

ABIOMED INC  
Form 10-K  
June 08, 2009  
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, 2009

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-20584

**ABIOMED, Inc.**

*(Exact Name of Registrant as Specified in Its Charter)*

**Delaware**  
*(State or Other Jurisdiction of*

*Incorporation or Organization)*

**22 Cherry Hill Drive**

**Danvers, Massachusetts**  
*(Address of Principal Executive Offices)*

**04-2743260**  
*(I.R.S. Employer*

*Identification No.)*

**01923**  
*(Zip Code)*

**(978) 646-1400**

*(Registrant's Telephone Number, Including Area Code)*

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

# Edgar Filing: ABIOMED INC - Form 10-K

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

Accelerated filer

Non-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, 2008, 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 \$649,874,573.

As of May 29, 2009, 37,350,501 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 2009 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**

**10-K - FORM 10-K**

**PART I**

ITEM 1.	<u>BUSINESS</u>	1
ITEM 1A.	<u>RISK FACTORS</u>	16
ITEM 1B.	<u>UNRESOLVED STAFF COMMENTS</u>	27
ITEM 2.	<u>PROPERTIES</u>	28
ITEM 3.	<u>LEGAL PROCEEDINGS</u>	28
ITEM 4.	<u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	28

**PART II**

ITEM 5.	<u>MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	29
ITEM 6.	<u>SELECTED FINANCIAL DATA</u>	31
ITEM 7.	<u>MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	32
ITEM 7A.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u>	43
ITEM 8.	<u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	44
ITEM 9.	<u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	44
ITEM 9A.	<u>CONTROLS AND PROCEDURES</u>	44
ITEM 9B.	<u>OTHER INFORMATION</u>	46

**PART III**

ITEM 10.	<u>DIRECTOR, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	47
ITEM 11.	<u>EXECUTIVE COMPENSATION</u>	47
ITEM 12.	<u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCK HOLDER MATTERS</u>	47
ITEM 13.	<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	47
ITEM 14.	<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	47

**PART IV**

ITEM 15.	<u>EXHIBITS AND FINANCIAL STATEMENT SCHEDULES SIGNATURES</u>	48
EX-10.24	<u>(SUMMARY OF EXECUTIVE OFFICER COMPENSATION)</u>	
EX-21.1	<u>(SUBSIDIARIES OF THE REGISTRANT)</u>	
EX-23.1	<u>(CONSENT OF DELOITTE &amp; TOUCHE LLP)</u>	
EX-31.1	<u>(CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER)</u>	
EX-31.2	<u>(CERTIFICATION OF PRINCIPAL ACCOUNTING OFFICER)</u>	
EX-32.1	<u>(SECTION 1350 CERTIFICATION)</u>	

**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 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;*

*the 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 and our goal of achieving 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 medical devices in circulatory support and we offer a continuum of care in heart recovery to heart failure patients. Our strategy is focused on establishing heart recovery as the goal for all acute cardiac attacks. Our products are designed to enable the heart to rest, heal and recover by improving blood flow and/or performing the pumping function of the heart. We believe we are the only company with commercially available cardiac assist devices approved for heart recovery from all causes by the U.S. Food and Drug Administration, or FDA, and our products have been used to treat thousands of patients to date. Our products have been used globally in a broad range of clinical settings, including by heart surgeons for patients in profound shock and by interventional cardiologists for patients who are in shock, pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab. Our circulatory care products are designed to provide hemodynamic support for acute patients from the cath lab to the surgery suite aimed towards heart recovery and sending the patient home with his or her native heart. We believe heart recovery is the optimal clinical outcome because it allows patients to return home with their own hearts, ultimately restoring their quality of life. In addition, we believe heart recovery is the most cost-effective path for the healthcare system. Since 2004, our executive team has focused our efforts on expanding our product portfolio. We have significantly increased our portfolio to several circulatory care products that have either been approved or cleared by the FDA in the U.S., have received CE mark approval in Europe, or have received registration or regulatory approval in numerous other countries. We also have additional new circulatory care products under development.

**Industry Background****Heart Disease Overview**

According to the American Heart Association, or AHA, 2007 Heart Disease Update Report, there are an estimated 865,000 heart attack patients treated annually at U.S. hospitals. The AHA has also reported that coronary heart disease is the leading cause of death in the U.S. 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. The AHA estimates that there are approximately 2.0 million hospital visits per year with coronary heart disease as the first-listed diagnosis and approximately 1.1 million hospital visits per year with congestive heart failure as the first-listed diagnosis. Approximately 267,000 women die each year in the U.S. from heart attacks, which is approximately six times as many as women who die from breast cancer annually.

A broad spectrum of therapies exists for the treatment of patients in early stages of coronary heart disease. 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 have potentially 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 a heart 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 patients in profound cardiogenic shock, including those suffering from myocarditis, a viral attack of the heart, or those suffering from 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.

**The Market for Mechanical Circulatory Support Devices in the U.S.**

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.

An IAB is an inflatable balloon inserted via a catheter into the patient's circulation and is inflated and deflated in synchrony with the heart. This is used as an initial line of therapy in the cath lab or the surgery suite for patients with diminished heart function. However, IABs

---

## **Table of Contents**

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. However, the use of these drugs 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. However, there are an estimated 160,000 annual IAB procedures globally, with an estimated 110,000 IAB procedures annually in the U.S.

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 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 be removed once the heart has recovered. If possible, recovery of one's own 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 the patient, 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 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. According to the United Network for Organ Sharing, there were only approximately 1,850 heart transplants in the U.S in 2006. As a result, about one third of the patients eligible for transplant must rely on bridge-to-transplant devices for an extended period while waiting for a heart transplant. During this time, these patients frequently experience significant medical complications, such as infection. Moreover, the implant of these devices generally requires the removal of a portion of the patient's heart tissue, significantly limiting the chance of recovery of the patient's heart.

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. Destination VAD therapy only prolongs the end-stage disease, as the patient's heart condition is terminal and the patient's heart is not expected to recover. Furthermore, artificial replacement hearts, another destination therapy modality, may be suitable for end-stage heart failure patients requiring full support.

### **Our Solution**

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 from hours to months and longer to align with the clinical needs of the patient, whether in pre-shock or profound shock. Our cath lab products include an IAB and our catheter-based Impella<sup>®</sup> pumps for support of acute pre-shock patients or for prophylactic support of patients undergoing high-risk percutaneous coronary intervention. Our surgery suite products include our Impella pumps (the Impella 2.5, Impella 5.0, and Impella LD), our IAB, our BVS<sup>®</sup> 5000 blood pump and AB5000<sup>™</sup> VAD. Our BVS 5000 and AB5000 are designed to support acute heart failure patients in need of more blood flow and longer duration of support for AMI, cardiogenic shock post-AMI, and myocarditis.

Our Impella products are CE-marked in Europe. In June 2008, we received FDA 510(k) clearance for our Impella 2.5 device for partial circulatory support for up to six hours. In April 2009, we received FDA 510(k) clearance of our Impella 5.0 and Impella LD Circulatory Support Devices. These clearances allow us to sell the Impella pumps for commercial purposes. Our Impella 2.5 device is also the subject of two U.S. pivotal studies comparing the Impella 2.5 to the IABP. Our Impella 5.0 device is also currently in a U.S. study. Impella expands our product portfolio to include devices that address the majority of heart attack and high-risk angioplasty patients treated by interventional cardiologists in the cath lab. This population consists of patients whose hearts can potentially recover with assistance but without open heart surgery.

Our Impella 2.5 and 5.0 catheters are micro heart pumps that can be utilized in the cath lab by cardiologists and quickly inserted percutaneously via the femoral artery using a guide wire to reach the left ventricle of the heart. The procedure time facilitates early patient stabilization, giving an interventional cardiologist additional time to evaluate the most effective and clinically prudent treatment option for the patient. These devices allow the heart to rest, heal and potentially recover without the use of inotropes, which are drugs commonly used with IABs that increase the risk of mortality. In addition, the higher blood flow rate of our Impella 5.0 enables clinical use by surgeons as well to treat more severe heart conditions in the surgery suite. We believe our Impella products can provide solutions to patients with less severe heart disease, improving patient outcomes and increasing the number of patients who return home with their own hearts.

We developed our first heart recovery products for use in open heart centers and transplant centers. Our AB5000 and BVS 5000 are capable of assuming the pumping function of the heart. Unlike destination therapy and bridge-to-transplant devices, which are designed for

**Table of Contents**

heart patients with irreversible heart damage, our AB5000 and BVS 5000 systems are designed for heart recovery, requiring only a minimal incision in the left ventricle of the heart. We believe the AB5000's high flow rates, ease of implant, and historically low incidence of adverse events facilitate heart recovery, avoiding unnecessary heart transplantation for patients with potential for heart recovery and thereby improving patient outcomes. The Centers for Medicare & Medicaid Services, or CMS, increased reimbursement in October 2007 for our AB5000 and BVS 5000 products for patients that recover using our devices to levels similar to those for patients who undergo heart transplants. These reimbursement levels for AB5000 and BVS 5000 are now the highest paying diagnosis-related group, or DRG code of all CMS codes. Since its introduction in 1992, the BVS 5000 has supported thousands of patients in hundreds of medical centers around the world. The AB5000, our next-generation heart recovery device introduced in 2004, provides up to six liters of pulsatile flow, and provides patient mobility. In January 2008, we received FDA labeling approval for one year bench reliability for our AB5000 VAD which is expected to complement the durability of our new Portable Circulatory Support Driver that is discussed below.

We recently announced that we have developed a new Portable Circulatory Support Driver, or Portable Driver, for both in-hospital and out-of-hospital patients. The Portable Driver is designed to support our AB5000 VAD. We received CE mark approval for our Portable Driver in March 2008 and in fiscal year 2009 began to sell the product commercially in Europe and other countries outside the U.S. that accept the CE mark designation. In January 2008, we submitted for an Investigational Device Exemption, or IDE, to conduct a patient discharge study in the U.S. In May 2008, we received conditional approval for the Portable Driver for this IDE to conduct a U.S. patient discharge study at 20 hospitals for 30 patients. In March, 2009, we received FDA approval of our Premarket Approval Application, or PMA, supplement for the AB Portable Driver. This clearance allows for immediate commercial shipment of the device to U.S. hospitals for use as a primary driver in hospitals and for transporting patients. Discharging inpatients is still limited to the trial in the U.S.

We believe our AB5000 and BVS 5000 products are the only commercially available cardiac assist devices approved by the FDA for heart recovery for patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. In addition, our Impella products together with our FDA-cleared IAB and FDA-approved iPulse combination console, will expand our heart recovery devices beyond the surgery suite by providing circulatory support for pre-shock heart failure patients in the cath lab. This expansion into the cath lab will significantly increase our target market opportunity and is expected to enable us to offer an array of products to interventional cardiologists in the approximately 1,900 U.S. hospitals with cath labs. We estimate that there are approximately 14,000 interventional cardiologists in the U.S. The potential target patient population in the cath lab for our Impella and IAB devices includes approximately one million percutaneous coronary intervention, or PCI, U.S. patients annually who enter the hospital for heart attacks and high-risk angioplasty procedures. This target patient base is in addition to our existing target U.S. patient population of approximately 75,000 patients annually suffering from cardiogenic shock after a heart attack or heart surgery, or suffering from myocarditis. Our existing target patients are those treated in the approximately 1,000 open heart centers and transplant centers in the U.S., which continue to represent a significant opportunity for growth as well. We are also focusing on markets outside the U.S. to enhance the standard of circulatory care worldwide and increase our revenue growth potential.

We received 510(k) clearance from the FDA for our IAB in December 2006 and CE Mark approval in January 2007. Our IAB is inserted percutaneously into a patient's descending aorta and inflates and deflates in counter pulsation to the patient's heart pumping cycle. The IAB extends our clinical and market reach further upstream in the care of acute heart disease patients, including direct usage in the intensive care unit, cath lab and surgery suite.

To support the IAB, we developed our iPulse™ combination console. The iPulse console is also designed to support our AB5000 and BVS 5000 systems, other manufacturers' IABs and products we may offer in the future. We believe the ability of the iPulse console to support multiple devices will make it more attractive than consoles designed to operate a single device. The iPulse console supports procedures with associated Medicare reimbursement that extends across four DRGs. The iPulse console has CE mark approval in Europe and was approved by the FDA in late December 2007 for commercial sale in the U.S. The iPulse console is designed to support our IAB as well as other manufacturers' IABs, which are used in the cath lab and surgery suite. Because our multi-functional console also supports our AB5000 and BVS 5000 blood pumps, we believe the iPulse will provide our customers additional flexibility in allocating console resources between the surgery suite and the cath lab. In addition, we believe adoption of our iPulse console and our Portable Circulatory Support Driver, as well as the introduction of the Impella 5.0 and Impella LD, will increase utilization of our AB5000 ventricle over time as we focus more attention on the surgery business.

In January 2008, we received Humanitarian Device Exemption, or HDE, supplement approval from the FDA for our engineering and product enhancements to our AbioCor® Implantable Replacement Heart or AbioCor, the first completely self-contained artificial heart. The AbioCor can be made available to a limited patient population, with no more than 4,000 patients receiving the technology under the limits of the HDE approval in the U.S. each year. Because the AbioCor is only available to a limited patient population, we do not expect that the demand will meet the 4,000 patient limit under HDE approval. We have no current plans to seek a broader regulatory approval of the AbioCor. The AbioCor gives chronic patients with biventricular heart failure who are not eligible for a transplant and whose sole alternative is death, the opportunity to extend life. The AbioCor has no wires piercing the skin and allows the patient improved quality of life outside the hospital. The use of AbioCor is limited to normal to larger sized male patients and has a product life expectancy of 18-24 months. We are testing a newer version of the AbioCor, the AbioCor II, that will be smaller and may have a longer product life expectancy than the AbioCor. We began selling the AbioCor in the fourth quarter of fiscal 2008 in a controlled roll-out to a limited number of heart centers in the U.S. We did not record any revenue from sales of the AbioCor in fiscal 2009. We do not expect that sales of the AbioCor will be a material portion of our total revenues for the foreseeable future.

---

## **Table of Contents**

### **Our Strategy**

Our strategic objective is to establish heart recovery as the goal for all acute cardiac attacks. To achieve this objective, we intend to:

*Expand our global distribution and clinical expertise in the cath lab.* With the growth in our product portfolio and recent regulatory clearances for certain products, we now have greater opportunities to market and sell our products to both heart surgeons and interventional cardiologists in the U.S. and abroad. To address this larger market, we plan to continue to expand our global sales and clinical headcount with extensive clinical experience, particularly in the cath lab, to enhance our ability to market and sell our products to interventional cardiologists.

*Establish recovery awareness through clinical data and published scientific studies.* Many heart surgeons and cardiologists are unfamiliar with the clinical results that have been achieved with our heart recovery devices. We are using evidence-based medicine to promote heart recovery as the goal for patients with failing but potentially recoverable hearts. Through our U.S. pivotal trials, we are working to demonstrate that our Impella products are superior to the use of IABs and inotropes as the initial treatment for less severe heart failure patients. As discussed above, our Impella 2.5 device received 510(k) clearance from the FDA in June 2008 for partial circulatory support for up to six hours. We intend to continue to support the publication of papers that illustrate the benefits of heart recovery, provide webcasts and seminars on the cost savings associated with recovery, promote heart recovery at industry trade shows and hold training sessions for clinicians to begin using our heart recovery products. We will also continue to educate hospitals about CMS and commercial insurance reimbursement options available for our products.

*Continue to enhance our product portfolio to address patients along the entire continuum of care for heart recovery, from the cath lab, to the surgery suite, to the intensive care unit, to home discharge.* Our earliest circulatory assist product, the BVS 5000 system, and our next-generation AB5000 system address heart failure patients requiring surgical intervention to improve their heart function and are sold primarily to open heart centers and transplant centers. We now have Impella 2.5 and 5.0 catheters and recently launched our IAB and iPulse platform. These products target the larger population of acute heart failure patients in the cath lab, whose hearts might recover with assistance but without open heart surgery. Our Impella 2.5 and 5.0 products, iPulse platform and Portable Driver are CE marked. Our IAB and iPulse are FDA-cleared and approved, respectively. Our Impella 2.5, Impella 5.0, and Impella LD circulatory devices have received 510(k) clearance, and we have received FDA approval of our PMA supplement for our Portable Driver in the U.S. We intend to continue to develop and introduce additional new products to cover a broader population of potential heart recovery patients and we also plan to seek regulatory approval for the use of our products for a broader range of patient indications. We also have a number of new circulatory support products at various stages of development.

*Evaluate strategic opportunities to add complementary products and technologies.* We constantly evaluate strategic opportunities to add complementary products and technologies and we may pursue selective additions that would provide products or intellectual property that enhance our product portfolio to address patients across the continuum of care in heart recovery.

**Table of Contents****Our Products**

We are building a portfolio of cardiac assist solutions for cardiologists and surgeons. Our cardiac assist products provide circulatory support to acute heart failure patients across the continuum of care in heart recovery. (ü = approved or cleared)

Product Name	Description of Use	Regulatory Status	
		US	CE Mark
<b>Disposable Products for the Surgery Suite</b>			
BVS 5000 Blood Pump	Provides temporary LVAD, RVAD or BiVAD support until recovery for cardiogenic shock from heart attack; post-cardiotomy cardiogenic shock; myocarditis, failed transplant and certain other clinical instances where the physician believes heart recovery is possible.	ü	ü
AB5000 Ventricle	Provides temporary LVAD, RVAD or BiVAD support until recovery for cardiogenic shock from heart attack; post-cardiotomy cardiogenic shock; myocarditis, failed transplant and certain other clinical instances where the physician believes heart recovery is possible; allows for full patient mobility.	ü	ü
Integrated Cannula System	Connects the BVS 5000 and AB5000 ventricle to the body and provides an option for the removal of the devices without re-opening the chest.	ü	Not yet submitted
Impella LD	Provides temporary LVAD support for recovery from post-cardiotomy hemodynamic instability where the physician believes heart recovery is possible.	ü	ü
	Provides temporary LVAD support for recovery from cardiogenic shock.	510(k) clearance; IDE approved. Safety in progress	
<b>Disposable Products for the Cardiac Catheterization Lab and the Surgery Suite</b>			
Impella 2.5	Miniature percutaneous heart pump providing up to 2.5 liters of blood flow per minute intended to support the heart while undergoing high-risk angioplasty procedures or for assisting the heart while in pre-shock for hemodynamic stabilization.	ü	ü
	Under 510(k) clearance, approved for partial circulatory support for up to six hours.	510(k) clearance; IDE approved and pivotal studies in progress for high-risk PCI and AMI shock	
Impella 5.0	Percutaneous heart pump providing up to 5.0 liters of blood flow per minute for low cardiac output post-surgery patients intended to assist the heart while in pre-shock or profound shock for recovery.	ü	ü
		510(k) clearance; IDE approved. Safety in progress	
IAB	Percutaneous intra-aortic balloon used to support a wide variety of prophylactic, pre-shock and profound shock conditions.	ü	ü
<b>Consoles</b>			
AB5000 Console	Driver console for both BVS 5000 Blood Pump and AB5000 Ventricle.	ü	ü
Mobile Pump Console	Driver console for Impella products.	ü	ü
		510(k) clearance; IDE approved 2.5, 5.0, and LD	
iPulse Console	Multi-purpose driver console for IAB, AB5000, BVS 5000 and other manufacturers IABs.	ü	ü
Portable Discharge Driver	Driver console for AB5000 for in-hospital and out-of-hospital patients; enables patient discharge while on support.	FDA approval for in-hospital use; IDE approval for patient discharge	ü
<b>Disposable Implants</b>			
AbioCor	Fully implantable replacement heart for severe biventricular heart failure when chronic patients are ineligible for a heart transplant.	HDE Approved	Not yet submitted



## **Table of Contents**

### ***Impella 2.5, Impella 5.0, and Impella LD***

Our Impella 2.5 and 5.0 catheters are percutaneous micro heart pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. These devices are designed for use by interventional cardiologists to support pre-shock patients in the cath lab who may not require as much support as patients in the surgery suite or for use in surgery for patients who may require assistance to maintain their circulation. Our Impella catheters are also designed to provide ventricular support for patients requiring hemodynamic stabilization or suffering from reduced cardiac output, and can aid in recovering the hearts of patients following a heart attack. These products are intended to increase flow to the heart and organs without the need for drugs such as inotropes while reducing the workload of the heart.

These catheters can be quickly inserted via the femoral artery using a guide wire to reach the left ventricle of the heart where they are directly deployed to draw blood out of the ventricle and deliver it to the circulation. This function is intended to reduce ventricular work (resting the heart) and provide flow to the rest of the organs. The Impella 2.5 is introduced with normal interventional cardiology procedures, while the Impella 5.0 is implanted via a small incision in the femoral artery in the groin. The Impella 2.5 can pump up to 2.5 liters of blood per minute and the Impella 5.0 can pump up to five liters of blood per minute. The Impella 5.0 has been used to treat patients in need of cardiac support resulting from post-cardiotomy cardiogenic shock, myocarditis, low cardiac output after a heart attack, or post-coronary intervention procedures.

Our Impella 2.5 device received 510(k) clearance from the FDA in June 2008 and our Impella 5.0 and Impella LD devices received 510(k) clearance in April 2009, in each case for partial circulatory support for up to six hours. Our Impella devices have CE mark approval in Europe, are approved in over 40 countries, have already been used to treat more than 1,500 patients in Europe and other countries outside the U.S. and have been the subject of over 40 peer-reviewed publications and other clinical presentations and publications.

In addition, we are pursuing FDA approval for our Impella heart pumps through a pre-market approval, or PMA path, for our Impella 2.5 and 5.0 products. In August 2007, we received approval from the FDA to begin a high-risk percutaneous coronary intervention, or PCI, pivotal clinical trial, known as the Protect II study, for the Impella 2.5. This approval was based on the submission of the clinical results of the safety pilot clinical trial. The pivotal study will determine the safety and effectiveness of the Impella 2.5 as compared to optimal medical management with an IAB, during high-risk angioplasty procedures. The study inclusion criteria have been extended to include patients with triple vessel disease with low ejection fraction. The study is approved under category B2 status and the trial sites are eligible for full reimbursement from CMS. The randomized pivotal study, in which 654 patients at up to 150 hospitals will undergo a high-risk PCI procedure, is comprised of two arms comparing nearly equal number of Impella 2.5 supported patients and IAB supported patients during the procedure. Patients receiving the Impella 2.5 can be supported for up to five days as a left VAD. We have commenced shipments of Impella 2.5 disposables and Impella consoles to the enrolled pivotal sites. As of March 31, 2009, a total of 95 hospitals are participating in the Protect II study and a total of 223 patients have completed the Protect II study, or 34% of the 654 patients required. Based on current trial enrollment rates, we expect to complete the Protect II study in early 2012.

The market for PCI, which includes high-risk patients, provides a significant addressable market opportunity for the Impella 2.5 and represents the highest individual utilization for IABs. More than 20,000 IABs are used per year in the U.S. alone for PCI. There are an estimated one million PCI procedures in the U.S. and an estimated 60,000 patients are high-risk and may benefit from our Impella 2.5 if approved or cleared by the FDA.

In March 2008, we received approval from the FDA to begin a second pivotal study for our Impella 2.5 in the U.S. under an IDE for hemodynamically unstable patients undergoing a PCI procedure due to acute myocardial infarction, or AMI, commonly referred to as heart attack. The AMI study, known as Recover II, will determine the safety and effectiveness of the Impella 2.5 as a left ventricular assist device for heart attack patients as compared to optimal medical management with an IAB. The study is approved under category B2 status and the trial sites are eligible for full CMS reimbursement. The randomized study, at up to 150 hospitals, is comprised of two arms; those patients that receive the Impella 2.5 for up to five days and patients that receive IAB therapy. The study will compare 192 Impella 2.5 patients to 192 IAB patients relative to a composite end point comparing safety and efficacy. The proposed primary endpoint will be a composite endpoint of major events assessed at 30 days post-AMI. These major events include but are not limited to: death, acute renal failure, and need for a major cardiovascular operation. The secondary endpoint will be a composite of cardiac function such as ejection fraction, requirement for inotropic support and cardiac power output. We plan to ship Impella 2.5 disposables and Impella consoles to enrolled sites. There are estimated to be approximately 100,000 AMI anterior infarct patients annually in the U.S. and these patients suffer failure of the left ventricle, the large main pumping muscle of the heart. Feasibility studies suggest that of heart attack patients, these are the patients that can be most helped by the Impella 2.5 technology.

The clinical experience to date with our Impella 2.5 has been favorable, including our recently completed U.S. safety pilot clinical trial. Factors that affect the length of time to complete the pivotal studies in the U.S. study include the timing of each center receiving IRB approval, the timing of the training we will provide each center, and the rate of patient enrollment. At this time we cannot estimate the duration of the Recover II Impella 2.5 pivotal study discussed above.

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

---

## **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. The AB5000 and BVS 5000 systems, which are implanted in the surgery suite, can assume the full pumping function of a patient's failing heart, allowing the heart to rest, heal and potentially recover. Both systems are designed to provide either univentricular or biventricular support. We believe the AB5000 and BVS 5000 systems are the only commercially available cardiac assist devices that are approved by the FDA for heart recovery for patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability.

The BVS 5000 Biventricular Support System was our first product and has been available for sale since 1992. It was the first FDA-approved heart assist device capable of assuming the pumping function of the heart. Since its introduction, the BVS 5000 has supported thousands of patients in the U.S., Europe and other countries.

The AB5000 Circulatory Support System, our next-generation product for heart recovery, is designed to provide a longer duration of support than the BVS 5000 and facilitates patient mobility in the hospital. The AB5000 can provide up to 6.0 liters of pulsatile blood flow per minute to support patients in profound shock and was approved by the FDA in 2003. Our AB5000 is designed to provide enhanced patient mobility within and between medical centers and to provide enhanced features and ease of use for caregivers. We believe the AB5000 system's high flow rates, ease of implant and historically low incidence of adverse events facilitate heart recovery, for patients with potential for recovery, potentially avoiding the need for heart transplantation and thereby improving patient outcomes. In January 2008, we received FDA labeling approval of one year bench reliability for our AB5000 ventricle.

Each of the AB5000 and BVS 5000 systems consists of a ventricle or blood pump, one atrial or ventricular cannula, one arterial cannula and a driver console to operate the pump. Other than the console, each component is a disposable item. The AB5000 console supports biventricular BVS 5000 blood pumps, AB5000 ventricles or a combination of the two. Both the AB5000 and BVS 5000 systems use the same cannulae and console, allowing for seamless transition of devices without requiring an additional surgical procedure. We expect customer demand to shift from the AB5000 console to our iPulse combination console. Our iPulse combination console can run our AB5000 ventricle and BVS 5000 blood pump and our IAB and other manufacturers' IABs.

### ***Portable Driver***

We have developed a Portable Circulatory Support Driver for both in-hospital and out-of-hospital patients. The Portable Driver is designed to support our AB5000 VAD. The combination of our Portable Driver and AB5000 VAD is designed to provide support of acute heart failure patients. In many cases, profound shock heart patients require biventricular support (both sides of the heart).

AB5000 is designed to provide either uni-ventricular or bi-ventricular support. Our FDA labeling approval of one year bench reliability for our AB5000 VAD, is expected to complement the Portable Driver reliability. We received CE mark approval for our Portable Driver in March 2008 and in January 2008 we submitted for an IDE to conduct a patient discharge study in the U.S. In May 2008, we received conditional approval for the Portable Driver for this IDE to conduct a U.S. patient discharge study at 20 hospitals for 30 patients. In March, 2009, we received FDA approval of our PMA supplement for the AB Portable Driver. This clearance allows for immediate commercial shipment of the device to U.S. hospitals for in hospital and transport use. The out of hospital use is being studied in a clinical trial to allow patients to go home while waiting for recovery.

### ***IAB and iPulse***

Our IAB is easy to insert and is designed to enhance blood flow to the heart and other organs for patients with diminished heart function. To support the IAB, we developed our iPulse combination console. The iPulse console is also designed to support our AB5000 ventricle and BVS 5000 blood pump, other manufacturers' IABs and products we may offer in the future. We believe the ability of the iPulse console to support multiple devices will make it more attractive than consoles designed to operate a single device. The iPulse console will support procedures with associated Medicare reimbursement that extends across four diagnostic related groups, which further enhances its attractiveness to customers.

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

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

---

## **Table of Contents**

### ***Cannulae***

Each of our AB5000 and BVS 5000 systems requires two cannulae, or tubes, that connect the ventricle or blood pump to the heart and an associated artery. We offer a variety of cannulae. We introduced our integrated cannula system, which was approved by the FDA in July 2006. This integrated cannula system, which is easier to implant and can be removed through a small incision, has the potential for use off-pump (also called beating heart) with minimally invasive procedures. For example, although removal of the cannulae requires a surgical procedure, it does not require a sternotomy, a substantially more invasive procedure that separates the breastbone in order to access the heart. Moreover, because the AB5000 and the BVS 5000 blood pumps use the same cannulae, clinicians can seamlessly transfer patients from one device to another without requiring an additional surgical procedure.

### ***AbioCor***

Our AbioCor Implantable Replacement Heart is the first completely self-contained artificial heart. Designed to sustain the body's circulation, the AbioCor is intended for end-stage biventricular heart failure patients whose other treatment options have been exhausted. Patients with advanced age, impaired organ function or cancer are generally ineligible for a heart transplant and are potential candidates to receive the AbioCor implantable heart. The complete AbioCor system consists internally of a thoracic unit, a rechargeable battery, an electronics package and a power receiver coil, and externally, a power transmitter coil, power and battery pack, handheld alarm monitor, patient home electronics and an in hospital console. Once implanted, the AbioCor system does not penetrate the skin, reducing the chance of infection. This technology provides patients with mobility and remote diagnostics. The use of AbioCor is limited to normal to larger sized male patients and has a product life expectancy of 18-24 months. We are testing a newer version of the AbioCor, the AbioCor II, that will be smaller and may have a longer product life expectancy than the AbioCor.

We received HDE supplement approval from the FDA for product enhancement of the AbioCor in January 2008. HDE approval signifies that no comparable alternative therapy exists for patients facing imminent death without the technology. HDE approval allows the AbioCor to be made available to a limited patient population, with no more than 4,000 patients receiving the technology in the U.S. each year under HDE approval limits. Because the AbioCor is only available to a limited patient population, we do not expect that demand will meet the 4,000 patient limit under HDE approval. We have no current plans to seek a broader regulatory approval of the AbioCor. We began selling the AbioCor in the fourth quarter of fiscal 2008 in a controlled roll-out to a limited number of heart centers in the U.S. We have selected the following sites to date as AbioCor centers: The Johns Hopkins Hospital in Baltimore, MD; Robert Wood Johnson University Hospital in New Brunswick, NJ; and St. Vincent's Hospital in Indianapolis, IN. We are unable to determine how many patient procedures will be performed after the centers are trained; however, we do not expect it to be a material number. In May 2008, we received a positive National Coverage Determination, or NCD, from CMS to reimburse hospitals for the cost of the AbioCor replacement heart and the cost of implanting the device as part of Coverage with Evidence Development, or CED. Three insurance companies have existing coverage policies for the AbioCor: Cigna, Humana and Healthnet. We did not record any revenue from sales of the AbioCor in fiscal 2009. We do not expect that revenues from sales of the AbioCor will be a material portion of our total revenues for the foreseeable future as our primary strategic focus is centered around heart recovery for acute heart failure patients.

### **Research and Product Development**

Over the last 28 years, we have gained substantial expertise in circulatory support while developing the BVS and the AB5000 systems and our AbioCor. Our current strategy is to develop a complete portfolio of products to treat acute heart failure patients with the goal of heart recovery. We have used this expertise to develop our IAB, iPulse and Portable Driver, and 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 with the Impella technology platform.

As of March 31, 2009, research and development staff consisted of 103 professional and technical personnel, including 34 engineers with advanced degrees, covering disciplines such as electrical engineering, mechanical engineering, computer science, reliability engineering, fluid mechanics, materials and physiology.

We expended \$25.3 million, \$24.9 million, and \$22.3 million on research and development in fiscal years 2009, 2008, and 2007, respectively. Our research and development expenditures include costs related to clinical trials, including ongoing pilot and pivotal clinical trials for our Impella products.

### **Sales, Clinical Support, Marketing and Field Service**

As of March 31, 2009, our worldwide sales, clinical support, marketing and field service teams included 119 full-time employees, 97 of whom are in the U.S. and 22 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., Germany, and France.

---

## **Table of Contents**

Our clinical support personnel consist primarily of registered nurses with 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 14%, 17%, and 11% of total product revenue during the fiscal years ended March 31, 2009, 2008, and 2007, respectively.

### **Manufacturing**

We currently manufacture our products in Danvers, Massachusetts and Aachen, Germany. Our U.S. operations manufacture the BVS 5000, AB5000, AbioCor, IAB, iPulse and Portable Driver. Our Aachen, Germany facility manufactures all of our Impella products. In addition, 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 some of the manufacturing of our consoles.

We believe our existing manufacturing facilities give us the necessary capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months based on our revenue forecast. In fiscal 2008 and 2009, we invested in capacity expansion in our German facility to meet the growing demand of our Impella 2.5 product after the 510(k) clearance that we received in June 2008. In July 2008, we entered into an agreement to lease additional manufacturing space in Athlone, Ireland in anticipation of supporting future demand of Impella 2.5. We are presently constructing the production line for this facility and are hopeful of manufacturing our first Impella 2.5 devices for human use from this facility in late fiscal 2010. Our U.S. and German manufacturing facilities are ISO certified 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 AB5000, the BVS 5000 and the AbioCor 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 2009 to 2026 and our foreign patents have expiration dates ranging from 2011 to 2025. We also own or have rights to certain pending U.S. and foreign patent applications. We believe patents will be issued 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

---

## **Table of Contents**

and 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.

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

The AB5000 and BVS 5000 systems can assume the full pumping function of the heart. The FDA approved these systems as recovery devices for the treatment of patients with potentially reversible heart failure. These products compete with a temporary cardiac assist device from Thoratec Corporation, which is also capable of assuming the full pumping function of the heart and is today approved as a recovery device for post-cardiotomy support only. The Thoratec device was originally approved for bridge-to-transplant indications and we believe bridge-to-transplant continues to be the primary use of the device. In addition, the AB5000 and BVS 5000, as well as our Impella products, compete with other blood pumps that are used in medical centers for a variety of applications, such as intra-aortic balloon pumps, including those offered by Maquet (formerly known as Datascope) and Arrow International, and centrifugal pumps. Levitronix is conducting clinical trials in the U.S. for a device that may compete with our heart assist products in some applications. Levitronix has licensed this product to Thoratec for distribution in the U.S. These pumps are cleared under a 510(k) submission in which their labeling does not allow for specific indications beyond six hours of use. These pumps are limited to either providing partial pumping support of failing hearts, or are non-pulsatile, or are not recommended for the duration of support generally required for recovery. The FDA provided 510(k) clearance for a product designed by CardiacAssist, Inc. that may compete with our products. Approval by the FDA of products that compete directly with our products could increase competitive pricing and other pressures. We believe that we will compete with such products based primarily on clinical effectiveness, scientific evidence, global customer relationships and customer relations.

We are aware of other heart replacement device research efforts in the U.S., Canada, Europe and Japan, but we are not aware of any plans for any other totally implantable replacement heart to commence clinical trials in the U.S. or anywhere in the world. The FDA has approved Syncardia Systems CardioWest Total Artificial Heart for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from non-reversible biventricular failure. Unlike our AbioCor, the CardioWest heart is not fully implantable. In addition, there are a number of companies including Thoratec, Jarvik Heart, World Heart Corporation, MicroMed Technology, Ventracor, EvaHeart, Terumo Heart and several early-stage companies that are developing permanent heart assist products, including implantable left ventricular assist devices, or LVADs, and miniaturized rotary ventricular assist devices, that may address markets that overlap with certain segments of the markets targeted by our products. In addition to these devices, several companies and institutions have been for many years investigating xenotransplantation, the transplantation of a heart from another species, as a potential therapy. Research is also being conducted by others to develop gene and cell therapy potentially to reverse the disease process or to supplant diseased heart cells.

### **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. CMS is responsible for administering the Medicare program and, along with its contractors, establishes coverage and reimbursement policies for the Medicare program. Because a large percentage of the population for which our products are intended includes elderly individuals who are Medicare beneficiaries, Medicare's coverage and reimbursement policies are particularly significant to our business. In addition, private payers often follow the coverage and reimbursement policies of Medicare. We cannot assure you 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 the facilities 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

---

## **Table of Contents**

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 the AB5000 and BVS 5000 are well-established in the U.S. market. For instance, Medicare covers the use of VADs, such as our AB5000 and BVS 5000 devices, 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. CMS recently increased Medicare reimbursement for patients that recover during an in-patient stay using external VADs, such as our AB5000 and BVS 5000 devices, to levels similar to those for patients who undergo heart transplants. Reimbursements for patients who do not recover remain at lower levels.

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 AB5000 or BVS 5000 devices. 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 AB5000 or BVS 5000 devices 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.

In May 2008, we received positive National Coverage Determination, or NCD, from CMS to reimburse hospitals for the cost of the AbioCor replacement heart and the cost of implanting the device as part of Coverage with Evidence Development, or CED. Three insurance companies have existing coverage policies for the AbioCor: Cigna, Humana and Healthnet.

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, redesign of benefits, second opinions required prior to major surgery, careful review of bills, encouragement of healthier lifestyles and exploration of 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.

### **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***

The FDA strictly regulates medical devices under the authority of the Federal Food, Drug and Cosmetic Act, or FDCA, and its regulations. The FDCA and the implementing regulations govern, among other things, the following activities relating to our medical devices: preclinical and clinical testing, design, development, manufacture, safety, efficacy, labeling, storage, record keeping, sales and distribution, post-market adverse event reporting, and advertising and promotion.

In the U.S., medical devices are classified 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 premarket approval, or 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 IDE application before commencing clinical trials. The IDE application must be supported by data, which typically include the results of extensive device bench testing, animal testing performed in conformance with Good Laboratory Practices, and formal laboratory testing and documentation in accordance with appropriate design controls and scientific justification.

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. When all approvals are obtained, the study may be initiated to evaluate the device.

The FDA, and the IRB at each institution at which a clinical trial is being performed, 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. During a study, we are required to comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, recordkeeping and prohibitions on the promotion of investigational devices or making safety

---

## Table of Contents

or efficacy claims for them. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. Following completion of a study, we would need to collect, analyze and present the data in an appropriate submission to the FDA, either a 510(k) premarket notification or a PMA.

In the 510(k) process, the FDA reviews a premarket notification and determines whether or not a proposed device is substantially equivalent to predicate devices. In making this determination, the FDA compares the proposed device to predicate devices. If the intended use and safety and effectiveness are comparable to a predicate device, the device may be cleared for marketing. A device that raises a new question of safety or effectiveness is not eligible for the 510(k) clearance pathway and must undergo the PMA approval process. The FDA's 510(k) clearance pathway usually takes from 3 to 12 months, but it can 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 also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Also, 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 preamendment 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 the devices. In addition, the FDCA requires the FDA either to down-classify preamendment Class III devices to Class I or Class II or to publish a classification regulation retaining the devices in Class III. Manufacturers of preamendment Class III devices that the FDA retains in Class III must have PMA applications accepted by the FDA for filing within 90 days after the publication of a final regulation in which the FDA calls for PMA applications. Failure to meet the deadline can lead the FDA to prevent continued marketing of the device during the PMA application review period. Our IAB received 510(k) clearance based on a preamendment Class III device. The Impella 2.5, Impella 5.0, and Impella LD received clearance based on a preamendment Class III device. If the FDA calls for a PMA for a preamendment Class III device, 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 preamendment Class III device to Class I or Class II, a PMA application will not be required.

In April 2009, the FDA published a notice about the reclassification of certain preamendment Class III medical devices for which regulations requiring submission of PMAs have not been issued. The FDA is seeking information to evaluate the risk-level of each type of device and determine if the devices should be classified to require the submission of a PMA (maintained in Class III) or reclassified into Class I or II. Manufacturers of these devices must submit the required information about their respective device/s to the FDA by August 7, 2009. The required information will vary, but can include details about indications for use, device description, labeling, risks, summaries of pre-clinical / clinical data, and descriptions of treatment alternatives. We are required to submit a response to an FDA request for evaluating Class III device classes currently cleared for marketing under 510(k) regulations. We plan to comply with the FDA request by submitting the appropriate responses for its Class III 510(k) cleared devices, which include the Impella 2.5 and Impella 5.0 catheters, and the iPulse Balloon Catheter and Console. If the FDA does not reclassify these devices to a Class I or Class II device, we may be required to pursue PMA approval of these devices.

The PMA approval pathway requires proof 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 the PMA, the FDA will 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 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. 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, promotion, sale and distribution. 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. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

By regulation, the FDA has 180 days to review a PMA application, during which time an advisory committee may evaluate the application and provide recommendations to the FDA. 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. This process is lengthy and expensive and there can be no assurance that FDA approval will be obtained.

Both a 510(k) and a PMA, if cleared or approved, may include significant limitations on the indicated uses for which a product 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.

## **Table of Contents**

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 available therapy 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. In January 2008 we received HDE supplement approval from the FDA for the AbioCor.

Our AB5000 and BVS 5000 systems are approved by the FDA for heart recovery for patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. In 1992, the FDA approved our PMA for the BVS 5000. In 1996 and 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 new 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, and we received FDA 510(k) clearance of our Impella 5.0 and Impella LD devices in April 2009, in each case for partial circulatory support for up to six hours. Our AB Portable Driver received FDA approval of our PMA supplement in March 2009. All of these products have CE Mark approval in Europe.

### ***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 QSR 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 that a firm report to the FDA any incident in which its product may have caused or contributed to a death or serious injury, required an unnecessary intervention for a patient, or in which its product malfunctioned and, if the malfunction were to recur, it 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 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 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 Department of Justice.

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. These 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, 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 subject to FDA export requirements.

### ***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 medical devices such as ours 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 comply with one or more of a selection of conformity routes. 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 International Organization for Standardization, or ISO, certifications in order to sell our products. Our BVS 5000, AB5000, Impella products, IAB, iPulse console and Portable Driver are CE marked and available for sale in the European Union. We are also subject to regulations in Canada (CAMCAS) 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.

---

## **Table of Contents**

### ***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, is primarily responsible for enforcing the federal Anti-Kickback Statute and generally 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 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.

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.

We have various arrangements with customers and physicians that may implicate these laws. For example, some physicians who use our products also provide medical advisory and other consulting and personal services. Some of these physician arrangements may not meet Anti-Kickback Statute safe harbor protections, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws. Additionally, we do not maintain a formal compliance plan concerning interactions with healthcare professionals nor have we formally adopted the recommendations issued by the OIG. The OIG may interpret the absence of such formal plan negatively in the case of an enforcement action, which could result in a material adverse effect on our financial condition and results of operations. Further, the absence of a formal compliance plan causes us to be out of compliance with certain state laws such as in Nevada and California that require drug and device companies to have formal compliance plans. We are in the process of adopting a formal compliance plan under recently enacted laws in Massachusetts, the adoption of which should put us in compliance with laws in Nevada and California as well.

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

### ***Federal False Claims Act***

The federal False Claims Act prohibits the knowing 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

---

## **Table of Contents**

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 entail 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.

### **Employees**

As of March 31, 2009, we had 386 full-time employees, including:

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

119 in sales, clinical support, marketing and field service;

97 in manufacturing and quality control; and

67 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.

### **Our Corporate Information**

We are a Delaware corporation and commenced operations in 1981. Our principal executive offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, and our telephone number is (978) 646-1400. Our web address is [www.abiomed.com](http://www.abiomed.com). We make available free of charge through the Investors section of our website, all reports filed with the Securities and Exchange Commission. We do not incorporate the information on our website into this report, and you should not consider it part of this report.

## **Table of Contents**

### **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 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 not operated at a profit and do not expect to be profitable in our fiscal year 2010.*

We have incurred net losses in each of the past three fiscal years and for most of our history. We plan to make significant expenditures in fiscal 2010 and subsequent fiscal years for, among other things, the expansion of our global distribution network and ongoing product development, which we expect will result in losses in our fiscal year 2010 and potentially in future periods. These expenditures include costs associated with hiring additional personnel, performing clinical trials, continuing our research and development relating to our products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing activities. The amount of these expenditures is difficult to forecast accurately and cost overruns may occur. We also expect that we will need to make significant expenditures to begin to market and manufacture in commercial quantities our recently approved circulatory care products, and any other new products for which we may receive 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 from three to 12 months, but it can often last longer. The process of obtaining premarket approval is much more costly and uncertain than the 510(k) clearance process. It generally takes from one to three years, or even longer, from the time the PMA application is submitted to the FDA. We cannot assure you that any regulatory clearances or approvals, either foreign or domestic, will be granted on a timely basis, if at all. If we are 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. Although we received 510(k) clearance of our Impella 2.5 device in June 2008 for partial circulatory support for up to six hours, we are also pursuing premarket approval for the Impella 2.5 for additional indications.

Historically, certain Class III devices that were on the market before May 28, 1976, known as preamendment Class III devices, and devices that are determined to be substantially equivalent to them, could be brought to market through the 510(k) process. In April 2009, the FDA published new regulations requiring manufacturers of certain Class III preamendment devices to submit to the FDA a summary of, and citation to, any known, or otherwise available, safety or efficacy information by August 7, 2009. Based on the safety information a manufacturer submits to the FDA concerning its medical device product, the agency can make a determination concerning whether the product must seek PMA approval, or whether the class III device can be reclassified as a class I or class II device, and therefore remain available for sale under the 510(k) clearance. We are required to submit a response to an FDA request for evaluating Class III device classes currently cleared for marketing under 510(k) regulations. We plan to comply with the FDA request by submitting the appropriate responses for its Class III 510(k) cleared devices, which include the Impella 2.5 and Impella 5.0 catheters, and the iPulse Balloon Catheter and Console. If the FDA does not reclassify these devices to a Class I or Class II device, we may be required to pursue PMA approval of these devices. Our understanding of the timeframe for the FDA's decision to reclassify all of the product classes is that it will be a multiple year process, including a 30 month window after the FDA final decision on classification, during which we can continue to market each of the devices, so long as we are in the process of obtaining a PMA. There is no guarantee as to whether we will receive PMA approval for these devices and how long a PMA approval will take to obtain. If we are unable to market and sell those products in the U.S. it would have a material adverse effect on our revenues, operations and prospects.

---

## **Table of Contents**

We intend to market our new 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.

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

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

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

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

## Edgar Filing: ABIOMED INC - Form 10-K

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

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. Since 2004, we have experienced significant growth in the scope of our operations and the number of our employees, including the addition of our operations in Germany, France, the United Kingdom, and Ireland. 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;

---

## **Table of Contents**

expansion of foreign regulatory compliance capabilities;

implementing appropriate operational and financial systems and controls;

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

training, managing and supervising our personnel worldwide.

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 results of operations. We need to create markets for our Impella micro heart pumps, AB5000, IAB, iPulse console, Portable Driver, AbioCor, AbioCor II and 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 the potential failure to develop successive improvements, including increases in service life;

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

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

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

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

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

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

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

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

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

## Edgar Filing: ABIOMED INC - Form 10-K

any of which could harm our reputation and product sales. Furthermore, our inability to educate and train clinicians to use our products may lead to inadequate demand for our products.

## **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. For example, the current configuration of the AbioCor's thoracic unit, or replacement heart, is sized for patients with relatively large chest cavities and we anticipate that we will need to obtain regulatory approval of thoracic units of other sizes, such as the AbioCor II. If the FDA requires us to seek clearance or approval for modification of a previously cleared product for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval and we may be subject to significant regulatory fines or penalties, which could have a material adverse effect on our financial results and competitive position. We also cannot assure you that we will be successful in obtaining clearances or approvals for our modifications, if required. We and our third-party suppliers of product components are also subject to inspection and market surveillance by the FDA and other regulatory agencies for QSR and other requirements, the interpretation of which can change. Compliance with QSR and similar legal requirements can be difficult and expensive. Enforcement actions resulting from failure to comply with government requirements could result in fines, suspensions of approvals or clearances, recalls or seizure of products, operating restrictions or shutdown, and criminal prosecutions 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.

***Our AB5000 and BVS 5000 are vulnerable to competitive pressures.***

Until recently, we have derived most of our product revenues from sales of the AB5000 and BVS 5000. Revenues from these products, especially the BVS 5000, have been declining in recent quarters. If another company were to introduce new treatments, products or technologies that compete with our products, add new features to its existing products or reduce its prices to make its products more financially attractive to customers, revenue from our AB5000 and BVS 5000 could decline further. For example, in the event of the expansion of technologies that allow heart surgical procedures to be performed without stopping the heart, a reduction in the market for these products could result. In addition, variations in the quantity and timing of sales of our consoles have a disproportionate effect on our revenues, because the price of a console is substantially greater than the price of our disposable blood pumps. The higher price of our consoles may limit sales of our consoles in the future by third-party payers. If we cannot maintain and increase our disposable revenues from our AB5000 and BVS 5000, our overall business and financial condition could be adversely affected.

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

To be successful, we believe we will need to increase our manufacturing capacity. In July 2008, we executed a lease for a facility in Athlone, Ireland, in which we are establishing a high-throughput manufacturing facility for the production of our Impella products. 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, adequacy of control policies and procedures and lack of skilled personnel. If we cannot hire, train and retain enough experienced and capable scientific and technical workers, we may not be able to manufacture sufficient quantities of our current or future products at an acceptable cost and on time.

---

## **Table of Contents**

which could limit market acceptance of our products or otherwise damage our business. We expect our Ireland facility to be operational by the end of fiscal year 2010. If we are unable to get our Ireland facility operational by the time we expect, 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 at our facility in Danvers, Massachusetts. In addition, we expect our Ireland facility, in which we are establishing a high-throughput manufacturing facility for the production of our Impella products, to be operational by the end of fiscal year 2010. Events such as fire, flood, power loss or other disasters could prevent us from manufacturing our products in compliance with applicable FDA and other regulatory requirements, which could result in 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. In addition, if we are unable to get our Ireland facility operational on a timely basis as a result of disasters or other business interruptions, it could inhibit our revenue growth.

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

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

Our AbioCor products involve even greater manufacturing complexities than our other current commercial products, such as our BVS 5000, AB5000, and Impella products. Our AbioCor products must be significantly more durable and meet different standards, which may be more difficult to achieve, than those that apply to our current products. If we are unable to manufacture our AbioCor products or other future products on a timely basis at acceptable quality and cost, or if we experience unanticipated technological problems or delays in production, our business will suffer.

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

Sales of medical devices largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. 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 AB5000, BVS 5000, Impella products, Portable Driver, and iPulse console. 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.***

The Federal government is considering ways to change, and has changed, the manner in which healthcare services are provided and paid for in the U.S. Occasionally, the U.S. Congress passes laws that impact reimbursement for health care services, including reimbursement to hospitals and physicians. States may also enact 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, establishes payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities.

In particular, the new administration has set in motion a number of proposed initiatives to reform healthcare and contain costs, and we cannot predict how pending and future legislative and regulatory proposals would influence the manner in which medical devices, including

---

## **Table of Contents**

ours, are purchased or covered and reimbursed. For example, the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, includes \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This funding will be used, among other things, to conduct, support or synthesize research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of medical products. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact coverage, reimbursement or other third-party payor policies. To the extent these or other reform measures impact the coverage and reimbursement of our current or future products, our revenues and results of operations could be adversely impacted.

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.

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

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

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

state law equivalents to the Anti-Kickback Statute, which may not be limited to government-reimbursed items.

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

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

***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, 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 intense 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.

---

## **Table of Contents**

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

We rely on third-party suppliers to provide us with some components used in our existing products and products under development. For example, we outsource the manufacturing of all of our consoles other than final assembly and testing. Relying on third-party suppliers makes us vulnerable to component part failures and to interruptions in supply, either of which could impair our ability to conduct clinical tests or to ship our products to our customers on a timely basis. Using third-party vendors makes it difficult and sometimes impossible for us to test fully certain components, such as components on circuit boards, maintain quality control, manage inventory and production schedules and control production costs. Manufacturers of our product components may be required to comply with the FDA or other regulatory manufacturing regulations and to satisfy regulatory inspections in connection with the manufacture of the components. Any failure by a supplier to comply with applicable requirements could lead to a disruption in supply. Vendor lead times to supply us with ordered components vary significantly and 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. Sole source vendors may decide to limit or eliminate sales of certain components to the medical industry due to product liability or other concerns and we might not be able to find a suitable replacement for those products. Our inventory may run out before we find alternative suppliers and we might be forced to purchase substantial inventory, if available, to last until we qualify an alternate supplier. If we cannot obtain a necessary component, we may need to find, test and obtain regulatory approval or clearance for a replacement component, produce the component ourselves or redesign the related product, which would cause significant delay and could increase our manufacturing costs. Any of these events could adversely impact our results of operations.

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

We are seeking to expand our international sales of the AB5000, Portable Driver, iPulse console, and Impella circulatory assist systems, by recruiting direct sales and support teams outside the U.S. Our international operations in Germany, France, Ireland, 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;

fluctuations in the values of foreign currencies; and

political and economic instability.

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

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

We rely on distributors to market and sell our products in parts of Europe, Asia, South America and Australia. Many of these distributors have the exclusive right to distribute our products in their territory. We may hire distributors to market our products in additional international markets. Our success in these markets will

## Edgar Filing: ABIOMED INC - Form 10-K

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.

---

## **Table of Contents**

### ***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, particularly for our consoles, which are substantially more expensive than our disposable products;

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, IAB, Portable Driver, iPulse console, AbioCor, AbioCor II and any other product products;

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

the effect of fluctuations in currency exchange rates on our results of operations;

economic conditions in the healthcare industry; and

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

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

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

At March 31, 2009, we had federal and state net operating loss ( NOL ) carryforwards of approximately \$145.1 million and \$97.1 million, respectively, which begin to expire in fiscal 2010. Additionally, at March 31, 2009, we had federal and state research and development credit carryforwards of approximately \$8.1 million and \$4.2 million, respectively, which also begin to expire in fiscal 2010.

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 net deferred tax assets and liabilities. Additionally, the future utilization of our NOL and research and development credit carry forwards 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 s and research and development credit carry forwards that a company can use each year to offset future taxable income and taxes payable. We believe that all of our federal and state NOL s 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 carry forwards, before they can be utilized, would reduce our gross deferred tax assets. We will monitor subsequent ownership changes, which could impose limitations in the future.

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

## Edgar Filing: ABIOMED INC - Form 10-K

*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.

**Table of Contents*****Our marketable securities are subject to market risks and decreased liquidity.***

Marketable securities at March 31, 2009 consist of \$7.0 million in the Columbia Fund and \$52.1 million in four funds that invest in U.S. backed government securities. In December 2007, the Columbia Fund ceased accepting redemption requests from investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 83% of its carrying value as of March 31, 2009, and we do not expect to recover the loss of value in liquidation. This determination of the fair value of our holdings in the Columbia Fund requires significant judgment or estimation. As discussed in Note 4 to our financial statements, certain of these securities were valued primarily using broker pricing models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity. The Columbia Fund has been partially liquidated during fiscal 2008 and 2009 and is expected to continue making redemptions through the next twelve months. Since December 6, 2007 and through May 27, 2009, we have received disbursements of approximately \$40 million from the Columbia Fund with the most recent disbursement occurring on May 27, 2009 at approximately 86% of its original value. We have recorded \$3.7 million of the Columbia Fund as long-term marketable securities at March 31, 2009 because Bank of America, the sponsor of the Columbia Fund, has indicated that it cannot predict with certainty whether or not the Columbia Fund will redeem this amount within the next year. We expect conditions in the credit markets to remain uncertain for the foreseeable future. While it is our intent to liquidate securities in the Columbia Fund in future periods to reduce our exposure to future deterioration of these securities, we believe that operating results or cash flows could be affected significantly by fair value adjustments to the Columbia Fund. There can be no assurance that we will not have to take additional losses on the Columbia Fund.

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

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

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

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

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

---

## **Table of Contents**

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

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

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

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

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

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

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

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

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

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

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

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

---

## **Table of Contents**

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

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

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

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use 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.

*Our investment in World Heart Corporation is subject to risk.*

In fiscal 2008, we invested \$5.0 million in WorldHeart in the form of a convertible note and warrant. On July 31, 2008, our investment in WorldHeart was converted to 86,000,000 shares of WorldHeart's common stock, which represented approximately 21.6% of WorldHeart's outstanding shares. Following a reverse stock split that WorldHeart completed in October 2008, we held 2,866,666 shares of WorldHeart. In December 2008, we sold 135,000 shares of WorldHeart for net proceeds of \$0.3 million. As of March 31, 2009, we now hold 2,731,666 common shares of WorldHeart, or approximately 20.6% of WorldHeart's issued and outstanding stock. Our investment in WorldHeart is subject to a number of risks and uncertainties. WorldHeart currently is not profitable and has limited financial resources and we may lose some or all of our investment. In addition, applicable securities law restrictions and low trading volumes may result in an inability to liquidate our WorldHeart investment.

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

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign currency exchange rates, primarily the Euro. The functional currency of our subsidiaries in Germany, Ireland, and France is 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 March 31, 2008 to March 31, 2009 the price of our stock ranged from a high of \$20.07 per share to a low of \$4.67 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;

## Edgar Filing: ABIOMED INC - Form 10-K

acquisitions or strategic alliances involving us or our competitors;

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

---

**Table of Contents**

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

the hiring or departure of key personnel;

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

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

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

***The sale of additional shares of our common stock, or the exercise of 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.***

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.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.



---

**Table of Contents**

**ITEM 2. PROPERTIES**

Our headquarters are located at 22 Cherry Hill Drive in Danvers, Massachusetts and consists of approximately 80,000 square feet of space under an operating lease which would have expired in 2010. In June 2008, we amended this lease, which extended the lease from February 28, 2010 to February 28, 2016. The lease continues to be accounted for as an operating lease. The amendment changed the rent payments under the lease from \$64,350 per month to the following schedule:

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

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

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

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

In addition, we have certain rights to terminate the lease early, subject to the payment of a specified termination fee based on the timing of the termination, as further outlined in the amendment. 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. Our lease expires in December 2012. The monthly rent due under the lease agreement is 51,646 (Euro) (approximately U.S. \$69,000) per month or 619,752 (Euro) (approximately U.S. \$828,000) per year. The building houses most of the research and development and manufacturing operations for our Impella product line as well as the sales, marketing and general and administrative functions for most of our product lines sold in Europe and the Middle East.

In light of the 510 (k) clearance of our Impella 2.5 device and in advance of potential PMA approvals for our Impella 5.0 and LD devices, we evaluated opportunities outside the U.S. for a high-throughput manufacturing facility. In July 2008, we entered into a lease agreement providing for the lease of a 33,000 square foot manufacturing facility in Athlone, Ireland. The lease agreement is for a term of 25 years and one week, commencing on April 18, 2008. The monthly rent due under the lease agreement and payable monthly is 22,455.33 (Euro) (approximately U.S. \$30,000) per month or 269,464 (Euro) (approximately U.S. \$360,000) per year for the first five years of the lease, through April 17, 2013. On April 18, 2013 and each fifth anniversary thereafter, the rental rate will be set to a current market rate, as determined by the procedures set forth in the lease agreement. We have the right to terminate the lease after five years, subject to the payment of a termination fee equal to 18 months rent, and the right to terminate the lease after 10 years, subject to the payment of a termination fee equal to six months of the then current rent.

We lease a small office in France, which focuses on the sales and marketing of our product lines sold in France and we lease a small office in Leeds, United Kingdom for our sales and marketing efforts in the United Kingdom.

**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. At March 31, 2009 there were no pending legal proceedings.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended March 31, 2009.

**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:

<b>Fiscal Year Ended March 31, 2008</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 13.96	\$ 10.50
Second Quarter	14.31	9.95
Third Quarter	15.96	11.68
Fourth Quarter	15.75	12.27
<b>Fiscal Year Ended March 31, 2009</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 20.00	\$ 12.87
Second Quarter	20.07	16.29
Third Quarter	18.03	10.54
Fourth Quarter	16.74	4.67

**Number of Stockholders**

As of May 29, 2009, we had approximately 655 holders of record of our common stock and there were approximately 9,585 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.

**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, 2004 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 (\$)					
	3/31/2004	3/31/2005	3/31/2006	3/31/2007	3/31/2008	3/31/2009
ABIOMED, Inc.	100	129.18	157.51	166.79	160.44	59.83
Nasdaq Composite Index	100	100.25	117.33	121.43	114.29	76.65
Nasdaq Medical Equipment SIC Code 3840-3849	100	105.05	154.79	147.53	149.56	79.57

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)

	<b>Fiscal Years Ended March 31,</b>				
	<b>2009</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>Statement of Operations Data:</b>					
Revenue:					
Products	\$ 72,512	\$ 58,322	\$ 50,408	\$ 43,322	\$ 37,945
Funded research and development	698	619	241	348	271
	73,210	58,941	50,649	43,670	38,216
Costs and expenses:					
Cost of product revenue excluding amortization of intangibles	20,437	15,065	12,012	11,685	9,366
Research and development	25,328	24,917	22,292	16,739	13,350
Selling, general and administrative	55,357	52,658	42,448	30,923	18,566
Arbitration decision		1,206			
Expensed in-process research and development			800	13,306	
Amortization of intangible assets	1,606	1,582	1,608	1,308	187
	102,728	95,428	79,160	73,961	41,469
Loss from operations	(29,518)	(36,487)	(28,511)	(30,291)	(3,253)
Other (expense) income:					
Investment (expense) income, net	(1,404)	1,625	1,045	1,194	801
Gain on sale of WorldHeart stock	313				
Change in fair value of WorldHeart note receivable and warrant		(5,000)			
Other (expense) income, net	(236)	(541)	60	4	110
	(1,327)	(3,916)	1,105	1,198	911
Loss before provision for income taxes	(30,845)	(40,403)	(27,406)	(29,093)	(2,342)
Provision for income taxes	752	527	475	356	
Net loss	\$ (31,597)	\$ (40,930)	\$ (27,881)	\$ (29,449)	\$ (2,342)
Basic and diluted net loss per share	\$ (0.91)	\$ (1.26)	\$ (1.03)	\$ (1.15)	\$ (0.11)
Weighted average shares outstanding	34,882	32,465	27,124	25,649	21,845
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, and short and long term marketable securities	\$ 60,900	\$ 38,299	\$ 75,125	\$ 30,835	\$ 43,617
Working capital	70,910	52,027	83,485	37,704	50,342
Total assets	135,958	118,031	136,183	78,537	61,061
Stockholder s equity	115,983	93,594	122,095	69,488	56,179

**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 sales, gross profit 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 medical devices in circulatory support and we offer a continuum of care in heart recovery to acute heart failure patients. Our strategy is focused on establishing heart recovery as the goal for all acute cardiac attacks. Our products are designed to enable the heart to rest, heal and recover by improving blood flow and/or performing the pumping function of the heart. We believe we are the only company with commercially available cardiac assist devices approved for heart recovery from all causes by the U.S. Food and Drug Administration, or FDA and our products have been used to treat thousands of patients to date. Our products can be used in a broad range of clinical settings, including by heart surgeons for patients in profound shock and by interventional cardiologists for patients who are in pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab. Our circulatory care products are designed to provide hemodynamic support for acute patients from the cath lab to the surgery suite, with a goal of heart recovery and sending the patient home with his or her native heart. We believe heart recovery is the optimal clinical outcome for patients because it provides a better quality of life than alternatives. In addition, we believe heart recovery is the most cost-effective path for the healthcare system. Since 2004, our executive team has focused our efforts on expanding our product portfolio. We have significantly increased our product portfolio, which now includes several circulatory care products that either have been approved or cleared by the FDA in the U.S., have received CE mark approval in Europe, or have received registration or regulatory approval in numerous other countries. We also have additional new circulatory care products in development.

Our strategic focus and the driver of the most recent revenue growth in our business is the market penetration of our Impella 2.5 product, which received 510(k) clearance in June 2008. In addition to the 510(k) clearance, we are also conducting clinical trials of our Impella 2.5 for additional indications of use, with the goal of establishing Impella as the standard of care in the cath lab. We have found that the 510(k) clearance of our Impella 2.5 has significantly slowed our progress in completing the clinical trials, since our customers are now able to use the Impella 2.5 commercially outside of the clinical trials. We recently received 510(k) clearance in April 2009 for our Impella 5.0 and Impella LD devices, which are larger and provide more blood flow than the Impella 2.5. We are also currently in clinical trials with our Impella 5.0 and LD devices. Similar to our experience with the Impella 2.5, we expect that the 510(k) clearance of the Impella 5.0 and LD will slow down our efforts to complete clinical trials with these devices.

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

Revenues from our other heart recovery products have decreased recently as we have strategically shifted our sales and marketing efforts towards our Impella products. We expect that sales from these other products will have limited or no growth in the short term as we dedicate the majority of our focus and resources on our Impella products. We have from time to time engaged in console placement programs related to our iPulse consoles, in order to encourage utilization of our BVS and AB5000 disposables. We have also developed a portable driver for our AB5000 product which received FDA approval under a PMA supplement in March 2009. This clearance allows for immediate commercial shipment of the device to U.S. hospitals for in hospital and transport use. The out of hospital use is being studied in a clinical trial to allow patients to go home while waiting for recovery. We believe that the added mobility afforded by the portable driver will help our overall AB5000 revenues. Our BVS product was launched 17 years ago and revenue from this product has been declining as AB5000, our next-generation product for heart recovery, is designed to provide a longer duration of support than the BVS 5000 and facilitates patient mobility in the hospital. We expect revenue from BVS to continue to decline as our customers transition more to AB5000 disposables and also as our new Impella products, especially our recently cleared Impella 5.0 and LD devices, are introduced in the U.S. We expect limited or no growth in our revenues from our AB5000 business during fiscal 2010 as we continue to focus on our Impella products. We do not expect that revenues from sales of our replacement heart product, the AbioCor, will be a material portion of our total revenues for the foreseeable future as our primary strategic focus is centered around heart recovery for acute heart failure patients. We did not recognize any AbioCor revenue during the fiscal 2009.

We have incurred net losses since our inception, including net losses of \$31.6 million and \$40.9 million in fiscal years 2009 and 2008, respectively. We expect to incur additional net losses in the future as we continue to invest in research and development expenses related to our products, increase our inventory levels, and ramp up our manufacturing facility in Ireland.

---

## **Table of Contents**

Our financial condition has been bolstered by our public offering in August 2008, which yielded us approximately \$42.0 million in net proceeds after deducting offering expenses. We expect that our existing cash resources, together with our revenues, will be sufficient to fund our operations for at least the next 12 months.

### **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 accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, inventories, impairment of intangible assets and goodwill, financial instruments, accrued expenses, income taxes including the valuation allowance for deferred tax assets, stock-based compensation, valuation of long-lived assets and investments, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimated.

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 in accordance with SEC Staff Accounting Bulletin No. 104 ( SAB 104 ). We also follow the guidance of Emerging Issues Task Force ( EITF ) No. 00-21, *Revenue Arrangements with Multiple Deliverables* when transactions include multiple elements. Revenue from product sales to new customers is deferred until training on the use of the products has occurred. All costs related to product shipment are recognized at time of shipment. We do not provide for rights of return to customers on product sales.

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

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. 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.

#### *Goodwill and Intangible Assets*

We evaluate goodwill for impairment at least annually using forecasts of discounted future cash flows. Estimates of future cash flows require assumptions related to revenue and operating income growth, asset-related expenditures, working capital levels and other factors. Different assumptions from those made in our analysis could materially affect projected cash flows and our evaluation of goodwill for impairment. Should the fair value of goodwill decline because of reduced operating performance, market declines, delays in regulatory approval, other indicators of impairment, or as a result of changes in the discount rate, charges for impairment of goodwill may be necessary. We performed our annual impairment review for fiscal 2009 as of October 31, 2008 and determined that goodwill was not impaired. In light of a decrease in our market capitalization since October 31, 2008 and the difficult worldwide economic conditions in recent months, we updated our impairment review as of March 31, 2009 and determined that our goodwill was not impaired. The carrying amount of goodwill at March 31, 2009 was \$31.3 million.

We estimate the fair value of acquisition-related intangible assets principally based on projections of cash flows that will arise from identifiable intangible assets of acquired businesses. The projected cash flows are discounted to determine the present value of the assets at the dates of acquisition. We review intangible assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Factors considered important which could trigger an impairment review include significant changes relative to: (i) projected future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the undiscounted cash flows to the recorded value of the asset. If it is determined that the carrying value of intangible assets may not be recoverable, the asset is written down to its estimated fair value on a discounted cash flow basis. The net book value of intangible assets at March 31, 2009 was \$4.4 million.

---

## **Table of Contents**

### *Allowance for Doubtful Accounts*

We regularly monitor collections and payments from our customers and maintain a provision for estimated losses based upon our historical experience and any specific customer collection issues that we have identified. Although such credit losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same credit loss rates that we have in the past. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances would be required.

### *Warranties*

Our products are subject to rigorous regulation and quality standards. Although we have established extensive product quality programs and processes, including monitoring and evaluating the quality of our component suppliers, we record a warranty obligation related to anticipated product failure rates and product recalls. Our consoles are covered by a one-year limited manufacturer's warranty. We estimate and record a warranty obligation in cost of revenue at the time of shipment and we record any additional amounts when we determine that such costs are probable and we can reasonably estimate them. Historically, our warranty provision has not been substantial; however, our operating results could be adversely affected if the actual cost of any product failures, including product recalls, exceeds our estimated warranty provision.

### *Inventories*

We value our inventory of products held for sale at the lower of cost or current estimated market value. We regularly review inventory quantities on hand and write down to its net realizable value any inventory believed to be impaired. If actual demand or market conditions are less favorable than projected demand, additional inventory write-downs may be required that could adversely impact financial results for the period in which the additional excess or obsolete inventory is identified. We recorded write-downs of inventory in the amount of \$1.4 million, \$1.0 million, and \$0.2 million for fiscal 2009, 2008, and 2007, respectively.

### *Accrued Expenses*

As part of the process of preparing our financial statements, we are required to estimate accrued expenses. This process involves identifying services that third parties have performed on our behalf and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include contract service fees, such as amounts due to clinical research organizations, professional service fees, such as fees of attorneys and accountants, fees of investigators in conjunction with clinical trials and third party expenses relating to marketing efforts associated with commercialization of our product and product candidates. In the event that we do not identify certain costs that have been incurred or we under or over-estimate the level of services or the costs of such services, our 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 our judgment. We make these judgments and estimates based upon known facts and circumstances.

### *Stock-Based Compensation*

We record stock-based compensation in our statements of operations based on the fair value method in accordance with Statements of Financial Accounting Standards (SFAS) No. 123(R) *Share-Based Payment*. This expense is determined after consideration of several significant judgments and estimates. The fair value of each stock option we granted is estimated using the Black-Scholes option pricing model. Use of a valuation model requires us to make certain assumptions with respect to selected model inputs. The risk-free interest rate is based on the 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. The calculation of the fair value of the options is net of estimated forfeitures. The expected term of options represents the period of time that options granted are expected to be outstanding. We estimated the average expected life based on historical experience of our option exercises. 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. In addition, an expected dividend yield of zero is used in the option valuation model because we do not pay dividends and do not expect to pay any cash dividends in the foreseeable future.

### *Income Taxes*

As part of the process of preparing our consolidated financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. At March 31, 2009, we had federal and state net operating loss carryforwards, or NOLs, of approximately \$145.1 million and \$97.1

## Table of Contents

million, respectively, which begin to expire in fiscal 2010. Additionally, at March 31, 2009, we had federal and state research and development credit carryforwards of approximately \$8.1 million and \$4.2 million, respectively, which begin to expire in fiscal 2010. We acquired Impella, a German-based company, in May 2005. The utilization of pre-acquisition NOLs of Impella in future periods is also subject to certain statutory approvals and business requirements.

Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a valuation allowance of \$109.0 million at March 31, 2009 has been established to offset our net deferred tax assets and liabilities. In the event that we determine in the future that we will be able to realize all or a portion of our net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income in the period such a determination was made. Additionally, the future utilization of our NOL and research and development credit carry forwards 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 carry forwards and research and development credit carry forwards that a company can use each year to offset future taxable income and taxes payable. We believe that all of our federal and state NOLs will be 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 carry forwards, before they can be utilized, would reduce our gross deferred tax assets. We will monitor subsequent ownership changes, which could impose limitations in the future.

### *Fair Value Measurements*

Effective April 1, 2008, we adopted the provisions under SFAS No. 157, *Fair Value Measurements*, as required for the valuation of our financial assets and liabilities. However, the Financial Accounting Standards Board, or FASB, deferred the effective date of SFAS 157 for one year as it relates to fair value measurement requirements for nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value on a recurring basis. SFAS No. 157 establishes a three-level hierarchy which prioritizes the inputs used in measuring fair value. In general, fair value determined by Level 1 inputs utilize quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and includes situations where there is little, if any, market activity for the asset or liability. The value of our Level 1 instruments was \$52.1 million and the value of our Level 3 investments was \$7.0 million as of March 31, 2009.

### *Financial Instruments*

We entered into a convertible note purchase agreement with World Heart Corporation ( WorldHeart ) in December 2007, a developer of implantable mechanical circulatory support systems for chronic heart failure patients. Under the agreement, we loaned \$5.0 million to WorldHeart, with the note and accrued interest, at 8% per annum, convertible at our option into common stock of WorldHeart. We advanced \$1.0 million of the loan in December 2007 with the remaining \$4.0 million advanced in January 2008. The conversion feature within the note was an embedded derivative instrument under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and accordingly, was separately valued within the carrying value of the note receivable. We also received a warrant to purchase up to 3,400,000 shares of WorldHeart common stock.

The grant date fair values of the assets associated with the note receivable and the warrant, in excess of cash paid were deemed to be deferred income, as analogized to SFAS No. 91, *Accounting for Nonrefundable Fees and Costs Associated with Originating or Acquiring Loans and Initial Direct Costs of Leases*. Similar to other loan fees, the deferred income related to grant date fair value of the note receivable and the warrant would be recognized over the life of the note receivable, if deemed to be realizable as a yield adjustment.

We initially recorded the derivative financial instruments on our consolidated balance sheet at fair value. Changes in the fair value of these derivative financial instruments were recorded as "Change in fair value of WorldHeart note receivable and warrant" in the consolidated statements of operations. The measurement of fair value was based on valuation methodologies considered appropriate by our management. The estimated fair value of the embedded derivative and warrant was determined using the Black-Scholes method. Because of inherent uncertainty of valuations of derivative instruments, estimated fair values may differ from the value that would have been used had a ready market for the investment existed and these differences could have a material impact in the consolidated statements of operations.

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

In July 2008, WorldHeart completed the transactions contemplated by the recapitalization agreement dated June 20, 2008, as amended on July 31, 2008, we entered into with WorldHeart and the other parties named therein. As a result of the transaction, we received 86 million

---

## **Table of Contents**

common shares of WorldHeart, which represented approximately 21.6% of WorldHeart's issued and outstanding common shares following the transaction. The shares were received as a result of our conversion of the full amount of principal and interest owed on the \$5.0 million convertible note issued in December 2007, our release of the security interest in all of the assets of WorldHeart that secured the note, termination of the warrant we held to purchase 3.4 million common shares of WorldHeart, forgiveness of other amounts owed to us by WorldHeart, the amendment of our rights with respect to the distribution of WorldHeart products, and the appointment of a director or observer to WorldHeart's board of directors. In October, 2008, WorldHeart completed a 30-to-1 reverse stock split, as a result of which we held 2,866,666 common shares of WorldHeart. In December 2008, we sold 135,000 shares of WorldHeart for net proceeds of \$0.3 million, which was, as a result of our basis having been reduced to zero, recorded as a gain on the sale of WorldHeart common stock during the three months ended December 31, 2008. As of March 31, 2009, we held 2,731,666 common shares of WorldHeart, or approximately 20.6% of WorldHeart's issued and outstanding shares. We are accounting for this investment using the equity method of accounting. The carrying value of this investment was zero at March 31, 2009.

### **Recent Accounting Pronouncements**

**SFAS No. 141(R)** In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*. SFAS No. 141(R) applies to any transaction or other event that meets the definition of a business combination. Where applicable, SFAS No. 141(R) establishes principles and requirements for how the acquirer recognizes and measures identifiable assets acquired, liabilities assumed, noncontrolling interest in the acquiree and goodwill or gain from a bargain purchase. In addition, SFAS No. 141(R) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This statement is to be applied prospectively for transactions occurring in fiscal years beginning after December 15, 2008. SFAS 141(R) will impact our accounting for business combinations, if any, completed beginning April 1, 2009.

**SFAS No. 160** In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, an amendment of ARB No. 51. SFAS No. 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of the consolidation procedures under ARB No. 51 for consistency with the requirements of FASB Statement No. 141(R). This statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The statement shall be applied prospectively as of the beginning of the fiscal year in which the statement is initially adopted. We will adopt SFAS No. 160 for any acquisitions closing after March 31, 2009.

**SFAS No. 161** In March 2008, the FASB issued Statement No. 161, *Disclosures About Derivative Instruments and Hedging Activities*. This statement is intended to improve financial reporting about derivative instruments and hedging activities by enhanced disclosures to better understand their effects on a company's financial position, results of operation and cash flows. This standard is effective for interim and annual financial statements beginning after November 15, 2008. We adopted the disclosure requirements of this pronouncement in the quarter ending December 31, 2008.

**EITF 08-06** In November 2008, the Emerging Issues Task Force, or EITF, reached a final consensus on Issue No. 08-06 ( EITF No. 08-06 ), *Equity Method Investment Accounting Considerations*, effective on a prospective basis for fiscal years, beginning after December 15, 2008. We will adopt EITF 08-06 effective April 1, 2009, and do not expect it to have a material impact on our financial position or results of operations.

**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 (which includes revenues from products and funded research and development):

	Year Ended March 31,		
	2009	2008	2007
<b>Revenues:</b>			
Product	99.0%	98.9%	99.5%
Funded research and development	1.0	1.1	0.5
<b>Total revenues</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>
<b>Costs and expenses:</b>			
Cost of product revenue excluding amortization of intangibles	27.9	25.6	23.7
Research and development	34.6	42.3	44.0
Selling, general and administrative	75.6	89.3	83.8
Arbitration decision		2.0	
Expensed in-process research and development			1.6
Amortization of intangible assets	2.2	2.7	3.2
<b>Total costs and expenses</b>	<b>140.3</b>	<b>161.9</b>	<b>156.3</b>
<b>Loss from operations</b>	<b>(40.3)</b>	<b>(61.9)</b>	<b>(56.3)</b>
<b>Other income and expense:</b>			
Investment (expense) income, net	(1.9)	2.8	2.1
Gain on sale of WorldHeart stock	0.4		
Change in fair value of WorldHeart note receivable and warrant		(8.5)	
Other expense, net	(0.3)	(0.9)	0.1
	(1.8)	(6.6)	2.2
<b>Loss before provision for income taxes</b>	<b>(42.1)</b>	<b>(68.5)</b>	<b>(54.1)</b>
Provision for income taxes	1.0	0.9	0.9
<b>Net loss</b>	<b>(43.2)%</b>	<b>(69.4)%</b>	<b>(55.0)%</b>

*Fiscal Years Ended March 31, 2009 and March 31, 2008 ( fiscal 2009 and fiscal 2008 )*

**Revenue**

Our revenues are comprised of the following:

	Year Ended March 31, 2009      2008 (in \$000 s)	
Impella	\$ 36,364	\$ 12,311
Other	36,148	46,011
<b>Total product revenues</b>	<b>72,512</b>	<b>58,322</b>
Funded research and development	698	619

## Edgar Filing: ABIOMED INC - Form 10-K

Total revenues	\$ 73,210	\$ 58,941
----------------	-----------	-----------

Product revenues for fiscal 2009 increased by \$14.2 million, or 24%, to \$72.5 million from \$58.3 million for fiscal 2008. The increase in product revenue was primarily due to an increase in Impella revenue of 195% due to greater demand in the U.S. following 510(k) clearance of the Impella 2.5 in June 2008, offset by a decrease in our other non-Impella revenue.

## **Table of Contents**

Impella revenues for fiscal 2009 increased by \$24.1 million, or 195% to \$36.4 million from \$12.3 million for fiscal 2008. Most of our Impella revenue was from disposable product sales of Impella 2.5, primarily as a result of sales occurring after our 510(k) clearance in June 2008. Our launch strategy of Impella 2.5 has been focused on increasing demand for disposable products by providing consoles to initial sites at no cost. We expect these console promotions to decrease as the number of hospitals using our Impella 2.5 products increase. We have sold the Impella 2.5 to over 200 hospitals in the U.S. and our focus for fiscal 2010 will be concentrated on working with hospitals to assist them in adopting the Impella 2.5 on a regular basis, thus creating continued demand for the product.

Other revenues for fiscal 2009 decreased by \$9.9 million or 21%, to \$36.1 million from \$46.0 million for fiscal 2008. The decrease in other revenue was due to a decrease in BVS and AB disposable revenue as well as a decrease in console revenue supporting these product lines. We expect that BVS revenue will continue to decline as the product is 17 years old. We expect that our AB5000 revenue will be rejuvenated somewhat with the approval of the Portable Driver in the U.S. in March 2009. Also, our recent 510(k) clearance for the Impella 5.0 in April 2009 will allow us an opportunity to sell AB5000 as we refocus our efforts on the surgery market.

We expect that demand for our Impella products should increase in fiscal 2010 and will comprise a higher percentage of total sales in the future based on 510(k) clearances of our Impella 2.5, 5.0 and LD products in the U.S. and as we enroll more patients in our PCI and AMI pivotal studies for the Impella 2.5 clinical trial. As a result, we expect that most of our revenue growth in fiscal 2010 will come from our Impella product line, with limited or no growth for most of our other products.

### **Cost of Product Revenues**

Cost of product revenues for fiscal 2009 increased by \$5.3 million or 35%, to \$20.4 million from \$15.1 million for fiscal 2008. This was due to shipments of higher volumes of Impella 2.5 disposable products in fiscal 2009. This resulted in gross margin for fiscal 2009 of 72% compared to 74% for fiscal 2008. The decrease in gross margin was primarily due to the effect of certain Impella, AB 5000, iPulse, and Portable Driver console programs implemented to generate future disposable revenue. Cost of product revenues also was negatively impacted during fiscal 2009 from materials, training and other expenses related to our capacity ramp-up of Impella. During fiscal 2009, we also wrote off approximately \$1.4 million of inventory for slow moving or obsolete products.

### **Research and Development Expenses**

Research and development expenses for fiscal 2009 increased by \$0.4 million, or 2%, to \$25.3 million from \$24.9 million in fiscal 2008. The increase in research and development expenses was due to higher clinical trial activity for Impella, offset by lower program spending on Portable Driver and AbioCor. Research and development expenses for fiscal 2009 and 2008 included \$7.1 million and \$2.8 million, respectively, in clinical trial expenses primarily associated with our Impella 2.5 and 5.0 U.S. trials. The increase in product development costs reflects our efforts to expand and enhance our product lines across a clinical spectrum of circulatory care.

We expect research and development spending to increase slightly in fiscal 2010 in order to support our efforts in enrolling patients in our PCI and AMI pivotal studies for the Impella 2.5 clinical trial. We also will incur expenses to support improvement of our Impella product line and continue to invest in research on new products.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses for fiscal 2009 increased by \$2.7 million, or 5%, to \$55.4 million from \$52.7 million in fiscal 2008. The increase is due to an increase of \$2.9 million in stock based compensation primarily associated with grants of restricted stock made in May 2008 and August 2008. We have also made recent investments in marketing initiatives and in sales and clinical representatives with commercial headcount in the U.S. up from 75 at March 31, 2008 to 97 at March 31, 2009. We are investing in our commercial organization to support the launch of the Impella platform following 510(k) approval in the U.S.

We expect to continue to increase our expenditures on sales and marketing activities in fiscal 2010, with particular investments in clinical personnel with cath lab expertise and 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.

### **Amortization of Intangibles**

Amortization of intangible assets was \$1.6 million for each of fiscal 2009 and fiscal 2008, respectively. Amortization primarily relates to specifically identified assets from the Impella acquisition.

## **Table of Contents**

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

Investment expense, net, was \$1.4 million for fiscal 2009, representing a decrease of \$3.0 million from investment income of \$1.6 million for fiscal 2008. The decrease in investment income for the fiscal 2009 was due to realized and unrealized losses incurred on our investment in the Columbia Fund and a decrease in interest rates on short-term marketable securities. Investment income and expense, net, consists primarily of interest earned on our cash and investments and changes in the value of the Columbia Fund.

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

In December 2007, we entered into an agreement in which 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 December 2008, we sold 135,000 shares of WorldHeart common stock, which, as a result of our basis having been reduced to zero, resulted in a gain of \$0.3 million that was recorded during fiscal 2009. The changes in other expense are mainly due to foreign exchange effects.

### **Provision for Income Taxes**

During fiscal 2009 and 2008, we recorded a provision for income taxes of \$0.8 million and \$0.5 million, respectively. The income tax provision is primarily due to a deferred tax liability related to a difference in accounting for our goodwill, which is amortizable over 15 years for tax purposes but not amortized for book purposes. Differences between amounts recorded as a deferred tax liability on the balance sheet versus amounts recorded in the statements of operations are due to an unrealized gain from fluctuations in foreign currency with respect to our European operations. The net deferred tax liability cannot be offset against our deferred tax assets since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period.

### **Net Loss**

During fiscal 2009, we incurred a net loss of \$31.6 million, or \$0.91 per share compared to a net loss of \$40.9 million, or \$1.26 per share, for the prior fiscal year. The decrease in the net loss in fiscal 2009 compared to fiscal 2008 is due primarily to increased Impella sales as a result of 501(k) clearance of the Impella 2.5 in the U.S. in June 2008. We also incurred in fiscal 2008 a \$5.0 million charge relating to the change in value of the WorldHeart note receivable and warrant and a \$1.2 million charge relating to the arbitration award and warrant repurchase. We expect to continue to incur net losses for the foreseeable future as we plan to invest in expanding our global distribution to support revenue growth and as we invest in research and development and our Impella pivotal studies to bring Impella and other new products to market.

### ***Fiscal Years Ended March 31, 2008 and March 31, 2007 ( fiscal 2008 and fiscal 2007 )***

### **Revenues**

Total revenue for fiscal 2008 increased by \$8.3 million, or 16%, to \$58.9 million from \$50.6 million for fiscal 2007. Our revenues are primarily from sales of medical products for heart recovery.

Product revenues for fiscal 2008 increased by \$7.9 million, or 16%, to \$58.3 million from \$50.4 million for fiscal 2007. Revenues from disposables, service and other products (non-console revenues) comprised approximately 88% and 84% of total revenues for fiscal 2008 and fiscal 2007, respectively. For fiscal 2008 compared to fiscal 2007, revenues from Impella disposables increased 211%, AB5000 disposables revenue increased 10% and revenues from BVS declined approximately 16%. The Impella disposables revenue increase was due to revenue recognized during our fiscal year 2008 from products used for the U.S. pivotal studies for the Impella 2.5 device, as well as higher sales of the Impella 2.5 in Europe. We also recorded \$1.3 million in revenue during our fourth quarter of fiscal 2008 from sales of the AbioCor Total Replacement Heart. Comparing total revenues for fiscal 2008 to fiscal 2007, total sales of our Impella products (consoles and disposables) increased approximately 186%, total sales of our AB 5000 products (consoles and disposables) decreased approximately 1%, and total sales of our BVS 5000 products declined by approximately 16%.

### **Cost of Product Revenues**

Cost of product revenues for fiscal 2008 increased by \$3.1 million or 26%, to \$15.1 million from \$12.0 million for fiscal 2007. This was due to an increase in cost of sales of disposable products as more of these products were sold in fiscal 2008 compared fiscal 2007 partially offset by lower cost of sales for consoles as console revenue declined in fiscal 2008 compared to fiscal 2007. In addition, we recorded cost of product revenues for product shipped during fiscal 2008 in connection with the Impella 2.5 U.S. pivotal studies and recently approved AbioCor product. There were no AbioCor product sales in fiscal 2007. Cost of product revenues also was unfavorably impacted during fiscal 2008 from materials, training and other expenses related to our strategic capacity ramp-up of Impella and AB5000 console deployment programs. During fiscal 2008, we recorded an impairment charge of \$1.0 million for a write-off of inventory.

---

## **Table of Contents**

### **Research and Development Expenses**

Research and development expenses for fiscal 2008 increased by \$2.6 million, or 12%, to \$24.9 million from \$22.3 million in fiscal 2007. Research and development expenses for fiscal 2008 and 2007 included \$2.8 and \$1.2 million, respectively, in clinical trial expenses primarily associated with our Impella 2.5 and 5.0 U.S. trials. The increase in product development costs reflected our efforts to expand and enhance our product lines across a clinical spectrum of circulatory care, particularly related to increased clinical trial activity on Impella 2.5.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses for fiscal 2008 increased by \$10.3 million, or 24%, to \$52.7 million from \$42.4 million in fiscal 2007. The increase was due to increased investments in our global distribution of sales and clinical representatives with headcount up approximately 17% as compared to fiscal 2007, and is also due to our increased investments in our marketing initiatives.

### **Arbitration Decision**

In May 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a demand for arbitration (subsequently amended) with the American Arbitration Association. The claims arose out of our purchase of intellectual property rights relating to the Penn State Heart program and the related warrant agreements. In November 2007, we paid the warrant holders \$2.2 million of cash consideration to repurchase the warrants and in final settlement to release us of all potential claims by the warrant holders. The excess of the \$2.2 million of cash consideration over the \$1.9 million estimated fair value of the warrants at October 3, 2007 was recorded as selling, general and administrative expense in the statements of operations during fiscal 2008. We expect that there will be no other future payments to warrant holders relating to this arbitration decision.

### **Amortization of Intangibles**

Amortization of intangible assets was \$1.6 million for both fiscal 2008 and 2007. Amortization primarily relates to specifically identified assets from the Impella acquisition.

### **Change in Fair Value of WorldHeart Note Receivable and Warrant**

We marked to market the fair value of the conversion feature on the note receivable and warrant associated with the WorldHeart transaction through March 31, 2008. In May 2008, WorldHeart filed a Form 8-K disclosing that it had limited cash available to continue operations and that if it was unable to secure additional funding, it would be forced to take extraordinary business measures which could include filing for bankruptcy, ceasing operations and liquidating assets. Due to these events, we recorded an impairment charge of \$5.0 million during fiscal 2008 related to our note receivable from WorldHeart and its associated derivative instruments.

### **Investment Income, net**

Investment income, net, was \$1.6 million for fiscal 2008, representing an increase of \$0.5 million from \$1.1 million for fiscal 2007 due primarily to a higher cash and investments balance during fiscal 2008 compared to fiscal 2007. Investment income, net, consists primarily of interest earned on our cash and investments less \$0.3 million in realized losses associated with our Columbia Fund for fiscal 2008. Also included in investment income, net, is an unrealized loss on short-term marketable securities of \$0.9 million incurred during fiscal 2008 due to a write down to fair value of securities we held in the Columbia Fund. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 97% of its carrying value.

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

The decrease in other income for fiscal 2008 was due to foreign exchange effects of \$0.6 million and miscellaneous income.

### **Provision for Income Taxes**

During fiscal 2008 and 2007, we recorded a provision for income taxes of \$0.5 million in each year. The income tax provision is primarily due to a deferred tax related to a difference in accounting for our goodwill, which is amortizable over 15 years for tax purposes but not amortized for book purposes. Differences between amounts recorded as a deferred tax liability on the balance sheet versus amounts recorded in the statements of operations are due to an unrealized gain from fluctuations in foreign currency with respect to our European operations. The net deferred tax liability cannot be offset against our deferred tax assets since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period.

## **Table of Contents**

### **Net Loss**

During fiscal 2008, we incurred a net loss of \$40.9 million, or \$1.26 per share compared to a net loss of \$27.9 million, or \$1.03 per share, for the prior fiscal year. The increase in the net loss in fiscal 2008 compared to fiscal 2007 was due primarily to increased selling, general and administrative expenses of \$10.2 million related to the expansion of our global distribution and an increase of \$2.6 million in research and development expenses for costs of our Impella U.S. pivotal studies. Included in the net loss for fiscal 2008 is a \$5.0 million charge relating to the change in value of the WorldHeart note receivable and warrant, \$1.2 million charge relating to the arbitration award and warrant repurchase and \$0.9 million for the unrealized loss on marketable securities.

### ***Liquidity and Capital Resources***

At March 31, 2009, our cash, cash equivalents, short-term marketable securities and long-term marketable securities totaled \$60.9 million, an increase of \$22.6 million compared to \$38.3 million in cash, cash equivalents and short-term marketable securities at March 31, 2008. In August 2008, we completed a public offering in which we received net proceeds of \$42.0 million. We believe that our revenue from product sales together with existing resources, including the cash received from our public offering, will be sufficient to fund our operations for at least the next twelve months.

Marketable securities at March 31, 2009 include \$7.0 million of marketable securities held in the Columbia Fund. At March 31, 2009, other short-term marketable securities consist of \$52.1 million held in funds that invest solely in U.S. Treasury securities. In December 2007, the Columbia Fund ceased accepting redemption requests from new or current investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. As a result, we reclassified the securities in the Columbia Fund from cash equivalents to short-term marketable securities as the Columbia Fund was no longer expected to have a maturity of less than 90 days. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 83% of its carrying value at March 31, 2009. The Columbia Fund is being liquidated with distributions to us occurring from December 2007 through May 2009. Since December 6, 2007 and through May 27, 2009, we have received disbursements of approximately \$40.0 million from the Columbia Fund with the most recent disbursement occurring on May 27, 2009 at approximately 86% of its original value. We have recorded \$3.7 million of the Columbia Fund as long-term marketable securities at March 31, 2009 because Bank of America, the sponsor of the Columbia Fund, has indicated that it cannot predict with certainty whether or not the Columbia Fund will redeem this amount within the next year.

The recent and unprecedented disruption in the credit markets has had a significant adverse impact on a number of financial and other institutions. Our investments in the Columbia Fund have been frozen since December 2007 and we are subject to redemptions of these investments based on the discretion of the Fund. When redemptions have occurred, we have realized losses on our original investment and we expect to incur losses on future redemptions. Since December 2007, we have incurred \$1.8 million in realized losses and \$1.4 million in unrealized losses on the Columbia Fund through March 31, 2009. 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. We continue to monitor our cash position closely with recent economic events and currently only invest excess cash in short term U.S. Treasury securities.

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

We will continue to closely monitor our liquidity and the overall health of the credit markets. However, we cannot predict with any certainty the impact on us of any further disruption in the credit environment. Our primary liquidity needs are to fund the expansion of our Impella manufacturing capacity in Germany and Ireland, to fund new product development, and general working capital needs. Through March 31, 2009, we have funded our operations principally from product revenue and through the sale of equity securities, including our August 2008 stock offering in which we received proceeds of \$42.0 million. We also generate funds from product and funded research and development revenue.

Our operating activities during the year ended March 31, 2009 used cash of \$18.3 million as compared to \$28.9 million during the same period in the prior year. Our net loss for the year ended March 31, 2009 of \$31.6 million was the primary cause of our cash use from operations. Increases in accounts receivable used cash of \$2.5 million during fiscal 2009 due to increased sales activity, primarily related to Impella. In addition, the increases in inventories used cash of \$1.6 million during the year ended March 31, 2009, reflecting our inventory build-up to support anticipated increases in global demand for our products, particularly Impella 2.5. Additionally, we recorded \$1.4 million in write downs of inventory for excess and obsolescence during fiscal 2009. These decreases in cash were partially offset by non-cash adjustments of \$8.8 million related to stock-based compensation expense and \$5.0 million of depreciation and amortization.

Our investing activities during the year ended March 31, 2009 used cash of \$26.8 million as compared to \$40.9 million during the same period in the prior year. Cash used by investment activities for the year ended March 31, 2009 consisted primarily of \$23.4 million of

**Table of Contents**

purchases of short-term marketable securities, net of sales of short-term marketable securities during the quarter. Additionally, we incurred \$3.8 million related to cash expenditures for property and equipment primarily on computer software projects and manufacturing equipment related to our expansion in Ireland.

Our financing activities during the year ended March 31, 2009 provided cash of \$46.2 million as compared to \$2.1 million during the same period in the prior year. Cash provided by financing activities for the year ended March 31, 2009 was primarily comprised of \$42.0 million in net proceeds related to our August 2008 public offering and \$5.0 million attributable to the exercise of stock options and proceeds from our employee stock purchase plan.

Capital expenditures for fiscal 2010 are estimated to be \$2.5 to \$3.0 million, which relate primarily to our planned manufacturing capacity increases for Impella in Germany, our expansion in Ireland, and software development projects.

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. Exclusive of activities involving any future acquisitions of products or companies that complement or augment our existing line of products, we believe that current available funds and cash generated from operations will provide sufficient liquidity to meet operating requirements for the foreseeable future. We believe that our existing cash balances and cash flow from operations will be sufficient to meet our projected capital expenditures, working capital, and other cash requirements at least through the next 12 months. We continue to review our long-term cash needs on a regular basis. Currently, we have no debt outstanding.

**Contractual Obligations and Commercial Commitments**

The following table summarizes our contractual obligations at March 31, 2009 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
<b>Contractual Obligations</b>					
Operating Lease Commitments	\$ 10,690	\$ 2,313	\$ 4,267	\$ 2,592	\$ 1,518
Contractual Obligations (1)	9,457	4,619	4,838		
<b>Total Obligations</b>	<b>\$ 20,147</b>	<b>\$ 6,932</b>	<b>\$ 9,105</b>	<b>\$ 2,592</b>	<b>\$ 1,518</b>

(1) Contractual obligations represent future cash commitments and expected liabilities under agreements with third parties for clinical trials. We have no long-term debt, capital leases or other material commitments for open purchase orders and clinical trial agreements at March 31, 2009 other than those shown in the table above.

In May 2005, we acquired all the shares of outstanding capital stock of Impella CardioSystems AG, a company headquartered in Aachen, Germany. The aggregate purchase price excluding contingent payments, was approximately \$45.1 million, which consisted of \$42.2 million of our common stock, \$1.6 million of cash paid to certain former shareholders of Impella and \$1.3 million of transaction costs, consisting primarily of fees paid for financial advisory and legal services. At the time of the transaction, we agreed to make additional contingent payments to Impella's former shareholders based on additional milestone payments related to product sales and FDA approvals in the amount of up to \$16.8 million. In January 2007 upon the sale of 1,000 Impella units, we paid \$5.6 million in the form of common stock. In June 2008 we received 510(k) clearance of our Impella 2.5, and we paid \$5.6 million in the form of common stock. In April 2009, we received 501(k) clearance of our Impella 5.0, triggering an obligation to make the final \$5.6 million milestone payment. On May 15, 2009, we paid \$1.75 million of this final milestone in cash and elected to pay the remaining amount through the issuance of approximately 664,612 shares of our common stock. This contingent payment will result in an increase to the carrying value of goodwill.

In June 2008, we amended the lease for our facility in Danvers, Massachusetts. The amendment extended the lease from February 28, 2010 to February 28, 2016. The lease continues to be accounted for as an operating lease. The amendment changed the rent payments under the lease from \$64,350 per month to the following schedule:

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

## Edgar Filing: ABIOMED INC - Form 10-K

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

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

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

**Table of Contents**

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

In July 2008, we entered into a lease agreement providing for the lease of a 33,000 square foot manufacturing facility in Athlone, Ireland. The lease agreement is for a term of 25 years and one week, commencing on April 18, 2008. The monthly rent due under the lease agreement and payable monthly is 22,455.33 (Euro) (approximately U.S. \$30,000) per month or 269,464 (Euro) (approximately U.S. \$360,000) per year for the first five years of the lease, through April 17, 2013. On April 18, 2013 and each fifth anniversary thereafter, the rental rate will be set to a current market rate, as determined by the procedures set forth in the lease agreement. We have the right to terminate the lease after five years, subject to the payment of a termination fee equal to 18 months rent, and the right to terminate the lease after 10 years, subject to the payment of a termination fee equal to six months of the then current rent.

We also lease approximately 33,000 square feet in Aachen, Germany for our European headquarters. This lease expires in December 2012. Monthly rent due under the lease agreement is 51,646 (Euro) (approximately U.S. \$69,000) per month or 619,752 (Euro) (approximately U.S. \$828,000) per year.

We apply the disclosure provisions of FIN No. 45, *Guarantors Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others, and Interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34*, or FIN No. 45 to our agreements that contain guarantee or indemnification clauses. These disclosure provisions expand those required by SFAS No. 5 by requiring that guarantors disclose certain types of guarantees, even if the likelihood of requiring the guarantors 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, 2009.

**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. Under the provisions of FIN No. 45, intellectual property indemnifications require disclosure only.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**  
**Primary Market Risk Exposures**

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at March 31, 2009, we believe the decline in fair market value of our investment portfolio would be immaterial. Short term and long term marketable securities at March 31, 2009 consist of \$7.0 million in the Columbia Fund and \$52.1 million in five funds that invest in U.S. Treasury securities and related interest. In December 2007, the Columbia Fund ceased accepting redemption requests from new or current investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. As a result, we reclassified the securities in the Columbia Fund from cash equivalents to short-term marketable securities as the Columbia Fund was no longer expected to have a maturity of less than 90 days. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 83% of its carrying value at December 31, 2007 and the Company did not expect to recover the value in liquidation. The Columbia Fund is being liquidated with distributions to us occurring during fiscal 2008 and 2009. Since December 6, 2007 and through May 27, 2009, we have received disbursements of approximately \$40.0 million

## **Table of Contents**

from the Columbia Fund with the most recent disbursement occurring on May 27, 2009 at approximately 86% of its original value. We have recorded \$3.7 million of the Columbia Fund as long-term marketable securities at March 31, 2009 because Bank of America, the sponsor of the Columbia Fund, has indicated that it cannot predict with certainty whether or not the Columbia Fund will redeem this amount within the next year. While it is our intent to liquidate securities in the Columbia Fund in future periods to reduce our exposure to future deterioration of these securities, we believe that our operating results and cash flows could be affected significantly by market value adjustments to the Columbia Fund. There can be no assurance that we will not have to take additional losses on the Columbia Fund.

In July 2008, WorldHeart completed the transactions contemplated by the recapitalization agreement dated June 20, 2008, as amended on July 31, 2008, among us, WorldHeart, World Heart, Inc., Venrock Partners V, L.P., Venrock Associates V, L.P., Venrock Entrepreneurs Fund V, L.P., Special Situations Fund III QP LP, Special Situations Cayman Fund, L.P., Special Situations Private Equity Fund, L.P., Special Situations Life Sciences Fund, L.P., Austin Marx and New Leaf Ventures II, L.P. As a result of the transaction, we received 86 million common shares of WorldHeart, which represented approximately 21.6% of WorldHeart's issued and outstanding common shares following the transaction. The shares were received as a result of our conversion of the full amount of principal and interest owed on the \$5.0 million convertible secured note issued in December 2007, our release of the security interest in all of the assets of WorldHeart that secured the note, termination of the warrant we held to purchase 3.4 million common shares of WorldHeart issued in December 2007, and forgiveness of other amounts owed to us by WorldHeart. In October 2008, WorldHeart completed a 30-to-1 reverse stock split, as a result of which we held 2,866,666 common shares of WorldHeart. In December 2008, we sold 135,000 shares of WorldHeart for net proceeds of \$0.3 million. As a result, as of March 31, 2009, we now hold 2,731,666 common shares of WorldHeart, or approximately 20.6% of WorldHeart's issued and outstanding shares. We are accounting for this investment using the equity method of accounting. The carrying value of this investment was zero at March 31, 2009.

### ***Currency Exchange Rates***

Our foreign subsidiaries' functional currency is the Euro. 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 income (loss) component of stockholders' equity. Had a 10% depreciation in the Euro occurred relative to the U.S. dollar as of March 31, 2009, the result would have been a reduction of stockholders' equity of approximately \$4.5 million.

### ***Fair Value of Financial Instruments***

Our financial instruments consist primarily of cash and cash equivalents, short-term and long-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, 2009. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2009, 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.



## **Table of Contents**

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

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

### ***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, 2009.

### ***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 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, 2009, 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, 2009, 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, 2009, 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, 2009 of the Company and our report dated June 8, 2009 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

June 8, 2009

**ITEM 9B. OTHER INFORMATION**

Not applicable.

**Table of Contents**

**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 SCHEDULE**

(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, 2009 are attached hereto.

Report of Independent Registered Public Accounting Firm**Page**

F-1

Consolidated Balance Sheets at March 31, 2009 and 2008

F-2

Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2009, 2008, and 2007

F-3

Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended March 31, 2009, 2008, and 2007

F-4

Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2009, 2008, and 2007

F-5

Notes to Consolidated Financial Statements

F-6 to F-26

(2) Consolidated financial statement schedule  
Schedule II: Valuation and qualifying accounts

(3) Exhibits

**EXHIBIT INDEX**

Exhibit No.	Description	Filed with this Form		Incorporated by Reference	
		Form 10-K	Form	Filing Date	Exhibit No.
2.1	Share Purchase Agreement for the acquisition of Impella Cardio Systems AG, dated April 26, 2005.		8-K	May 16, 2005	2.1
3.1	Restated Certificate of Incorporation.		S-3	September 29, 1997	3.1
3.2	Restated By-Laws, as amended.		10-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

## Edgar Filing: ABIOMED INC - Form 10-K

10.5*	1989 Non-Qualified Stock Option Plan for Non-Employee Directors.	10-Q	October 27, 1995	10.1
10.7*	1998 Equity Incentive Plan.	10-Q/A	January 8, 1999	10
10.8*	2000 Stock Incentive Plan Agreement, as amended.	Schedule 14A	July 15, 2005	Appendix A
10.9*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Directors.	10-Q	February 9, 2006	10.16

**Table of Contents**

Exhibit No.	Description	Filed with	Incorporated by Reference		Exhibit No.
		this Form 10-K	Form	Filing Date	
10.10*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Employees or Consultants.		10-Q	February 9, 2006	10.17
10.11*	2008 Stock Incentive Plan.		Schedule 14A	July 9, 2008	Appendix A
10.12*	Form of Non-Statutory Stock Option Agreement for Employees and Consultants under 2008 Stock Incentive Plan.		8-K	August 18, 2008	10.1
10.13*	Form of Non-Statutory Stock Option Agreement for Non-Employee Directors under 2008 Stock Incentive Plan.		8-K	August 18, 2008	10.2
10.14*	Form of Restricted Stock Agreement under 2008 Stock Incentive Plan.		8-K	August 18, 2008	10.3
10.15*	Form of Change of Control Agreement.		8-K	August 18, 2008	10.4
10.16*	Employment Agreement of Michael R. Minogue dated April 5, 2004 (including Change in Control Agreement).		10-Q	August 9, 2004	10.10
10.17*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008.		10-Q	February 9, 2009	10.1
10.18*	Amendment to Change in Control Agreement with Michael R. Minogue dated December 31, 2008.		10-Q	February 9, 2009	10.1
10.19*	Inducement stock option granted to Michael R. Minogue dated April 5, 2004.		10-Q	August 9, 2004	10.11
10.20*	Restricted Stock Agreement between Abiomed, Inc. and Michael R. Minogue.		10-Q	October 9, 2005	10.15
10.21*	Offer Letter with Robert L. Bowen dated December 15, 2008.		8-K	December 22, 2008	99.2
10.22*	Offer letter with David Webber dated April 23, 2007		10-Q	August 9, 2007	10.1
10.23*	Separation agreement and release with Daniel J. Sutherby dated October 10, 2008.		10-Q	February 9, 2009	10.1
10.24*	Summary of Executive Compensation.	X			
10.25*	Summary of Director Compensation.		10-K	June 16, 2008	10.21
10.26*	Form of Employment, Nondisclosure and Non Competition Agreement.		10-K	June 14, 2006	10.20
10.27	Registration Rights and Stock Restriction Agreement between Abiomed, Inc. and Stockholders of Impella CardioSystems AG.		8-K	May 16, 2005	10.1
10.28	Facility Lease dated January 8, 1999 for the premises at 22 Cherry Hill Drive.		10-Q	February 12, 1999	10
10.29	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

**Table of Contents**

<b>Exhibit No.</b>	<b>Description</b>	<b>Filed with</b>		<b>Incorporated by Reference</b>	
		<b>this Form 10-K</b>	<b>Form</b>	<b>Filing Date</b>	<b>Exhibit No.</b>
10.30	Lease Agreement dated as of July 18, 2008 by and among Abiomed, Inc., Abiomed Athlone Limited, and J.J. Rhatigan and Co.		8-K	July 30, 2008	10.1
10.31	Recapitalization Agreement dated June 20, 2008 by and among World Heart Corporation, World Heart Inc., ABIOMED, Inc., Venrock Partners V, L.P., Venrock Associates V, L.P. and Venrock Entrepreneurs Fund V, L.P., Special Situations Fund III QP LP, Special Situations Cayman Fund, L.P., Special Situations Private Equity Fund, L.P., Special Situations Life Sciences Fund, L.P. and Austin Marx.		8-K	June 26, 2008	99.1
10.32	Amendment No. 1 to Recapitalization Agreement dated June 31, 2008 by and among World Heart Corporation, World Heart Inc., ABIOMED, Inc., Venrock Partners V, L.P., Venrock Associates V, L.P. and Venrock Entrepreneurs Fund V, L.P., Special Situations Fund III QP LP, Special Situations Cayman Fund, L.P., Special Situations Private Equity Fund, L.P., Special Situations Life Sciences Fund, L.P., Austin Marx and New Leaf Ventures II, L.P.		8-K	August 6, 2008	99.1
10.33	Software License Agreement between Abiomed, Inc. and AnswerThink, Inc. dated November 30, 2005.		10-Q	February 9, 2006	10.20
10.34	Consulting Agreement between Abiomed, Inc. and AnswerThink, Inc. dated September 15, 2006.		10-Q	February 8, 2007	10.23
10.35	Distribution Agreement between Abiomed, Inc. and MEDIX Japan, Inc. dated November 4, 2006.		10-Q	February 8, 2007	10.24
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			

\* Management contract or compensatory plan.

**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: June 8, 2009

By: */s/* ROBERT L. BOWEN  
**Robert L. Bowen**  
**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.

<b>SIGNATURE</b>	<b>TITLE</b>	<b>DATE</b>
<i>/s/</i> MICHAEL R. MINOGUE  <b>Michael R. Minogue</b>	Chief Executive Officer, President and Chairman (Principal Executive Officer)	June 8, 2009
<i>/s/</i> ROBERT L. BOWEN  <b>Robert L. Bowen</b>	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	June 8, 2009
<i>/s/</i> W. GERALD AUSTEN  <b>W. Gerald Austen</b>	Director	June 8, 2009
<i>/s/</i> RONALD W. DOLLENS  <b>Ronald W. Dollens</b>	Director	June 8, 2009
<i>/s/</i> LOUIS E. LATAIF  <b>Louis E. Lataif</b>	Director	June 8, 2009
<i>/s/</i> DESMOND H. O. CONNELL, JR.  <b>Desmond H. O. Connell, Jr.</b>	Director	June 8, 2009
<i>/s/</i> DOROTHY E. PUHY  <b>Dorothy E. Puhly</b>	Director	June 8, 2009
<i>/s/</i> ERIC A. ROSE  <b>Eric A. Rose</b>	Director	June 8, 2009
<i>/s/</i> HENRI A. TERMEER  <b>Henri A. Termeer</b>	Director	June 8, 2009

Edgar Filing: ABIOMED INC - Form 10-K

/s/ MARTIN P. SUTTER

Director

June 8, 2009

**Martin P. Sutter**

51

**Table of Contents**

**ABIOMED, INC.**

**Consolidated Financial Statements**

**Index**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets at March 31, 2009 and 2008</u>	F-2
<u>Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2009, 2008, and 2007</u>	F-3
<u>Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended March 31, 2009, 2008, and 2007</u>	F-4
<u>Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2009, 2008, and 2007</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6 to F-26

**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, 2009, and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended March 31, 2009. 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, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2009 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.

As discussed in Note 14 to the consolidated financial statements, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of Financial Accounting Standards Board Statement No. 109*, effective April 1, 2007.

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, 2009, 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 June 8, 2009 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

June 8, 2009

F-1

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Consolidated Balance Sheets****(in thousands, except share data)**

	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,785	\$ 2,042
Short-term marketable securities	55,394	36,257
Accounts receivable, net	15,724	14,071
Inventories	14,777	17,428
Prepaid expenses and other current assets	809	1,705
<b>Total current assets</b>	<b>88,489</b>	<b>71,503</b>
Property and equipment, net	7,792	7,551
Intangible assets, net	4,359	6,921
Goodwill	31,295	31,563
Long-term marketable securities	3,721	
Other assets	302	493
<b>Total assets</b>	<b>\$ 135,958</b>	<b>\$ 118,031</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,550	\$ 9,024
Accrued expenses	10,818	9,290
Deferred revenue	1,211	1,162
<b>Total current liabilities</b>	<b>17,579</b>	<b>19,476</b>
Long-term deferred tax liability	2,086	4,740
Other long-term liabilities	310	221
<b>Total liabilities</b>	<b>19,975</b>	<b>24,437</b>
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value		
Authorized 1,000,000 shares; Issued and outstanding none		
Common stock, \$.01 par value	367	328
Authorized 100,000,000 shares; Issued 36,736,843 shares at March 31, 2009 and 32,779,404 shares at March 31, 2008;		
Outstanding 36,685,889 shares at March 31, 2009 and 32,768,385 shares at March 31, 2008		
Additional paid-in-capital	362,097	300,787
Accumulated deficit	(243,991)	(212,394)
Treasury stock at cost 50,954 at March 31, 2009 and 11,019 shares at March 31, 2008	(827)	(116)
Accumulated other comprehensive (loss) income	(1,663)	4,989
<b>Total stockholders' equity</b>	<b>115,983</b>	<b>93,594</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 135,958</b>	<b>\$ 118,031</b>

*See notes to consolidated financial statements*



**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Consolidated Statements of Operations**

(in thousands, except per share data)

	<b>Fiscal Years Ended March 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Revenue:</b>			
Products	\$ 72,512	\$ 58,322	\$ 50,408
Funded research and development	698	619	241
	73,210	58,941	50,649
<b>Costs and expenses:</b>			
Cost of product revenue excluding amortization of intangibles	20,437	15,065	12,012
Research and development	25,328	24,917	22,292
Selling, general and administrative	55,357	52,658	42,448
Arbitration decision		1,206	
Expensed in-process research and development			800
Amortization of intangible assets	1,606	1,582	1,608
	102,728	95,428	79,160
Loss from operations	(29,518)	(36,487)	(28,511)
<b>Other (expense) income:</b>			
Investment (expense) income, net	(1,404)	1,625	1,045
Gain on sale of WorldHeart stock	313		
Change in fair value of WorldHeart note receivable and warrant		(5,000)	
Other (expense) income, net	(236)	(541)	60
	(1,327)	(3,916)	1,105
Loss before provision for income taxes	(30,845)	(40,403)	(27,406)
Provision for income taxes	752	527	475
Net loss	\$ (31,597)	\$ (40,930)	\$ (27,881)
Basic and diluted net loss per share	\$ (0.91)	\$ (1.26)	\$ (1.03)
Weighted average shares outstanding	34,882	32,465	27,124

*See notes to consolidated financial statements*

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

(in thousands, except share data)

	Common Stock				Accumulated Other Comprehensive Total			Stockholder Equity	Comprehensive Loss
	Number of shares	Par value	Additional Paid in Capital	Deferred Stock-based Compensation	Accumulated Deficit	Treasury Stock	Income		
Balance, April 1, 2006	26,468,091	\$ 265	\$ 214,666	\$ (171)	\$ (143,308)	\$ (66)	\$ (1,898)	\$ 69,488	
Common stock issued for milestone payment to Impella CardioSystems AG	402,279	4	5,570					5,574	
Common stock issued, net of issuance costs	5,000,000	50	63,501					63,551	
Restricted stock issued			(80)	171				91	
Stock options exercised	350,933	4	2,747					2,751	
Stock issued under employee stock purchase plan	27,095		305					305	
Stock compensation expense			5,758					5,758	
Return of common stock from escrow	(4,840)					(50)		(50)	
Net loss					(27,881)			(27,881)	\$ (27,881)
Foreign currency translation							2,508	2,508	2,508
Comprehensive loss									\$ (25,373)
Balance, March 31, 2007	32,243,558	323	292,467		(171,189)	(116)	610	122,095	
Common stock issued, net of issuance costs	80,068	1	873					874	
Restricted stock issued	54,000	1	(1)						
Stock options exercised	354,854	3	2,808					2,811	
Stock issued under employee stock purchase plan	23,930		253					253	
Stock issued to directors	11,975		150					150	
Stock compensation expense			5,376					5,376	
Repurchase of warrants associated with arbitration decision			(1,868)					(1,868)	
Issuance of warrants associated with arbitration decision			729					729	
Cumulative effect of adjustment upon FIN 48 adoption					(275)			(275)	
Net loss					(40,930)			(40,930)	\$ (40,930)
Foreign currency translation							4,379	4,379	4,379
Comprehensive loss									\$ (36,551)
Balance, March 31, 2008	32,768,385	328	300,787		(212,394)	(116)	4,989	93,594	
Common stock issued, net of issuance costs	2,419,932	24	41,946					41,970	
Common stock issued for milestone payment to Impella CardioSystems AG	343,075	3	5,571					5,574	
Restricted stock issued	666,251	7	(7)						
Stock options exercised	555,483	6	4,702					4,708	
Stock issued under employee stock purchase plan	45,823		264					264	
Return of common stock to pay withholding taxes on restricted stock	(39,935)					(711)		(711)	
Cancellation of restricted stock	(73,125)	(1)						(1)	
Stock compensation expense			8,834					8,834	
Net loss					(31,597)			(31,597)	\$ (31,597)
Foreign currency translation							(6,652)	(6,652)	(6,652)

Edgar Filing: ABIOMED INC - Form 10-K

Comprehensive loss

\$ (38,249)

Balance, March 31, 2009	36,685,889	\$ 367	\$ 362,097	\$	\$ (243,991)	\$ (827)	\$ (1,663)	\$ 115,983
-------------------------	------------	--------	------------	----	--------------	----------	------------	------------

*See notes to consolidated financial statements*

F-4

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows**

(in thousands)

	<b>Fiscal Years Ended March 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Operating activities:</b>			
Net loss	\$ (31,597)	\$ (40,930)	\$ (27,881)
<b>Adjustments required to reconcile net loss to net cash used for operating activities:</b>			
Depreciation and amortization	5,016	6,124	3,915
Bad debt expense (recoveries)	438	(50)	7
Stock-based compensation	8,834	5,376	5,848
Write-down of inventory	1,444	963	207
Loss on disposal of fixed assets	165	255	75
Deferred tax provision	721	527	475
Arbitration decision		729	
Change in unrealized loss on short-term marketable securities	510	1,157	
Write-down of WorldHeart note receivable and warrant		5,000	
Gain on sale of WorldHeart common stock	(313)		
<b>Changes in assets and liabilities:</b>			
Accounts receivable	(2,539)	(2,797)	(1,920)
Inventories	(1,598)	(11,078)	(4,095)
Prepaid expenses and other current assets	992	(177)	159
Accounts payable	(2,402)	3,237	1,572
Accrued expenses and other long-term liabilities	1,948	2,331	1,618
Deferred revenue	76	459	200
<b>Net cash used for operating activities</b>	<b>(18,305)</b>	<b>(28,874)</b>	<b>(19,820)</b>
<b>Investing activities:</b>			
Reclassification of cash equivalents to short-term marketable securities		(49,259)	
Purchases of short-term marketable securities	(60,180)	(17,131)	(17,663)
Proceeds from the sale and maturity of short-term securities	36,813	34,454	35,187
Proceeds from the sale of WorldHeart common stock	313		
Cost of acquisition, net of cash acquired			(9)
Loan to WorldHeart		(5,000)	
Increase in restricted cash		(140)	
Additions to intangible assets		(69)	(47)
Expenditures for property and equipment	(3,751)	(3,760)	(2,373)
<b>Net cash (used for) provided by investing activities</b>	<b>(26,805)</b>	<b>(40,905)</b>	<b>15,095</b>
<b>Financing activities:</b>			
Issuance of common stock	41,970	874	63,551
Return of common stock from escrow			(50)
Proceeds from the exercise of stock options	4,708	2,811	2,751
Payments in lieu of issuance of common stock for payroll taxes	(711)		
Proceeds from employee stock purchase plan	263	253	305
Repurchase of warrants		(1,868)	
<b>Net cash provided by financing activities</b>	<b>46,230</b>	<b>2,070</b>	<b>66,557</b>
Effect of exchange rate changes on cash	(1,377)	105	(18)
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(257)</b>	<b>(67,604)</b>	<b>61,814</b>
Cash and cash equivalents at beginning of year	2,042	69,646	7,832
<b>Cash and cash equivalents at end of year</b>	<b>\$ 1,785</b>	<b>\$ 2,042</b>	<b>\$ 69,646</b>

Supplemental disclosures:

## Edgar Filing: ABIOMED INC - Form 10-K

Taxes paid, net of refunds	\$ 242	\$ 32	\$ 18
Value of common shares issued for business acquisition	\$ 5,574	\$	\$ 5,574
Fixed assets in accounts payable	\$ 44	\$ 530	\$ 424

*See note to consolidated financial statements*

F-5

---

**Table of Contents**

**ABIOMED, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements**

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

**Note 1. Nature of Operations**

Abiomed, Inc. (the Company or Abiomed) is a leading provider of medical devices in circulatory support that offers a continuum of care in heart recovery to acute heart failure patients. The Company's strategy is focused on establishing heart recovery as the goal for all acute cardiac attacks. The Company's products are designed to enable the heart to rest, heal and recover by improving blood flow and/or performing the pumping function of the heart. The products can be used in a broad range of clinical settings, including by cardiologists for patients who are in pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab, and by heart surgeons for patients in profound shock. Abiomed is focused on increasing awareness of heart recovery and establishing it as the goal for all acute patients experiencing cardiac attacks, or heart attacks, with failing but potentially recoverable hearts. The Company expects that recovery awareness and utilization of its products will significantly increase the number of patients able to return home from the hospital with their own hearts.

**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 significant intercompany accounts and transactions have been eliminated in consolidation.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, inventories, impairment of intangible assets and goodwill, financial instruments, accrued expenses, income taxes including the valuation allowance for deferred tax assets, stock-based compensation, valuation of long-lived assets and investments, contingencies and litigation. The Company bases its estimates on historical experiences and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimated.

**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 2009, 2008, or 2007. No customer had an accounts receivable balance greater than 10% of total accounts receivable at the end of fiscal years 2009 and 2008.

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 collectibility 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.

Financial instruments which potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, and marketable securities. Management mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity and have a high credit quality. At March 31, 2009, the Company had \$52.1 million held in funds that invest solely in U.S. Treasury securities.

**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.

---

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

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, as amounts are not expected to be redeemed within a year. In accordance with Statement of Financial Accounting Standards ( SFAS ) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, securities that the Company has the positive intent and ability to hold to maturity are reported at amortized cost and classified as held-to-maturity securities. 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 in the consolidated statements of operations.

**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 believed to be impaired. If actual demand or market conditions are less favorable than projected demand, additional inventory write-downs may be required that could adversely impact financial results for the period in which the additional excess or obsolete inventory is identified.

**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. Expenditures for renewals or betterments are capitalized.

**Impairment of Long-Lived Assets, Intangible Assets and Goodwill**

Long-lived assets (primarily property and equipment, intangible assets and goodwill) are reviewed for impairment losses whenever events or changes in circumstances indicate the carrying amount may not be recoverable and, in the case of goodwill, at least annually. An impairment loss would be recognized based on the amount by which the carrying value of the asset exceeds its fair value. Fair value is determined primarily using the estimated future cash flows associated with the asset under review discounted at a rate commensurate with the risk involved and other valuation techniques.

The Company capitalizes intellectual property costs relating to patenting its technology as they are incurred, excluding costs associated with Company personnel. Capitalized costs, the majority of which represent legal costs, reflect the cost of both awarded patents and patents pending. The Company amortizes the cost of these patents over the estimated useful life of the patents, generally up to seven years. If the Company elects to stop pursuing a particular patent application, determines that a patent application is not likely to be awarded for a particular patent, or elects to discontinue payment of required maintenance fees for a particular patent, the Company records as expense the net capitalized amount of such patent application or patent.

In accordance with the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, the Company assesses the realizability of goodwill annually at October 31, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. These events or circumstances generally include operating losses or a significant decline in earnings associated with the acquired business or asset. The Company s ability to realize the value of the goodwill will depend on the future cash flows of the business. If the Company is not able to realize the value of goodwill, the Company may be required to incur material charges relating to the impairment of those assets. The Company completed its annual review of goodwill as of October 31, 2008 and determined that no write-down for impairment was necessary. In light of a decrease in the Company s market capitalization since October 31, 2008 and the difficult worldwide economic conditions in recent months, the Company updated its impairment review as of March 31, 2009 and determined that its goodwill was not impaired.

---

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

SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, requires disclosure for estimates of the fair value of financial instruments. The Company's financial instruments were comprised of cash and cash equivalents, marketable securities, accounts receivable, note receivable and warrant and accounts payable, the carrying amounts of which approximate fair market value.

The Company entered into a convertible note purchase agreement with World Heart Corporation ( WorldHeart ) in December 2007. Under the agreement, the Company loaned \$5.0 million to WorldHeart, with the note and accrued interest, at 8% per annum, convertible at the Company's option into common stock of WorldHeart. The Company advanced \$1.0 million of the loan in December 2007 with the remaining \$4.0 million advanced in January 2008. The conversion feature within the note was an embedded derivative instrument under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and accordingly, was separately valued within the carrying value of the note receivable. The Company also received a warrant to purchase up to 3,400,000 shares of WorldHeart common stock.

The grant date fair values of the assets associated with the note receivable and the warrant, in excess of cash paid were deemed to be deferred income, as analogized to SFAS No. 91, *Accounting for Nonrefundable Fees and Costs Associated with Originating or Acquiring Loans and Initial Direct Costs of Leases*. Similar to other loan fees, the deferred income related to the grant date fair value of the note receivable and the warrant will be recognized over the life of the note receivable, if deemed to be realizable as a yield adjustment.

The Company recorded derivative financial instruments on its consolidated balance sheet at fair value. Changes in the fair value of these derivative financial instruments were recorded as Change in fair value of WorldHeart note receivable and warrant in the consolidated statements of operations. The measurement of fair value was based on valuation methodologies considered appropriate by the Company's management. The estimated fair value of the embedded derivative and warrant was determined using the Black-Scholes method. Because of inherent uncertainty of valuations of derivative instruments, estimated fair values may differ from the value that would have been used had a ready market for the investment existed and these differences could have a material impact in the consolidated statements of operations.

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

In July 2008, WorldHeart completed the transactions contemplated by the recapitalization agreement dated June 20, 2008, as amended on July 31, 2008, among the Company, WorldHeart, and the other parties named therein. As a result of the transaction, the Company received 86 million common shares of WorldHeart, which represented approximately 21.6% of WorldHeart's issued and outstanding common shares following the transaction. The shares were received as a result of the Company's conversion of the full amount of principal and interest owed on the \$5.0 million convertible note issued in December 2007, the Company's release of the security interest in all of the assets of WorldHeart that secured the note, termination of the warrant the Company held to purchase 3.4 million common shares of WorldHeart, forgiveness of other amounts owed to the Company by WorldHeart, the amendment of the Company's rights with respect to the distribution of WorldHeart products, and the appointment of a director or observer to WorldHeart's board of directors. In October, 2008, WorldHeart completed a 30-to-1 reverse stock split, as a result of which the Company held 2,866,666 common shares of WorldHeart. In December 2008, the Company sold 135,000 shares of WorldHeart for net proceeds of \$0.3 million, which was, as a result of the Company's basis having been reduced to zero, recorded as a gain on the sale of WorldHeart common stock during the three months ended December 31, 2008. As of March 31, 2009, the Company held 2,731,666 common shares of WorldHeart, or approximately 20.6% of WorldHeart's issued and outstanding shares. The Company is accounting for this investment using the equity method of accounting. The carrying value of this investment was zero at March 31, 2009.

**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 in 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.



---

**Table of Contents**

**ABIOMED, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

**Note 2. Summary of Significant Accounting Policies (Continued)**

**Revenue Recognition**

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

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

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. 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**

Consoles sold are covered by a one-year warranty for which estimated contractual warranty obligations are recorded as an expense at the time of shipment. The Company's products are subject to rigorous regulation and quality standards.

**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 currency of non-U.S. subsidiaries is primarily denominated in Euro. Resulting translation adjustments are reflected in the accumulated other comprehensive (loss) income component of stockholders' equity. Currency transaction gains and losses are included in the statements of operations.

**Net Loss Per Share**

In accordance with SFAS No. 128, *Earnings Per Share*, basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the fiscal year. Diluted net loss per share is computed by dividing net loss by the weighted-average number of dilutive common shares outstanding during the fiscal year. Dilutive shares outstanding are calculated by adding to the weighted shares outstanding any potential (unissued) shares of common stock and warrants based on the treasury stock method. Since the Company reported a net loss in the fiscal years ended March 31, 2009, 2008 and 2007, 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 fiscal years when a loss is reported the calculation of basic and dilutive loss per share results in the same value.

The calculation of diluted weighted average shares outstanding for the fiscal year ended March 31, 2007 excludes warrants to purchase up to 400,000 shares of common stock issued in connection with the purchase of intellectual property. Also excluded from the calculation of diluted weighted average shares outstanding for the fiscal years ended March 31, 2009, 2008, and 2007 are stock options outstanding in the amount of 4,583,345, 4,435,928, and 4,305,920, respectively, and unvested shares of restricted stock for the fiscal years ended March 31, 2009, 2008, and 2007 in the amount of 480,374, 54,000, and 8,000, respectively.

**Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive (loss) income. Other comprehensive (loss) income includes certain changes in equity that are excluded from net loss such as foreign currency translation adjustments.

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

The Company accounts for stock-based compensation under SFAS No. 123(R), *Share-based Payment*. SFAS No. 123(R) requires entities to recognize compensation costs for all share-based payments, including grants of employee stock options, based on the grant-date fair value of those share-based payments (with limited exceptions), adjusted for expected forfeitures.

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

The Company has elected to calculate the available additional paid-in capital pool for purposes of determining the impact of tax deficiencies using the alternative transition method described in FSP 123(R)-3, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*.

**Recent Accounting Pronouncements**

**SFAS No. 141(R)** In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*. SFAS No. 141(R) applies to any transaction or other event that meets the definition of a business combination. Where applicable, SFAS No. 141(R) establishes principles and requirements for how the acquirer recognizes and measures identifiable assets acquired, liabilities assumed, noncontrolling interest in the acquiree and goodwill or gain from a bargain purchase. In addition, SFAS No. 141(R) determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This statement is to be applied prospectively for transactions occurring in fiscal years beginning after December 15, 2008. SFAS 141(R) will impact the Company's accounting for business combinations, if any, completed beginning April 1, 2009.

**SFAS No. 160** In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*, an amendment of ARB No. 51. SFAS No. 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of the consolidation procedures under ARB No. 51 for consistency with the requirements of FASB Statement No. 141(R). This statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The statement shall be applied prospectively as of the beginning of the fiscal year in which the statement is initially adopted. The Company will adopt SFAS No. 160 for any acquisitions closing after March 31, 2009.

**SFAS No. 161** In March 2008, the FASB issued Statement No. 161, *Disclosures About Derivative Instruments and Hedging Activities*. This statement is intended to improve financial reporting about derivative instruments and hedging activities by enhanced disclosures to better understand their effects on a company's financial position, results of operation and cash flows. This standard is effective for interim and annual financial statements beginning after November 15, 2008. The Company adopted the disclosure requirements of this pronouncement in the quarter ended December 31, 2008.

**EITF 08-06** In November 2008, the EITF reached a final consensus on Issue No. 08-06 ( EITF No. 08-06 ), *Equity Method Investment Accounting Considerations*, effective on a prospective basis for fiscal years, beginning after December 15, 2008. The Company will adopt EITF 08-06 effective April 1, 2009, and does not expect it to have a material impact on its financial position or results of operations.

**Note 3. Restricted Cash**

The Company had restricted cash of approximately \$0.3 million and \$0.4 million in other assets at March 31, 2009 and 2008, respectively. This cash represents a security deposit for a letter of credit expiring in January 2011 associated with a global telecommunications equipment operating lease.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 4. Fair Value Measurements**

Effective April 1, 2008, the Company implemented SFAS No. 157, *Fair Value Measurement* ( SFAS No. 157 ), for financial assets and liabilities that are re-measured and reported at fair value at each reporting period. However, the FASB deferred the effective date of SFAS No. 157 for one year as it relates to fair value measurement requirements for nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value on a recurring basis. The adoption of SFAS No. 157 did not have a material impact on financial results.

As defined in SFAS No. 157, fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three categories:

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

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

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

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

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

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

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2009 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value:

	Level 1	Level 2	Level 3	Total
	(in \$000 s)			
Assets:				
U.S. Treasury Securities	\$ 52,102	\$	\$	\$ 52,102
Columbia Strategic Cash Portfolio			7,006	7,006
	\$ 52,102	\$	\$ 7,006	\$ 59,108

Level 3 financial assets are comprised of the Columbia Fund investment. The Columbia Fund is an investment portfolio sponsored by Bank of America that contained approximately \$0.6 billion in assets at March 31, 2009. Certain of the securities in the Columbia Fund have their fair values determined through readily available market data, but there are many securities in the Columbia Fund for which there is limited market activity such that the determination of fair value requires significant judgment or estimation. Given current market conditions, as these securities are not actively traded, certain significant inputs (e.g. yield curves, spreads, prepayments and volatilities) are unobservable. These securities are valued primarily using broker pricing models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity. As a result, the Company has categorized these securities in Level 3 of the fair value hierarchy. At March 31, 2009, approximately 79% of the assets in the Columbia Fund were invested in mortgage-backed securities (U.S. subprime and non-subprime residential mortgages, U.S. commercial mortgages and foreign residential mortgages) and asset-backed securities (credit card, auto loan and student loan backed securities). The remaining assets in the Fund are in cash, corporate bonds and other assets, with these securities being valued based on recently executed prices.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 4. Fair Value Measurements (Continued)**

The table below provides a summary of the changes in fair value, including net transfers, of all financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) for the twelve months ended March 31, 2009:

	<b>Level 3 Columbia Strategic Cash Portfolio (in \$000 s)</b>
Balance at March 31, 2008	\$ 28,826
Total realized and unrealized losses included in earnings	(2,091)
Cash received in settlement	(19,729)
Balance at March 31, 2009	\$ 7,006

**Note 5. Marketable Securities**

The Company has marketable securities at March 31, 2009 and 2008, respectively, that consist of and are classified on the balance sheet as follows:

	<b>March 31, 2009      2008 (in \$000 s)</b>	
Short-term marketable securities	\$ 55,394	\$ 36,257
Long-term marketable securities		3,721
	\$ 59,115	\$ 36,257

The Company's marketable securities at March 31, 2009 and 2008 are invested in the following:

	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>
	<b>(in \$000 s)</b>			
<b>At March 31, 2009:</b>				
Columbia Strategic Cash Portfolio	\$ 8,404	\$	\$ (1,398)	\$ 7,006
US Treasury Securities	52,102			52,102
Accrued Interest	7			7
	\$ 60,513	\$	\$ (1,398)	\$ 59,115
<b>At March 31, 2008:</b>				
Columbia Strategic Cash Portfolio	\$ 29,715	\$	\$ (889)	\$ 28,826
US Treasury Securities	7,323			7,323
Accrued Interest	108			108
	\$ 37,146	\$	\$ (889)	\$ 36,257

## Edgar Filing: ABIOMED INC - Form 10-K

The Columbia Fund is comprised of investments in cash, corporate bonds, other assets, mortgage-backed securities and asset-backed securities. On December 6, 2007, the Columbia Fund ceased accepting redemption requests from new or current investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. As a result, the Company reclassified the securities in the Columbia Fund from cash equivalents to short-term marketable securities as the Columbia Fund was no longer expected to have a maturity of less than 90 days. The Company deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 83% of its carrying value at March 31, 2009 and the Company does not expect to fully recover the original value of its investment. The Company recorded realized and unrealized losses of \$2.1 million and \$1.2 million related to the Columbia Fund in the statements of operations for the years ended March 31, 2009 and 2008, respectively. The Columbia Fund is being liquidated with distributions to the Company occurring and expected to occur during the next twelve months and beyond. Since December 6, 2007 through May 27, 2009, the Company has received disbursements of approximately \$40.0 million, or 85% of the original units in the Columbia Fund, with the most recent disbursement occurring on May 27, 2009 at approximately 86% of original value. The Company has recorded \$3.7 million of the Columbia Fund as long-term marketable securities at March 31, 2009 because Bank of America has indicated that it cannot predict with certainty whether or not it will redeem this amount within the next year. The Company also has \$52.1 million in funds that invest solely in U.S. Treasury Securities at March 31, 2009.

F-12

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 5. Marketable Securities (Continued)**

The Company recorded \$1.4 million in investment expense in fiscal 2009, of which \$2.1 million related to losses on the Columbia Fund and \$0.7 million was net investment income. The Company recorded \$1.6 million and \$1.0 million in investment income for fiscal 2008 and 2007, respectively. The investment income for fiscal 2008 included a \$1.2 million loss on the Columbia Fund and \$2.8 million in net investment income.

**Note 6. Accounts Receivable**

The components of accounts receivable are as follows:

	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in \$000 s)</b>	
Trade receivables	\$ 15,908	\$ 14,224
Allowance for doubtful accounts	(184)	(153)
	<b>\$ 15,724</b>	<b>\$ 14,071</b>

**Note 7. Inventories**

The components of inventories are as follows:

	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in \$000 s)</b>	
Raw materials and supplies	\$ 4,635	\$ 7,419
Work-in-progress	2,509	4,748
Finished goods	7,633	5,261
	<b>\$ 14,777</b>	<b>\$ 17,428</b>

All of the Company's inventories relate to circulatory care product lines that include the iPulse, AB5000, BVS 5000, IAB, AbioCor and Impella product platforms. Finished goods and work-in-process inventories consist of direct material, labor and overhead. During the years ended March 31, 2009, 2008, and 2007, the Company recorded \$1.4 million, \$0.9 million, and \$0.2 million in writedowns for excess quantities and obsolescence.

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

	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
	<b>(in \$000 s)</b>	
Cost of inventory used for demo purposes	\$ 5,680	\$ 3,815
Accumulated amortization	(4,386)	(3,148)
	<b>\$ 1,294</b>	<b>\$ 667</b>

## Edgar Filing: ABIOMED INC - Form 10-K

Amortization expense related to demo inventory was \$1.4 million, \$2.3 million, and \$0.5 million for the years ending March 31, 2009, 2008 and 2007, respectively. During fiscal 2008, the Company recorded an impairment charge of \$1.2 million to accelerate the amortization for AB5000 consoles used for demo purposes as the Company no longer actively manufactures the AB5000 console.

F-13

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 8. Property and Equipment**

The components of property and equipment are as follows:

	March 31,	
	2009	2008
	(in \$000 s)	
Machinery and equipment	\$ 9,944	\$ 13,758
Furniture and fixtures	873	1,130
Leasehold improvements	2,696	2,434
Construction in progress	2,547	1,167
<b>Total cost</b>	<b>16,060</b>	<b>18,489</b>
Less accumulated depreciation	(8,268)	(10,938)
	<b>\$ 7,792</b>	<b>\$ 7,551</b>

Depreciation expense related to property and equipment was \$2.1 million, \$2.2 million, and \$1.9 million for the years ending March 31, 2009, 2008 and 2007, respectively.

**Note 9. Intangible Assets and Goodwill**

The carrying amount of goodwill at March 31, 2009 and 2008, was \$31.3 million and \$31.6 million, respectively, and has been recorded in connection with the Company's acquisition of Impella.

	(in \$000 s)
Balance at April 1, 2007	\$ 26,708
Exchange rate impact	4,855
<b>Balance at March 31, 2008</b>	<b>31,563</b>
Purchase price adjustments - milestone payment to Impella CardioSystems AG	5,583
Exchange rate impact	(5,851)
<b>Balance at March 31, 2009</b>	<b>\$ 31,295</b>

In June 2008, the Company received FDA 510(k) clearance of its Impella 2.5 product, triggering an obligation to pay approximately \$5.6 million of contingent payments related to the May 2005 acquisition of Impella. In connection with this transaction, the Company issued 343,075 shares of its common stock to the former Impella shareholders and recorded an increase to goodwill of \$5.6 million.

In April 2009, the Company received FDA 510(k) clearance of its Impella 5.0 product, triggering an obligation to pay approximately \$5.6 million of contingent payments related to the May 2005 acquisition of Impella. In May 2009, the Company paid \$1.8 million of this final milestone in cash and elected to pay the remaining amount through the issuance of approximately 664,612 shares of its common stock. This payment will result in a \$5.6 million increase in goodwill during the first quarter of fiscal 2010.

The components of intangible assets are as follows:

Edgar Filing: ABIOMED INC - Form 10-K

	March 31, 2009			March 31, 2008		
	Cost	Accumulated Amortization (in \$000 s)	Net Book Value	Cost	Accumulated Amortization (in \$000 s)	Net Book Value
Patents	\$ 6,725	\$ 3,800	\$ 2,925	\$ 8,836	\$ 4,192	\$ 4,644
Trademarks and tradenames	342	185	157	527	259	268
Distribution agreements	652	365	287	774	322	452
Acquired technology	2,247	1,257	990	2,669	1,112	1,557
	\$ 9,966	\$ 5,607	\$ 4,359	\$ 12,806	\$ 5,885	\$ 6,921

F-14

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

Amortization expense for intangible assets was \$1.6 million, \$1.6 million and \$1.3 million for the years ending March 31, 2009, 2008 and 2007, respectively. The Company's expected amortization expense will be \$1.4 million in each of fiscal 2010 through 2012 and \$0.1 million for fiscal 2013.

**Note 10. Warranties**

The Company accrues for estimated warranty costs on its product sales at the time of sale. The following table summarizes the activities in the warranty reserve for the fiscal years ended March 31, 2009, 2008 and 2007:

	2009	March 31, 2008 (in \$000 s)	2007
Balance at March 31	\$ 214	\$ 157	\$ 167
Accrual for warranties	442	271	132
Warranty cost incurred during the period	(264)	(214)	(142)
Balance at March 31	\$ 392	\$ 214	\$ 157

**Note 11. Arbitration Decision and Warrants Repurchase****Arbitration Decision**

In May 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a demand for arbitration (subsequently amended) with the American Arbitration Association. The claims arose out of the Company's purchase of intellectual property rights relating to the Penn State Heart program and the related warrant agreements. In June 2007, the Arbitrator issued his ruling and in his award the Arbitrator found that, during the period between July 2003 and September 2004, the Company terminated all material staffing and funding for development of the Penn State Heart program for a continuous period of three months, other than for reasons outside of the Company's control, which constituted a cancellation under the terms of the warrant agreement. In addition, the Arbitrator issued his ruling that certain holders of the warrants covered by the warrant agreement were entitled to exercise their warrants to purchase 143,496.50 shares of the Company's common stock for \$0.01 per share pursuant to the warrant agreement and that the Company should pay to the claimants \$0.5 million representing reimbursement for legal and arbitration fees and other disbursements.

During the year ended March 31, 2008, the Company expensed \$1.2 million for the aggregate arbitrator award, comprised of \$0.5 million representing reimbursement for legal and arbitration fees and other disbursements and \$0.7 million related to the fair value of the warrants not previously expensed by the Company, which is reflected in the accompanying statements of operations under the line item arbitration decision. Also during the year ended March 31, 2008, the Company repurchased all outstanding warrants as described in the below paragraph.

**Warrants Repurchase**

During the three months ended December 31, 2007, the Company repurchased all outstanding warrants held by the claimants discussed above in the Arbitration Decision section for cash consideration of approximately \$2.2 million in settlement of any remaining claims held by the selling stockholders related to the Company's acquisition of the Penn State Heart. In exchange for the cash consideration, the warrants were cancelled and the claimants released the Company from any future obligations or liabilities related to this matter. Management's estimate of the fair value of the warrants repurchased was approximately \$1.9 million. This was calculated as 143,496.50 warrants discussed above, valued at the price of the Company's stock per share of \$13.02, which was the price on the close of business on October 3, 2007, the effective date of the settlement. The excess of the \$2.2 million of cash consideration over the \$1.9 million estimated fair value of the warrants at October 3, 2007 was recorded as selling, general and administrative expense in the statements of operations during fiscal 2008. There will be no other future royalties or payouts owed to the selling stockholders on revenue generated from the AbioCor II under the terms of the agreement.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 12. Stock Award Plans and Stock Based Compensation****Stock Option Plans**

Virtually all outstanding stock options of the Company as of March 31, 2009 were granted with an exercise price equal to the fair market value on the date of grant. For options and restricted stock granted below fair market value, compensation expense is recognized ratably over the vesting period. Outstanding stock options, if not exercised, expire 10 years from the date of grant.

In August 2008, the Company's stockholders approved the Company's 2008 Stock Incentive Plan (the "Plan"). The Plan authorizes the grant of a variety of equity awards to the Company's officers, directors, employees, consultants and advisers, including awards of unrestricted and restricted stock, incentive and nonqualified stock options to purchase shares of common stock, performance share awards and stock appreciation rights. The Plan provides that options may only be granted at the current market value on the date of grant. The maximum number of shares of the Company's common stock issuable under the Plan is equal to 2,308,688 shares, which included 308,688 shares that remained available for future awards as of August 12, 2008 under the Company's 1989 Non-Qualified Stock Option Plan for Non-Employee Directors, the 1998 Equity Incentive Plan and 2000 Stock Incentive Plan. This amount may be increased by up to 4,191,312 shares to the extent that any stock options or other equity awards that have been issued under the other plans are forfeited or terminated after August 13, 2008. Each share of stock issued pursuant to a stock option or stock appreciation right counts as 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 1.5 shares against the maximum number of shares issuable under the Plan. At March 31, 2009, a total of 1,534,950 shares were available for future issuance under the Plan.

Total stock-based compensation recognized in the Company's consolidated statements of operations for the fiscal years ended March 31, 2009, 2008, and 2007 were as follows:

	2009	March 31, 2008 (in \$000 s)	2007
Cost of product revenue	\$ 377	\$ 301	\$ 255
Research and development	1,808	1,297	1,656
Selling, general and administrative	6,649	3,778	3,937
	\$ 8,834	\$ 5,376	\$ 5,848

The stock-based compensation expense for the year ended March 31, 2009 includes \$4.8 million related to stock options and \$4.0 million related to restricted stock and the Company's Employee Stock Purchase Plan (the "Purchase Plan" or "ESPP"). The stock-based compensation expense for the year ended March 31, 2008 includes \$5.0 million related to stock options and \$0.4 million related to restricted stock and the Company's Employee Stock Purchase Plan. The stock-based compensation expense for the year ended March 31, 2007 includes \$5.6 million related to stock options and \$0.2 million related to restricted stock and the Company's Employee Stock Purchase Plan.

The remaining unrecognized stock-based compensation expense for invested stock option awards at March 31, 2009 was \$8.7 million, net of forfeitures, and the weighted-average time over which this cost will be recognized is 1.3 years. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow. Because the Company does not recognize the benefit of tax deductions in excess of recognized compensation cost due to its net operating loss position, this had no impact on the Company's consolidated statement of cash flows for the year ended March 31, 2009.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 12. Stock Award Plans and Stock Based Compensation (Continued)****Stock Option Activity**

The following table summarized stock option activity for the year ended March 31, 2009:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at beginning of year	4,436	\$ 11.49	6.65	
Granted	907	14.34		
Exercised	(555)	8.82		
Cancelled	(203)	12.80		
Expired	(2)	5.63		
Outstanding at end of year	4,583	\$ 12.32	6.57	\$ 20
Exercisable at end of year	2,713	\$ 11.59	5.30	\$ 20
Options vested and expected to vest at end of year	4,488	\$ 12.28		

The total intrinsic value of options exercised for the fiscal years 2009, 2008, and 2007 was \$4.3 million, \$1.7 million, and \$2.0 million, respectively. The total cash received from employees as a result of employee stock option exercises during the years ended March 31, 2009, 2008, and 2007 was approximately \$4.7 million, \$2.8 million, and \$2.8 million, respectively. The total fair value of options vested in fiscal years 2009, 2008, and 2007 was \$6.6 million, \$6.4 million, and \$5.3 million, respectively.

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model. The fair value of options granted during the years ended March 31, 2009, 2008 and 2007 were calculated using the following weighted average assumptions:

	2009	2008	2007
Risk-free interest rate	2.77%	4.38%	4.97%
Expected life (years)	5.10	5.93	6.25
Expected volatility	50.4%	56.6%	65.0%

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 average expected term was estimated using the simplified method for stock option grants before January 1, 2008 as prescribed by the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment*. Beginning January 1, 2008, the Company estimates the expected term based on historical experience.

The calculation of the fair value of the options is net of estimated forfeitures. Forfeitures are estimated based on an analysis of actual option forfeitures, adjusted to the extent historic forfeitures may not be indicative of forfeitures in the future. In addition, an expected dividend yield of zero is used in the option valuation model, because the Company does not pay cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The weighted average grant-date fair value for options granted during years ended March 31, 2009, 2008, and 2007 was \$6.71, \$7.26, and \$8.75 per share, respectively.



**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 12. Stock Award Plans and Stock Based Compensation (Continued)****Restricted Stock**

The following table summarizes restricted stock activity for the fiscal year ended March 31, 2009:

	March 31, 2009	
	Number of Shares (in thousands)	Grant Date Fair Value
Restricted stock awards at March 31, 2008	54	\$ 11.52
Granted	666	16.75
Vested	(167)	14.65
Forfeited	(73)	17.53
Restricted stock awards at March 31, 2009	480	\$ 16.77

The remaining unrecognized compensation expense for restricted stock awards at March 31, 2009 was \$4.6 million. The weighted average remaining contractual life for restricted stock awards at March 31, 2009 and 2008 was 1.8 and 2.4 years, respectively.

In May 2008, 260,001 shares of restricted stock were issued to certain executive officers and certain members of senior management of the Company, of which 130,002 of these shares vest upon achievement of a prescribed performance milestone. In September 2008, the Company met the prescribed performance milestone, and all of these performance-based shares vested. In connection with the vesting of these shares, these employees paid withholding taxes due by returning 39,935 shares valued at \$0.7 million. These shares have been recorded as treasury stock as of March 31, 2009. The remaining 129,999 of the restricted shares award vest ratably over four years from the grant date. The stock compensation expense for the restricted stock awards is recognized on a straight-line basis over the vesting period, based on the probability of achieving the performance milestones.

In August 2008, 406,250 shares of restricted stock were issued to certain executive officers and certain members of senior management of the Company, all of which could vest upon achievement of certain prescribed performance milestones. In March 2009, the Company met a prescribed performance milestone, and a portion of these performance-based shares vested. The remaining stock compensation expense for the restricted stock awards is being recognized on a straight-line basis over the vesting period through March 31, 2011 based on the probability of achieving the performance milestones. The cumulative effects of changes in the probability of achieving the milestones will be recorded in the period in which the changes occur.

During the year ended March 31, 2008, 60,000 shares of restricted stock were issued to certain executive officers of the Company that vest on the third anniversary of the date of grant. The stock compensation expense for the restricted stock awards is recognized on a straight-line basis over the vesting period.

**Employee Stock Purchase Plan**

In March 1988, the Company adopted the 1988 Employee Stock Purchase Plan ( the Purchase Plan or ESPP ), as amended. Under the Purchase Plan, eligible employees, including officers and directors, who have completed 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 from 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 payment period, the amount withheld is used to purchase 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. Up to 500,000 shares of common stock may be issued under the Purchase Plan, of which 163,245 shares are available for future issuance as of March 31, 2009. During the years ended March 31, 2009, 2008 and 2007, 45,823, 23,930, and 27,095 shares of common stock, respectively, were sold pursuant to the Purchase Plan.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 12. Stock Award Plans and Stock Based Compensation (Continued)**

Compensation expense recognized related to the Company's ESPP was approximately \$0.1 million for each of the years ended March 31, 2009, 2008 and 2007 respectively. The fair value of shares issued under the employee stock purchase plan was estimated on the commencement date of each offering period using the Black-Scholes option-pricing model with the following assumptions:

	2009	2008	2007
Risk-free interest rate	1.01%	4.61%	4.84%
Expected life (years)	0.5	0.5	0.5
Expected volatility	67.2%	45.2%	39.8%

**Note 13. Capital Stock**

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

In March 2007, the Company issued 5,000,000 shares of common stock in a public offering, and in April 2007, an additional 80,068 shares of common stock were issued in connection with the offering upon the partial exercise of the underwriters' over-allotment option.

The Company has authorized 1,000,000 shares of Class B Preferred Stock, \$0.01 par value, of which the Board of Directors can set the designation, rights and privileges. No shares of Class B Preferred Stock have been issued or are outstanding.

**Note 14. Income Taxes**

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

At March 31, 2009, the Company had federal and state net operating loss carryforwards, or NOLs, of approximately \$145.1 million and \$97.1 million, respectively, which begin to expire in fiscal 2010. Additionally, at March 31, 2009, the Company had federal and state research and development credit carryforwards of approximately \$8.1 million and \$4.2 million, respectively, which begin to expire in fiscal 2010. The Company acquired Impella, a German-based company, in May 2005. Impella had pre-acquisition net operating losses of approximately \$18.2 million at the time of acquisition (which is denominated in Euros and is subject to foreign exchange remeasurement at each balance sheet date presented), and has since incurred net operating losses in each fiscal year since the acquisition. During fiscal 2008, the Company determined that approximately \$1.2 million of pre-acquisition operating losses could not be utilized. The utilization of pre-acquisition net operating losses of Impella in future periods is subject to certain statutory approvals and business requirements.

Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the Company's net deferred tax assets and liabilities. Additionally, the future utilization of the Company's 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 net operating loss carryforwards and research and development credit carryforwards that a company can use each year to offset future taxable income and taxes payable. The Company believes that all of its federal and state NOLs will be 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 the Company's gross deferred tax assets. The Company will monitor subsequent ownership changes, which could impose limitations in the future.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 14. Income Taxes (Continued)**

Loss before provision for income taxes is as follows for the years ended March 31:

	2009	2008 (in \$000 s)	2007
Loss before provision for income taxes:			
United States	\$ (20,672)	\$ (26,074)	\$ (15,660)
Foreign	(10,173)	(14,329)	(11,746)
Loss before income taxes	\$ (30,845)	\$ (40,403)	\$ (27,406)
Provision for income taxes:			
Current:			
Federal	\$	\$	\$
State	32	(53)	
Foreign			
Total current	32	(53)	
Deferred:			
Federal	\$ 612	\$ 493	\$ 404
State	108	87	71
Foreign			
Total deferred	720	580	475
Total tax provision	\$ 752	\$ 527	\$ 475

Differences between the federal statutory income tax rate and the effective tax rates for the years ended March 31, 2009, 2008 and 2007 are as follows:

	2009	2008	2007
Statutory income tax rate	34.0%	34.0%	34.0%
Increase (decrease) resulting from:			
Change in valuation allowance	(41.2)%	(39.9)%	(42.5)%
Credits	8.6	1.2	2.7
Rate differential on foreign operations	(1.9)	3.1	2.3
Stock based compensation	(1.5)	0.9	2.2
Other, net	(0.4)	(0.6)	(0.4)
Effective tax rate	(2.4)%	(1.3)%	(1.7)%

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 14. Income Taxes (Continued)**

The components of the Company's net deferred taxes were as follows as of March 31:

	March 31,	
	2009	2008
	(in \$000 s)	
<b>Assets</b>		
NOL carryforwards and tax credit carryforwards	\$ 67,564	\$ 43,212
Foreign NOL carryforwards	5,621	7,177
Stock-based compensation	6,079	4,419
Nondeductible reserves and accruals	1,243	814
Deferred revenue	484	439
Depreciation	616	584
Amortizable intangibles other than goodwill	5,089	5,210
Unrealized losses	2,442	2,355
Other, net	1,377	1,121
Capitalized research and development	20,131	33,580
	110,646	98,911
<b>Liabilities</b>		
Identified intangibles	(1,693)	(2,662)
Indefinite lived intangible	(2,086)	(1,365)
Cumulative foreign currency translation loss		(3,375)
	(3,779)	(7,402)
Net deferred tax asset	106,867	91,509
Valuation allowance	(108,953)	(96,249)
Net deferred taxes	\$ (2,086)	\$ (4,740)

The change in the valuation allowance was \$12.7 million and \$16.1 million for fiscal 2009 and 2008, respectively, and was primarily due to the impact of the annual operating losses without current tax benefit.

Management has determined that the Company is not likely to realize the income tax benefit of its net deferred tax assets. To the extent the Company generates income in future years, the tax provision will reflect the realization of such benefits.

As a result of the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets* and the fiscal year 2006 acquisition of Impella, the Company has recorded a valuation allowance in excess of its net deferred tax assets to the extent the difference between the book and tax basis of indefinite lived intangible assets is not expected to reverse during the net operating loss carryforward period.

As of March 31, 2009, the Company has accumulated a net deferred tax liability of \$2.1 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.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 14. Income Taxes (Continued)**

On April 1, 2007, the Company adopted Financial Interpretation FIN No. 48, *Accounting for Uncertainty in Income Taxes* an interpretation of FASB Statement No. 109 ( FIN No. 48 ), which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN No. 48 prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. FIN No. 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition and defines the criteria that must be met for the benefits of a tax position to be recognized. As a result of its adoption of FIN No. 48, the Company recorded the cumulative effect of the change in accounting principle of \$0.3 million as a decrease to opening retained earnings and an increase to other long-term liabilities as of April 1, 2007. This adjustment related to state nexus for failure to file tax returns in various states for the years ended March 31, 2003, 2004, and 2005. The Company initiated a voluntary disclosure plan, which it completed in fiscal year 2009. The Company elected to recognize interest and/or penalties related to income tax matters in income tax expense in its consolidated statements of operations. As of March 31, 2009, the Company had remitted all outstanding amounts owed to each of the states in connection with the outstanding taxes owed at March 31, 2008. As such, the Company had no FIN No. 48 liability at March 31, 2009.

On a quarterly basis, the Company accrues for the effects of uncertain tax positions and the related potential penalties and interest. It is reasonably possible that the amount of the unrecognized tax benefit with respect to certain of the unrecognized tax positions will increase or decrease during the next 12 months; however, it is not expected that the change will have a significant effect on the Company's results of operations or financial position.

A reconciliation of the beginning and ending balance of unrecognized tax benefits, excluding accrued interest recorded at March 31, 2009 (in thousands) is as follows:

Balance at March 31, 2008	\$ 168
Reductions for tax positions for closing of the applicable statute of limitations	(168)
Balance at March 31, 2009	\$

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

**Note 15. Commitments and Contingencies**

The Company's acquisition of Impella provided that Abiomed was required to make contingent payments to Impella's former shareholders as follows:

upon FDA approval of the Impella 2.5 device, a payment of \$5,583,333

upon FDA approval of the Impella 5.0 device, a payment of \$5,583,333, and

upon the sale of 1,000 units of Impella's products worldwide, a payment of \$5,583,334.

The two milestones related to sales and FDA approval of the Impella 2.5 device were achieved and paid prior to March 31, 2009.

In April 2009, the Company received FDA 510(k) clearance of its Impella 5.0 product, triggering an obligation to pay the milestone related to the Impella 5.0 device. In May 2009, the Company paid \$1.8 million of this final milestone in cash and elected to pay the remaining amount through the issuance of approximately 664,612 shares of common stock.



**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 15. Commitments and Contingencies (continued)**

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

The Company enters into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. Abiomed has never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of March 31, 2009.

**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's lease for its Aachen location expires in December 2012. The monthly rent due under the lease agreement and payable monthly is 51,646 (Euro) (approximately U.S. \$69,000) per month or 619,572 (Euro) (approximately U.S. \$828,000) per year. In June 2008, the Company amended the lease for its Danvers, Massachusetts facility. The amendment extended the lease from February 28, 2010 to February 28, 2016. The lease continues to be accounted for as an operating lease. The amendment changed the rent payments under the lease from \$64,350 per month to the following schedule:

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

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

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

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

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

In July 2008, the Company entered into a lease agreement providing for the lease of a 33,000 square foot manufacturing facility in Athlone, Ireland. The lease agreement is for a term of 25 years and one week, commencing on April 18, 2008. The monthly rent due under the lease agreement and payable monthly is 22,455 (Euro) (approximately U.S. \$30,000) per month or 269,464 (Euro) (approximately U.S. \$360,000) per year for the first five years of the lease, through April 17, 2013. On April 18, 2013 and each fifth anniversary thereafter, the rental rate will be set to a current market rate, as determined by the procedures set forth in the lease agreement. The Company has the right to terminate the lease after five years, subject to the payment of a termination fee equal to 18 months rent, and the right to terminate the lease after 10 years, subject to the payment of a termination fee equal to six months of the then current rent.

## Edgar Filing: ABIOMED INC - Form 10-K

Total rent expense for the Company's operating leases, included in the accompanying consolidated statements of operations approximated \$2.4 million, \$2.2 million, and \$1.6 million, for the fiscal years ended March 31, 2009, 2008 and 2007, respectively.

F-23

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 15. Commitments and Contingencies (continued)**

Future minimum lease payments under all significant non-cancelable operating leases as of March 31, 2009 are approximately as follows:

Fiscal Year Ending March 31,	Operating Leases (in \$000s)
2010	\$ 2,313
2011	2,275
2012	1,992
2013	1,784
2014	808
Thereafter	1,518
<b>Total future minimum lease payments</b>	<b>\$ 10,690</b>

**Litigation** From time to time, the Company is involved in legal and administrative proceedings and claims of various types. While any litigation contains an element of uncertainty, management presently believes that the outcome of each such other proceedings or claims which are pending or known to be threatened, or all of them combined, is not expected to have a material adverse effect on the Company's financial position, cash flow and results. At March 31, 2009, the Company did not have any pending litigation.

**Note 16. Research and Development**

Research and development is a significant portion of the Company's operations. The Company's research and development efforts are focused on the development of new products related to cardiac assist, recovery and heart replacement and to continually enhance and improve its existing products. Research and development costs are expensed when incurred and include direct materials and labor, depreciation, contracted services and other costs associated with developing new products and significant enhancements to existing products. Research and development expense for the fiscal years ended March 31, 2009, 2008 and 2007 are reflected below:

	2009	March 31, 2008 (in \$000 s)	2007
Internally funded	\$ 24,849	\$ 24,588	\$ 22,123
Incurred under government contracts and grants	479	329	169
	<b>\$ 25,328</b>	<b>\$ 24,917</b>	<b>\$ 22,292</b>

**Note 17. 401(k) Plan**

The Company has a 401(k) Plan that covers all employees who are at least 20 years of age. Amounts paid by the Company to match a portion of employees contributions and discretionary amounts determined by the Company's Board of Directors totaled \$0.2 million, \$0.3 million and \$0.2 million for the fiscal years ended March 31, 2009, 2008, and 2007, respectively.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 18. Accrued Expenses**

Accrued expenses consisted of the following:

	March 31,	
	2009	2008
	(in \$000 s)	
Salaries and benefits	\$ 5,710	\$ 6,443
Research and development	2,727	1,316
Professional, accounting and auditing fees	600	735
Warranty	392	214
Other	1,389	582
	\$ 10,818	\$ 9,290

**Note 19. 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 62% and 54% of the Company's total consolidated assets are located within the U.S. as of March 31, 2009 and 2008, respectively. Remaining assets are located in Europe, primarily related to the Company's Impella production facility, and include goodwill and intangibles of \$35.5 and \$38.2 million at March 31, 2009 and 2008, respectively, associated with the Impella acquisition from May 2005. Total assets in Europe excluding goodwill and intangibles amounted to 11% and 14% of total consolidated assets at March 31, 2009 and 2008, respectively. International sales (sales outside the U.S. and primarily in Europe) accounted for 14%, 17%, and 11% of total product revenue during the fiscal years ended March 31, 2009, 2008, and 2007, respectively.

**Table of Contents****ABIOMED, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****Note 20. 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, 2009 and 2008.

	<b>Fiscal Years Ended March 31,</b>				
	<b>1st</b>	<b>2nd</b>	<b>3rd</b>	<b>4th</b>	<b>Total</b>
	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>	<b>Quarter</b>	<b>Year</b>
<b>Fiscal Year 2009</b>					
Total revenues	\$ 16,357	\$ 19,999	\$ 17,271	\$ 19,583	\$ 73,210
Cost of product revenue excluding amortization of intangibles	5,627	4,793	4,519	5,498	20,437
Other operating expenses	20,084	21,159	18,792	22,256	82,291
Other income (expense), net	385	(104)	(1,477)	(131)	(1,327)
Loss before provision for income taxes	(8,969)	(6,057)	(7,517)	(8,302)	(30,845)
Provision for income taxes	145	273	182	152	752
Net loss	\$ (9,114)	\$ (6,330)	\$ (7,699)	\$ (8,454)	\$ (31,597)
Basic and diluted net loss per share	\$ (0.28)	\$ (0.18)	\$ (0.21)	\$ (0.23)	\$ (0.91)
<b>Fiscal Year 2008</b>					
Total revenues	\$ 14,063	\$ 11,355	\$ 16,015	\$ 17,508	\$ 58,941
Cost of product revenue excluding amortization of intangibles	3,532	2,877	3,773	4,883	15,065
Other operating expenses	19,569	18,449	20,826	21,519	80,363
Other income, net (1)	908	734	450	(6,008)	(3,916)
Loss before provision for income taxes	(8,130)	(9,237)	(8,134)	(14,902)	(40,403)
Provision for income taxes	145	145	167	70	527
Net loss	\$ (8,275)	\$ (9,382)	\$ (8,301)	\$ (14,972)	\$ (40,930)
Basic and diluted net loss per share	\$ (0.26)	\$ (0.29)	\$ (0.26)	\$ (0.46)	\$ (1.26)

- (1) Other income, net, includes an impairment charge of \$5.6 million during the fourth quarter of fiscal 2008 related to the Company's note receivable from WorldHeart, which includes the \$5.0 million write-off of the note receivable and a \$0.6 million reversal of a previously recognized gain on the WorldHeart derivative instruments.

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

(in thousands)

<b>Description</b>	<b>Balance at Beginning of Period</b>	<b>Additions</b>	<b>Deductions</b>	<b>Balance at End of Period</b>
Allowance for Doubtful Accounts				
Fiscal Year Ended March 31, 2007	\$ 211	\$ 106	\$ 114	\$ 203
Fiscal Year Ended March 31, 2008	\$ 203	\$ 173	\$ 223	\$ 153
Fiscal Year Ended March 31, 2009	\$ 153	\$ 384	\$ 353	\$ 184