,421

Stock Options

The following table summarized stock option activity for the year ended March 31, 2013:

Options (in thousands)	Weighted Average Exercise	Weighted Average Remaining	Aggregate Intrinsic Value
------------------------------	---------------------------------	----------------------------------	---------------------------------

Edgar Filing: ABIOMED INC - Form 10-K

		Price	Contractual Term (years)	(in thousands)
Outstanding at beginning of year	4,268	\$ 10.42	6.03	
Granted	367	21.44		
Exercised	(337)	8.68		
Cancelled and expired	(70)	10.67		
Outstanding at end of year	4,228	\$ 11.49	5.37	\$ 31,627
Exercisable at end of year	3,241	\$ 10.80	4.62	\$ 25,538
Options vested and expected to vest at end of year	4,002	\$ 11.47	5.25	\$ 29,914

F-16

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 9. Stock Award Plans and Stock-Based Compensation (Continued)**

The remaining unrecognized stock-based compensation expense for unvested stock option awards at March 31, 2013 was approximately \$3.6 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 2.7 years.

The aggregate intrinsic value of options exercised for fiscal years 2013, 2012 and 2011 was \$4.6 million, \$13.4 million and \$0.4 million, respectively. The total cash received as a result of employee stock option exercises during the years ended March 31, 2013, 2012 and 2011 was approximately \$2.9 million, \$14.3 million and \$1.0 million, respectively. The total fair value of options vested in fiscal years 2013, 2012 and 2011 was \$2.6 million, \$3.8 million and \$4.5 million, respectively.

The weighted average grant-date fair value for options granted during the years ended March 31, 2013, 2012 and 2011 was \$9.66, \$8.35 and \$4.72 per share, respectively.

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model. The fair value of options granted during the years ended March 31, 2013, 2012 and 2011 were calculated using the following weighted average assumptions:

	2013	2012	2011
Risk-free interest rate	0.78%	1.47%	2.04%
Expected option life (years)	4.31	5.19	5.30
Expected volatility	56.2%	53.1%	50.9%

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 the extent historic forfeitures may not be indicative of forfeitures in the future.

Restricted Stock and Restricted Stock Units

The following table summarizes restricted stock and restricted stock unit activity for the fiscal year ended March 31, 2013:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value (per share)
Restricted stock and restricted stock units at beginning of year	871	\$ 15.76
Granted	400	21.82
Vested	(220)	13.73
Forfeited	(29)	20.32
Restricted stock and restricted stock units at end of year	1,022	\$ 18.44

The remaining unrecognized compensation expense for outstanding restricted stock and restricted stock units, including performance-based awards, as of March 31, 2013 was \$9.3 million and the weighted-average period over which this cost will be recognized is 1.7 years.

Edgar Filing: ABIOMED INC - Form 10-K

The weighted average grant-date fair value for restricted stock and restricted stock units granted during the years ended March 31, 2013, 2012 and 2011 was \$21.82, \$18.13 and \$10.00 per share, respectively. The total fair value of restricted stock and restricted stock units vested in fiscal years 2013, 2012 and 2011 was \$3.0 million, \$1.5 million and \$1.0 million, respectively.

F-17

Table of Contents

ABIOMED, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

Note 9. Stock Award Plans and Stock-Based Compensation (Continued)

Performance-Based Awards

Included in the restricted stock and restricted stock units activity discussed above are certain awards granted in fiscal years 2013, 2012 and 2011 that vest subject to certain performance-based criteria.

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 March 31, 2013, the Company has met the prescribed performance milestones for these awards. These awards are still subject to service requirements for vesting for these employees.

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, all of which will vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. As of March 31, 2013, the Company has met the prescribed milestones for 184,000 shares underlying these awards and believes it is probable that the prescribed performance milestones will be met for the remaining 100,000 shares, and the compensation expense is being recognized accordingly.

During the year ended March 31, 2013, the Company has recorded \$3.8 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 March 31, 2013 is \$3.9 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 1.8 years.

Employee Stock Purchase Plan

The Company has an employee stock purchase plan, or ESPP. Under the ESPP, eligible employees, including officers and directors, who have completed at least three months of employment with the Company or its subsidiaries who elect to participate in the purchase plan instruct the Company to withhold a specified amount of the employee's income each payroll period during a six-month payment period (the periods April 1 - September 30 and October 1 - March 31). On the last business day of each six-month payment period, the amount withheld is used to purchase shares of the Company's common stock at an exercise price equal to 85% of the lower of its market price on the first business day or the last business day of the payment period. The Company recognized compensation expense of \$0.2 million, \$0.1 million and \$0.1 million for the fiscal years ended March 31, 2013, 2012 and 2011, respectively, related to the ESPP.

Note 10. Income Taxes

At March 31, 2013, the Company had federal and state net operating loss carryforwards, or NOLs, of approximately \$188.9 million and \$105.9 million, respectively, which expire in varying years from fiscal 2014 through fiscal 2033. During the year ended March 31, 2013, state NOLs of approximately \$21.2 million expired. In addition, at March 31, 2013, the Company had federal and state research and development credit carryforwards of approximately \$11.6 million and \$5.5 million, respectively, which expire in varying years from fiscal 2014 through fiscal 2033.

The Company acquired Impella, a German company, in May 2005, as a result of which, Impella became the Company's German subsidiary. Impella had pre-acquisition net operating losses of approximately \$19.4 million at the time of acquisition (which are denominated in euros and are subject to foreign exchange remeasurement at each balance sheet date presented). The utilization of pre-acquisition net operating losses of Impella in future periods is subject to certain statutory approvals and business requirements. Prior to the last two fiscal years, the German subsidiary has historically incurred net operating losses. During fiscal 2008, the Company had determined that approximately \$1.3 million of pre-acquisition operating losses could not be utilized. During fiscal 2013, the Company's German subsidiary was audited by the local tax authorities for fiscal years 2009 through 2011. Although the tax audit in Germany has not been finalized, there were no adjustments made as a result of the audit to the German subsidiary's NOLs to date. Based on this knowledge, the Company believes that all of its German NOLs of \$53.8 million should be available for utilization in the future prior to their expiration.

The future utilization of the Company's NOLs and research and development credit carryforwards to offset future taxable income may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to ownership changes that have occurred previously or that could occur in the future. Ownership changes, as defined in Section 382 of the Internal Revenue Code, can limit the amount of NOL and research and development credit carryforwards that a company can use each year to offset future taxable income and taxes payable. The Company completed a Section 382 study and analysis in fiscal 2008 to

Edgar Filing: ABIOMED INC - Form 10-K

determine whether changes in the composition of its stockholders, including the Company's acquisition of Impella or the Company's public offering in August 2008, resulted in an ownership

F-18

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 10. Income Taxes (Continued)**

change for purposes of Section 382. The Company believes that all of its federal and state NOLs will be available for carryforward to future tax periods, subject to statutory maximum carryforward limitations. Any future potential limitation to all or a portion of the NOL or research and development credit carryforwards, before they can be utilized, would reduce the Company's gross deferred tax assets. The Company will continue to monitor subsequent ownership changes, which could impose limitations in the future on the use of its NOLs or research and development credit carryforwards.

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, net operating losses incurred from the Company's inception to March 31, 2011, expiration of various federal and state attributes, the uncertainty relative to the Department of Justice investigation and the Company's planned PMA application for its Impella products, profits before tax for fiscal 2012 and 2013 and forecasted profit before tax for fiscal 2014. Based on its 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 March 31, 2013.

Income (loss) before provision for income taxes and the provision for income taxes is as follows for the years ended March 31:

	2013	2012 (in \$000 s)	2011
Income (loss) before provision for income taxes:			
United States	\$ 10,202	\$ 236	\$ (6,522)
Foreign	6,660	2,307	(4,341)
Income (loss) before income taxes	\$ 16,862	\$ 2,543	\$ (10,863)
Provision for income taxes:			
Current:			
Federal	\$ 97	\$	\$ (78)
State			81
Foreign	996	259	
Total current	1,093	259	3
Deferred:			
Federal	825	825	825
State	(70)	(36)	64
Foreign			
Total deferred	755	789	889
Total income tax provision	\$ 1,848	\$ 1,048	\$ 892

Differences between the federal statutory income tax rate and the effective tax rates are as follows for the years ended March 31:

	2013	2012	2011
Statutory income tax rate	34.0%	34.0%	34.0%

Edgar Filing: ABIOMED INC - Form 10-K

(Decrease) increase resulting from:

Credits	(15.3)	(54.0)	8.4
Rate differential on foreign operations	9.7	54.9	(0.1)
Permanent differences	(8.1)	(46.2)	0.3
State taxes, net	(7.7)	62.2	(14.1)
Change in valuation allowance	(2.0)	(96.0)	(33.8)
Stock based compensation	0.4	2.0	(0.3)
Expiry of state NOL carryforwards		78.9	(2.6)
Effective tax rate	11.0%	35.8%	(8.2)%

F-19

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 10. Income Taxes (Continued)**

The components of the Company's net deferred taxes were as follows:

	2013	March 31, 2012 (in \$000 s)
Deferred tax assets		
NOL carryforwards and tax credit carryforwards	\$ 88,304	\$ 84,831
Stock-based compensation	6,825	7,500
Capitalized research and development	5,366	8,040
Foreign NOL carryforwards	4,777	5,405
Nondeductible reserves and accruals	4,811	4,579
Amortizable intangibles other than goodwill	4,138	4,600
Deferred revenue	1,567	1,132
Depreciation	388	580
Change in unrealized losses on marketable securities	285	285
Other, net	1,488	1,327
	117,949	118,279
Deferred tax liabilities		
Indefinite lived intangibles	(5,554)	(4,799)
	(5,554)	(4,799)
Net deferred tax asset	112,395	113,480
Valuation allowance	(117,949)	(118,279)
Net deferred tax liability	\$ (5,554)	\$ (4,799)

The change in the valuation allowance was a decrease of \$0.4 million and \$2.4 million for fiscal 2013 and 2012, respectively. The decrease in valuation allowance during fiscal 2013 is due primarily to a reduction in capitalized research and development.

As of March 31, 2013, the Company has accumulated a net deferred tax liability of \$5.6 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 amortized for book purposes. The net deferred tax liability cannot be offset against the Company's deferred tax assets since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period.

The Company accrues for the effects of uncertain tax positions and the related potential penalties and interest. At March 31, 2013, the Company had no unrecognized tax benefits. It is reasonably possible that the amount of the unrecognized tax benefit with respect to certain of the unrecognized tax positions will increase or decrease during the next 12 months; however, it is not expected that the change will have a significant effect on the Company's results of operations or financial position.

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

Table of Contents

ABIOMED, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

Note 11. Commitments and Contingencies

Commitments

The following is a description of the Company's significant arrangements in which the Company is a guarantor.

Indemnifications In many sales transactions, the Company indemnifies customers against possible claims of patent infringement caused by the Company's products. The indemnifications contained within sales contracts usually do not include limits on the claims. The Company has never incurred any material costs to defend lawsuits or settle patent infringement claims related to sales transactions.

The Company enters into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. Abiomed has never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is immaterial. Accordingly, the Company has no liabilities recorded for these agreements as of March 31, 2013.

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

Facilities leases The Company rents its Danvers, Massachusetts facility under an operating lease agreement that expires on February 28, 2016. Monthly rent under the facility lease is as follows:

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

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

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

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

The Company rents its European headquarters in Aachen, Germany. The lease payments are approximately 36,000 (euro) (approximately U.S. \$50,000 at March 31, 2013 exchange rates) per month. The existing lease for this space expired on December 31, 2012. The Company entered into an arrangement with its landlord to continue renting its existing space in Aachen at the same monthly rental rate until June 30, 2013 while it negotiates a longer term lease agreement.

Total rent expense for the Company's operating leases included in the accompanying consolidated statements of operations approximated \$1.6 million, \$1.6 million and \$2.7 million for the fiscal years ended March 31, 2013, 2012 and 2011, respectively.

Future minimum lease payments under non-cancelable operating leases as of March 31, 2013 are approximately as follows:

Fiscal Year Ending March 31,

(in \$000s)

Edgar Filing: ABIOMED INC - Form 10-K

2014	\$ 1,157
2015	925
2016	760
2017	32
2018	32
Thereafter	96
Total future minimum lease payments	\$ 3,002

F-21

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 11. Commitments and Contingencies (Continued)****Contingencies**

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. The subpoena seeks documents related to the Impella 2.5. The Company is in the process of responding and intends to cooperate fully with the subpoena. Because the investigation is in the early stages, management 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 can anticipate, however, that it will incur significant expenses related to this investigation.

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 our securities between August 5, 2011 and October 31, 2012. The complaints allege that the defendants violated the federal securities laws in connection with disclosures related to the FDA and the marketing and labeling of its Impella 2.5 product and seek damages in an unspecified amount. The Court has consolidated these complaints. A consolidated amended complaint was filed by the plaintiffs on May 20, 2013.

Additionally, on February 4, 2013, an alleged holder of the Company's common stock filed a derivative action on its behalf against the Company and each of its directors in the U.S. District Court for the District of Massachusetts. The complaint alleges 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 the Company's Impella 2.5 product and seeks damages in an unspecified amount. The Company has moved to dismiss the complaint in its entirety, and that motion has been briefed, argued and is under advisement by the Court. Separately, on January 21, 2013 and February 5, 2013, the Company received demands from purported stockholders to inspect certain of our books and records related to these matters.

The Company is unable to estimate its potential liability with respect to the investigation and lawsuits. 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 12. Accrued Expenses

Accrued expenses consisted of the following:

	March 31,	
	2013	2012
	(in \$000 s)	
Employee compensation	\$ 9,664	\$ 9,272
Sales and income taxes	2,107	948
Research and development	1,025	519
Professional, legal and accounting fees	1,100	427
Warranty	708	726

Edgar Filing: ABIOMED INC - Form 10-K

Other

558

588

\$ 15,162

\$ 12,480

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at March 31, 2013 and 2012.

F-22

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 13. 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 71% and 68% of the Company's total consolidated assets are located within the U.S. as of March 31, 2013 and 2012, respectively. The remaining assets are located in Europe and are primarily related to the Company's Impella production facility in Germany, and include goodwill and intangibles of \$35.4 million and \$37.0 million at March 31, 2013 and 2012, respectively, associated with the Impella acquisition in May 2005. Total assets in Europe excluding goodwill and intangibles amounted to 8% of total consolidated assets at each of March 31, 2013 and 2012. International sales (sales outside the U.S. and primarily in Europe) accounted for 7%, 8% and 8% of total product revenue during the fiscal years ended March 31, 2013, 2012 and 2011, respectively.

Note 14. Quarterly Results of Operation (Unaudited)

The following is a summary of the Company's unaudited quarterly results of operations for the fiscal years ending March 31, 2013 and 2012:

	Fiscal Year Ended March 31, 2013				
	1st Quarter	2nd Quarter	3rd Quarter (in \$000 s)	4th Quarter	Total Year
Total revenues	\$ 38,783	\$ 37,417	\$ 38,250	\$ 43,674	\$ 158,124
Cost of product revenue	7,446	7,194	8,130	8,826	31,596
Other operating expenses	27,776	24,291	27,202	30,716	109,985
Other income (expense), net	(6)	(8)	325	8	319
Income before income tax provision	3,555	5,924	3,243	4,140	16,862
Income tax provision	436	455	559	398	1,848
Net income	\$ 3,119	\$ 5,469	\$ 2,684	\$ 3,742	\$ 15,014
Basic net income per share	\$ 0.08	\$ 0.14	\$ 0.07	\$ 0.10	\$ 0.38
Diluted net income per share	\$ 0.08	\$ 0.13	\$ 0.07	\$ 0.09	\$ 0.37

	Fiscal Year Ended March 31, 2012				
	1st Quarter	2nd Quarter	3rd Quarter (in \$000 s)	4th Quarter	Total Year
Total revenues	\$ 27,355	\$ 29,478	\$ 32,198	\$ 37,344	\$ 126,375
Cost of product revenue	5,891	5,551	6,279	6,786	24,507
Other operating expenses	25,885	23,161	23,686	27,616	100,348
Other income (expense), net	(77)	60	1,054	(14)	1,023
Income (loss) before income tax provision	(4,498)	826	3,287	2,928	2,543
Income tax provision	96	225	366	361	1,048
Net income (loss)	\$ (4,594)	\$ 601	\$ 2,921	\$ 2,567	\$ 1,495
Basic net income (loss) per share	\$ (0.12)	\$ 0.02	\$ 0.08	\$ 0.07	\$ 0.04
Diluted net income (loss) per share	\$ (0.12)	\$ 0.02	\$ 0.07	\$ 0.06	\$ 0.04

Table of Contents**ABIOMED, INC. AND SUBSIDIARIES****SCHEDULE II****Valuation and Qualifying Accounts****(in thousands)**

Description	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Allowance for Doubtful Accounts				
Fiscal Year Ended March 31, 2011	\$ 158	\$ 262	\$ 146	\$ 274
Fiscal Year Ended March 31, 2012	\$ 274	\$ 181	\$ 225	\$ 230
Fiscal Year Ended March 31, 2013	\$ 230	\$ 200	\$ 294	\$ 136

Description	Balance at Beginning of Period	Net Change	Balance at End of Period
Deferred Tax Asset Valuation Allowance			
Fiscal Year Ended March 31, 2011	\$ 117,047	\$ 3,674	\$ 120,721
Fiscal Year Ended March 31, 2012	\$ 120,721	\$ (2,442)	\$ 118,279
Fiscal Year Ended March 31, 2013	\$ 118,279	\$ (330)	\$ 117,949