

ABIOMED INC  
Form 10-K  
June 02, 2011

**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, 2011

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**

Edgar Filing: ABIOMED INC - Form 10-K

(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	Name of Each Exchange 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, 2010, 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 \$401,510,410.

As of May 27, 2011, 38,482,962 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 2011 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.



**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, our level of operating and capital expenses 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.

---

**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 acute heart failure patients. 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. Our products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists and/or in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophylactically during high risk angioplasty procedures or who are in pre-shock, shock or profound cardiogenic shock. We believe heart recovery is the optimal clinical outcome by restoring the quality of life of patients. In addition, we believe heart recovery is the most cost-effective path for the healthcare system.

**Our Products**

***Impella 2.5***

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

The Impella 2.5 catheter can be quickly inserted via the femoral artery to reach the left ventricle of the heart where it is directly deployed to draw blood out of the ventricle and deliver it to the systemic system. This function is intended to reduce ventricular work (resting the heart) and provide flow to vital organs. The Impella 2.5 is introduced with normal interventional cardiology procedures and can pump up to 2.5 liters of blood per minute.

In August 2007, we received approval from the FDA to begin a high-risk percutaneous coronary intervention, or PCI, pivotal clinical trial, known as the Protect II study, for the Impella 2.5. This pivotal study was to determine the safety and effectiveness of the Impella 2.5 as compared to optimal medical management with an intra-aortic balloon, or IAB, during high-risk angioplasty procedures. In December 2010, we announced the termination of the Protect II study based on a futility determination at the planned interim analysis regarding the primary end-point, which we view as likely to be due to how rotational atherectomy was used in the study. In April 2011, we announced final results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 21% reduction in major adverse events compared to the intra aortic balloon at 90 days per protocol.

In December 2010, we received conditional approval from the FDA to begin Mini-AMI, a prospective, randomized, controlled multi-site trial to assess the potential role of the Impella 2.5 in reducing infarct size in patients with ST-elevation myocardial infarction, or STEMI. The primary objective of the study is to evaluate whether the adjunctive use of the Impella 2.5 for 24 hours following primary PCI for STEMI has the potential to limit the infarction of at-risk myocardium compared to primary PCI with routine post-PCI care.

In addition to the FDA approved studies for Impella 2.5, we are also conducting USpella, the first U.S. multicenter observational registry collecting clinical data and outcomes for patients supported with Impella 2.5 during elective, urgent and emergent procedures. We invited 62 hospitals in the U.S. and Canada to participate in the USpella registry.

***Impella 5.0 and Impella LD***

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

The Impella 5.0 can be quickly implanted via the femoral artery using a guide wire to reach the left ventricle of the heart where it is directly deployed to draw blood out of the ventricle, deliver it to the systemic system and perfuse the heart muscle. This function is intended to reduce ventricular work (resting the heart). The Impella LD is similar to the Impella 5.0 but is implanted directly through an incision in the subclavian or through an aortic graft. The Impella 5.0 and Impella LD can pump up to five liters of blood per minute and have 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.

---

***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 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.

We have developed a Portable Circulatory Support Driver, or Portable Driver, for both in-hospital and out-of-hospital patients which is designed to support our AB5000 VAD. We received CE mark approval for our Portable Driver in March 2008. In May 2008, we received conditional approval for the Portable Driver under an investigational device exemption, or 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 Portable Driver. This clearance allows for 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, which, when successfully completed, would allow patients to go home while waiting for recovery.

***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. 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 received humanitarian device exemption, or 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 do not expect to earn revenues from sales of the AbioCor in the foreseeable future as our primary strategic focus is centered on heart recovery for acute heart failure patients.

**Our Markets**

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

A broad spectrum of therapies exists for the treatment of patients in early stages of CHD. Angioplasty procedures and stents are commonly used in the cath lab to restore and increase blood flow to the heart. These treatments are often successful in slowing the progression of heart disease, extending life, and/or improving the quality of life for some period of time. Patients presenting with acute cardiac injuries potentially have recoverable hearts. Treatment for these patients in pre-shock in the cath lab is primarily focused on hemodynamic stabilization. Acute heart failure patients in profound shock typically require treatment in the surgery suite. These are patients suffering from

cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock or myocarditis complicated with cardiogenic shock. Chronic heart failure patients have hearts that are unlikely to be recoverable due to left and/or right side heart failure and their conditions cause their hearts to fail over time. Limited therapies exist today for patients with severe, end-stage, or chronic heart failure.

In more severe cases of heart failure, patients are sent directly to the surgery suite for coronary bypass or valve replacement surgery. The most severe acute heart failure patients are 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.

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. There are an estimated 124,000 IAB procedures performed annually in the U.S. However, IABs typically provide only limited enhancement and depend on the patient's own heart to generate the majority of the patient's blood flow. In addition, IABs are often required to be used in conjunction with inotropes or other drugs to stimulate heart muscle ejection. The use of these drugs, however, increases the risk of mortality. Clinical publications have demonstrated that the need for two or more inotropes to improve blood flow results in mortality rates of approximately 80%. In addition, IABs have limited effectiveness in patients that are arrhythmic and/or in cardiogenic shock and published reports have indicated that IABs do not reduce mortality for patients in cardiogenic shock.

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

Recovery VADs are designed to enable the patient's heart to rest and potentially recover so that the patient can return home with his or her own heart. Because recovery is the goal, these devices are designed to minimize damage to heart tissue and are removed once the 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 approximately 2,300 heart transplants in the U.S in 2010. 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, including 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 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 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 to align with the clinical needs of the patient, whether in pre-shock or profound shock. Our primary cath lab products include the Impella® pumps for support of acute pre-shock patients or for prophylactic support of patients undergoing high-risk percutaneous coronary intervention. Our primary surgery suite products include our Impella 5.0 pump and Impella LD pump, our BVS 5000 blood pump, and our AB5000 VAD. Our surgery suite products 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.

## Research and Product Development

Since our founding in 1981, we have gained substantial expertise in circulatory support while developing the BVS and the AB5000 systems, our Impella platform 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 the Impella technology platform.

As of March 31, 2011, our research and development staff consisted of 89 employees. We expended \$26.7 million, \$26.0 million and \$25.3 million on research and development in fiscal years 2011, 2010 and 2009, respectively. Our research and development expenditures include costs related to clinical trials, including ongoing clinical studies for our Impella products.

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

As of March 31, 2011, our worldwide sales, clinical support, marketing and field service teams included 129 full-time employees, 114 of whom are in the U.S. and 15 of whom are in Europe. Over the past five years, we have significantly increased the number of our direct sales and clinical support personnel covering the U.S., Canada, Germany, France, and the U.K.

Our clinical support personnel consist primarily of registered nurses 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 8%, 9%, and 14% of total product revenue during the fiscal years ended March 31, 2011, 2010 and 2009, respectively.

#### **Manufacturing**

We manufacture our products in Danvers, Massachusetts and Aachen, Germany. Our U.S. operations manufacture the BVS 5000, AB5000, AbioCor, IAB, iPulse, Portable Driver, and certain Impella subsystems. Our Aachen, Germany facility manufactures most of our Impella products. In addition, we rely on third-party suppliers to provide us with components used in our existing products and products under development. For example, we outsource some of the manufacturing of our consoles.

We believe our existing manufacturing facilities give us the necessary physical capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months based on our current revenue forecast. 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 fiscal 2011, we started performing some subassembly work on the Impella product line in Danvers to supplement the main Impella manufacturing production in Aachen.

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 relocated the production equipment from the Athlone facility to our Aachen and Danvers facilities and vacated the Athlone facility in the first quarter of fiscal 2011. In March 2011, we terminated our lease agreement in Ireland and paid a termination fee of approximately \$0.8 million.

We expect to increase additional Impella manufacturing capacity in Aachen and Danvers in fiscal 2012 to support the growing demand for our Impella products. 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 2012 to 2029 and our foreign patents have expiration dates ranging from 2016 to 2023. We also own or have rights to certain pending U.S. and foreign patent applications. We believe patents will issue pursuant to such applications, but cannot guarantee it. Moreover, neither the timing of any issuance, the scope of protection, nor the actual issue date of these pending applications can be forecasted with precision. Where we have licensed patent rights from third parties, we are generally required to pay royalties.



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

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

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

### **Competition**

Competition among providers of treatments for the failing heart is intense and subject to rapid technological change and evolving industry requirements and standards. We compete with companies that have substantially greater or broader financial, product development 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. Among our medical device competitors are Getinge (Maquet Cardiovascular), Teleflex Inc, Thoratec Corporation, Levitronix, HeartWare International Inc., Jarvik Heart, CircuLite, Inc., CardiacAssist Inc., and WorldHeart Corporation.

Our customers are hospitals that 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.

### **Third-Party Reimbursement**

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

Third-party payers may include government healthcare programs such as Medicare or Medicaid, private insurers or managed care organizations. The Centers for Medicare & Medicaid Services, or CMS, is responsible for administering the Medicare program and, along with its contractors, establishes coverage and reimbursement policies for the Medicare program. 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 that government or private third-party payers will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

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

Coverage and reimbursements for procedures to implant, remove, replace or repair the AB5000 and BVS 5000 are generally established in the U.S. market. For instance, Medicare covers the use of VADs when used for support of blood circulation post-cardiotomy, as a temporary life-support system until a human heart becomes available for transplant, or as therapy for patients who require permanent mechanical cardiac support. Coverage and reimbursements for procedures to implant the Impella 2.5, 5.0, or LD are also established for in-hospital use by Medicare including ICD-9 for procedures and DRG coding. Actual coverage and payment may vary by local Medicare fiscal intermediary or third party insurer.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services when they perform surgeries to implant, remove, replace or repair our AB5000 or BVS 5000 devices or when they perform percutaneous insertion and removal of Impella. Physicians generally bill for such services using a coding system known as Current Procedural Terminology, or CPT, codes. Physician services performed in connection with the implantation, removal, replacement or repair of our AB5000, BVS 5000 or Impella 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 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. 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 investigational device exemption, or IDE, application before commencing clinical trials. The FDA reviews and must approve an IDE before a study may begin in the U.S. In addition, the study must be approved by an Institutional Review Board, or IRB, for each clinical site. 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. Following completion of a study, we would need to collect, analyze and present the data in an appropriate submission to the FDA, either through a 510(k) premarket notification or a PMA.

During the 510(k) process, the FDA reviews a premarket notification and determines whether or not a proposed device is substantially equivalent to predicate devices. If the intended use and technological characteristics are comparable to a predicate device, the device may be cleared for marketing. If the device has the same intended use as a predicate device and different technological characteristics, but data is submitted to the FDA showing that the device is at least as safe and effective as the legally marketed device, it may also be cleared for marketing. The FDA's 510(k) clearance pathway usually takes from 3 to 12 months, but it can often last longer and clearance is never assured. In reviewing a premarket notification, the FDA may request additional information, including clinical data. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the agency can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA 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 Safe Medical Devices Act of 1990 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 submit a PMA application within 90 days after the FDA publishes a final regulation requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Failure to meet the deadline can lead the FDA to prevent continued marketing of the device during the PMA application review period. The Impella 2.5, Impella 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.

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 may conduct an inspection of the manufacturing facilities and the clinical sites where the supporting study was conducted. The facility inspection evaluates the company's compliance with the QSR. An inspection of clinical sites evaluates compliance with the IDE requirements. Typically, the FDA will convene an advisory panel meeting to seek review of the data presented in the PMA. The panel's recommendation is given substantial weight, but is not binding on the agency. By regulation, the FDA has 180 days to review a PMA application, 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.

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. 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.

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 our AbioCor.

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

#### ***Postmarket Regulation***

The medical devices that we manufacture and distribute pursuant to FDA clearances or approvals are subject to continuing regulation by the FDA and other regulatory authorities. The FDA reviews design, manufacturing, and distribution practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. Among other FDA requirements, we must comply with the FDA's good manufacturing practice regulations. These regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. We must also comply with Medical Devices Reporting, or MDR, which requires that a firm report to the FDA any incident in which its product may have caused or contributed to a death or serious injury, or 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 Quality System Regulation, or QSR, and MDR requirements, as well as other applicable regulations. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, and require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal fines and penalties against our officers, employees, or us. The FDA may also recommend prosecution to the U.S. Department of Justice.

The FDA 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 undergo an appropriate conformity assessment procedure. A Notified Body assesses the quality management systems of the manufacturer and the product conformity to the essential and other requirements within the Medical Device Directive. In the European Union, we are also required to maintain certain 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 all CE marked and available for sale in the European Union. We are also subject to regulations in Canada 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.

### ***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.

In recent years, several states have enacted legislation requiring biotechnology, pharmaceutical and medical device companies to establish marketing compliance programs and file periodic reports on sales, marketing, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. We could face enforcement action, fines and other penalties and could receive adverse publicity, all of which could harm our business, if it is alleged that we have failed to fully comply with such laws and regulations. Similarly, if the physicians or other providers or entities 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 knowingly filing or causing the filing of a false claim or the knowing use of false statements to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim. Private individuals can file suits under the False Claims Act on behalf of the government. These lawsuits are known as qui tam actions, and the individuals bringing such suits, sometimes known as relators or, more commonly, whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

#### ***HIPAA***

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

HIPAA also protects the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses. HIPAA restricts the use and disclosure of patient health information, including patient records. Although we believe that HIPAA does not apply to us directly, most of our customers have significant obligations under HIPAA, and we intend to cooperate with our customers and others to ensure compliance with HIPAA with respect to patient information that comes into our possession. Failure to comply with HIPAA obligations can 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, 2011, we had 374 full-time employees, including:

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

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

116 in manufacturing; and

40 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**

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

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.

**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 2012.***

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 2012 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 fiscal 2012 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 make significant expenditures to market and manufacture in commercial quantities our 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 a PMA 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. In January 2011, the FDA announced plans to make changes to its 510(k) clearance process. These changes may further delay the time it takes us to prepare applications for 501(k) clearance or the length of time required to receive 510(k) clearance. We cannot assure you that any regulatory clearances or approvals, either foreign or domestic, will be granted on a timely basis, if at all. If we are unable to obtain regulatory approvals or clearances for use of our products under development, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of these products could be limited. The FDA may also limit the claims that we can make about our products.

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

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 PMA 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 the FDA. We have received IDE approval and are conducting clinical trials for our Impella 2.5 and Portable Driver medical devices. In December 2010, we announced the termination of our Protect II study based on a futility determination at the planned interim analysis regarding the primary end-point, which we view as likely to be due to unanticipated confounding variables related to the use of rotational atherectomy in the study.

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

---

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.

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

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

developing our global sales and marketing infrastructure and capabilities;



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

expanding manufacturing capacity, maintaining quality and increasing production;

expansion of foreign regulatory compliance capabilities;

implementing appropriate operational and financial systems and controls;

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

training, managing and supervising our personnel worldwide.

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, and other existing products, as well as other new or future products, including achieving market acceptance among physicians, medical centers, patients and third-party

payers. In particular, we need to gain acceptance of our Impella products among interventional cardiologists, who have not previously been users of our other devices. The obstacles we will face in trying to create successful commercial markets for our products include:

limitations inherent in first-generation devices, and 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 cost of our products; and

the potential reluctance of physicians, patients and society as a whole to accept medical devices that replace or assist the heart 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 and other products 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 business that we ensure that there are a sufficient number of clinicians familiar with, trained on and proficient in the use of our products. Convincing clinicians to dedicate the time and energy necessary to obtain adequate training in the use of our products is challenging and we may not be successful in these efforts. If clinicians are not properly trained, they may misuse or ineffectively use our products. Any improper use of our products may result in unsatisfactory outcomes, patient injury, negative publicity or lawsuits against us, any of which could harm our reputation and future product sales. Furthermore, our inability to educate and train clinicians to use our products may lead to inadequate demand for our products.

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

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

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

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

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 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 and consoles are not purchased as frequently. 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. 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, which could limit market acceptance of our products or otherwise damage our business. In order for our manufacturing to meet the expected demand for our Impella 2.5 product, we have been implementing process improvements on the Impella production line at our manufacturing facility in Aachen, Germany to increase the output that we can produce at the facility. In addition to programs designed to further increase yield and capacity levels, we plan to incrementally expand manufacturing employment in Aachen and relocate selected sub-assembly production to our manufacturing facility in Danvers, Massachusetts. We terminated the lease of our Athlone facility, which was intended to be used for high scale manufacturing production, in March 2011. We recorded an expense of approximately \$0.8 million to terminate the Athlone lease in fiscal 2011. We started a second production line for Impella in Aachen during fiscal 2011 and are developing additional Impella manufacturing capacity in Danvers. If we are unable to implement these process improvements on a timely basis, it could inhibit our revenue growth.

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

We currently manufacture our Impella heart pumps at our facility in Aachen, Germany and we manufacture our other products and certain Impella subassemblies at our facility in Danvers, Massachusetts. Events such as fire, flood, 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.

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

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

---

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

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

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

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

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

In March 2010, the federal government enacted healthcare reform legislation. The legislation has changed the manner in which healthcare services are provided and paid for in the U.S. These changes may impact reimbursement for health care services, including reimbursement to hospitals and physicians. States may also enact further legislation that impacts Medicaid payments to hospitals and physicians. In addition, the Centers for Medicare & Medicaid Services, the federal agency responsible for administering the Medicare program, has established new payment levels for hospitals and physicians in line with the new legislation, which can increase or decrease payment to such entities. The healthcare reform legislation and any future legislative and regulatory initiatives could adversely affect demand for our products and have a material adverse impact on our revenues. Our business and results of operations could therefore be adversely affected by the current healthcare reform legislation as well as future healthcare reform.

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

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

Beginning in 2013, under the newly enacted healthcare reform legislation, sales of medical devices will be taxed at a rate of 2.3%. As rules and regulations are developed under the new law, there may be exemptions created for certain types or classes of products. We may find, however, that there are no exemptions applicable to our products. This tax will impact our cost of doing business and may ultimately hinder profitability. Additionally, the increased cost of business caused by this tax may hinder our ability to spend money on research and development of our products. We may be required to increase the prices of our devices to offset the additional cost of the tax. Medicaid and health insurance providers may place a cap on the reimbursement for purchases of our devices which will not allow us to offset the cost of the tax. We may ultimately lose customers who are unwilling or unable to pay the increased costs, which could adversely affect our business and operating results.

***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.

In recent years, several states have enacted legislation requiring biotechnology, pharmaceutical and medical device companies to establish marketing compliance programs and file periodic reports on sales, marketing, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. We could face enforcement

action, fines and other penalties and could receive adverse publicity, all of which could harm our business, if it is alleged that we have failed to fully comply with such laws and regulations. Similarly, if the physicians or other providers or entities 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, of which only a limited number of whom seek employment with a company like ours. Competition for skilled and experienced management, scientific, clinical and sales personnel in the medical devices industry is intense. We face competition for skilled and experienced management, scientific, clinical and sales personnel from numerous medical device and life sciences companies, universities, governmental entities and other research institutions. If we lose the services of any of the principal members of our management and staff, or if we are unable to attract and retain qualified personnel in the future, especially scientific and sales personnel, our business could be adversely affected.

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

We rely on third-party suppliers to provide us with some components used in our existing products and products under development. For example, we outsource the manufacturing of most of our consoles other than final assembly and testing. Relying on third-party suppliers makes us vulnerable to component part failures 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, Canada, 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;

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

difficulty in collecting accounts receivable;

difficulty in supporting patients using our products;

fluctuations in the values of foreign currencies; and

political and economic instability.

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

---

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

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

***Our operating results may fluctuate unpredictably.***

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

the timing of customer orders and deliveries;

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

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

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

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

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, 2011, we had federal and state net operating loss ( NOL ) carryforwards of approximately \$182.6 million and \$127.0 million, respectively, which expire in varying years from fiscal 2012 through fiscal 2031. Additionally, at March 31, 2011, we had federal and state research and development credit carryforwards of approximately \$9.3 million and \$4.7 million, respectively, which expire in varying years from fiscal 2012 through fiscal 2031.

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 carryforwards to offset future taxable income may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to ownership changes that have occurred previously or that could occur in the future. Ownership changes, as defined in Section 382 of the Internal Revenue Code, can limit the amount of NOL s and research and development credit carry forwards that a company can use each year to offset future taxable income and taxes payable. We completed a Section 382 study and analysis in fiscal 2008 to determine whether changes in the composition of our stockholders, including our acquisition of Impella and our public offering, resulted in an ownership change for purposes of Section 382. We believe that all of our federal and state 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 carryforwards, before they can be utilized, would reduce our gross deferred tax assets. We plan to monitor subsequent ownership changes, which could impose limitations in the future.



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

*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, and product extensions of existing commercial products and new products. The development of new products and product extensions presents enormous challenges in a variety of areas, many or all of which we may have difficulty in overcoming, including blood compatible surfaces, blood compatible flow, manufacturing techniques, pumping mechanisms, physiological control, energy transfer, anatomical fit and surgical techniques. We may be unable to overcome all of these challenges, which could adversely affect our results of operations and prospects.

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

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

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

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

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

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

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

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

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

The risk of product liability claims is heightened when we sell products that are intended to support a patient until the end of life. The finite life of our products, as well as complications associated with their use, could give rise to product liability claims whether or not the products have extended or improved the quality of a patient's life. 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 inventory 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 sales or operating results may be harmed.***

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

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

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, HeartWare, World Heart Corporation, MicroMed Technology, 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, vendors 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.

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

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign currency exchange rates, primarily the Euro. The functional currency of our subsidiary, Abiomed Europe GmbH, 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, 2010 to March 31, 2011, the price of our stock ranged from a low of \$8.50 per share to a high of \$15.05 per share. Many factors could cause the market price of our common stock to rise and fall. Some of these factors are:

variations in our quarterly results of operations;

the status of regulatory approvals for our products;

the introduction of new products by us or our competitors;

acquisitions or strategic alliances involving us or our competitors;

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

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

the hiring or departure of key personnel;

results of clinical trials of our products;

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

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

In addition, the stock market in general and the market for shares of medical device companies in particular have experienced extreme price and volume fluctuations in recent years. These fluctuations are often unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the market price of our common stock. When the market price of a company's stock drops significantly, stockholders often institute securities class

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

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.

#### **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 that expires on February 28, 2016. Monthly rent is as follows:

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

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

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

In addition, we have certain rights to terminate the lease early, subject to the payment of a specified termination fee based on the timing of the termination, as further outlined in the 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 building houses most of the manufacturing operations for our Impella product line as well as certain research and development functions and the sales, marketing and general and administrative functions for most of our product lines sold in Europe and the Middle East.

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

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 was for a term of 25 years and one week, commencing on July 18, 2008. The monthly rent due under the lease agreement and payable monthly was 22,455.33 (Euro) (approximately U.S. \$30,000) per month through April 17, 2013. We relocated the production equipment from our Athlone, Ireland manufacturing facility to our Aachen and Danvers facilities and vacated the Athlone facility in the first quarter of fiscal 2011. In March 2011, we terminated our lease agreement for our Athlone facility. We paid a termination fee of approximately \$0.8 million as a result of the early termination.

**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.

**ITEM 4. (REMOVED AND RESERVED)**

## 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>High</b>	<b>Low</b>
<b>Fiscal Year Ended March 31, 2010</b>		
First Quarter	\$ 8.89	\$ 4.78
Second Quarter	10.10	6.87
Third Quarter	11.25	7.90
Fourth Quarter	11.15	7.80
<b>Fiscal Year Ended March 31, 2011</b>		
First Quarter	\$ 10.46	\$ 8.50
Second Quarter	11.73	8.63
Third Quarter	12.25	8.97
Fourth Quarter	15.05	9.42

**Number of Stockholders**

As of May 27, 2011, we had approximately 626 holders of record of our common stock and there were approximately 7,018 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.



**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, 2006 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 (\$)**

	3/31/2006	3/31/2007	3/31/2008	3/31/2009	3/31/2010	3/31/2011
ABIOMED, Inc	100	105.89	101.86	37.98	80.00	112.64
Nasdaq Composite Index	100	103.50	97.41	65.33	102.49	118.86
Nasdaq Medical Equipment SIC Code 3840-3849	100	88.78	84.26	46.12	83.47	91.35

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.

ITEM 6. *SELECTED FINANCIAL DATA*

## SELECTED CONSOLIDATED FINANCIAL DATA

(In thousands, except per share data)

	Fiscal Years Ended March 31,				
	2011	2010	2009	2008	2007
<b>Statement of Operations Data:</b>					
Revenue:					
Products	\$ 99,837	\$ 84,765	\$ 72,512	\$ 58,322	\$ 50,408
Funded research and development	1,314	948	698	619	241
	101,151	85,713	73,210	58,941	50,649
Costs and expenses:					
Cost of product revenue	21,977	22,529	20,437	15,065	12,012
Research and development	26,677	25,954	25,328	24,917	22,292
Selling, general and administrative	62,287	60,837	55,357	52,658	42,448
Arbitration decision				1,206	
Expensed in-process research and development					800
Amortization of intangible assets	1,395	1,469	1,606	1,582	1,608
	112,336	110,789	102,728	95,428	79,160
Loss from operations	(11,185)	(25,076)	(29,518)	(36,487)	(28,511)
Other income (expense):					
Investment income (expense), net	9	373	(1,404)	1,625	1,045
Gain on sale of WorldHeart stock	456	6,389	313		
Change in fair value of WorldHeart note receivable and warrant				(5,000)	
Other (expense) income, net	(143)	(39)	(236)	(541)	60
	322	6,723	(1,327)	(3,916)	1,105
Loss before income tax provision	(10,863)	(18,353)	(30,845)	(40,403)	(27,406)
Income tax provision	892	671	752	527	475
Net loss	\$ (11,755)	\$ (19,024)	\$ (31,597)	\$ (40,930)	\$ (27,881)
Basic and diluted net loss per share	\$ (0.32)	\$ (0.52)	\$ (0.91)	\$ (1.26)	\$ (1.03)
Weighted average shares outstanding	37,167	36,875	34,882	32,465	27,124
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, and short and long term marketable securities	\$ 60,312	\$ 58,265	\$ 60,900	\$ 38,299	\$ 75,125
Working capital	62,394	64,604	70,910	52,027	83,485
Total assets	131,588	129,570	135,958	118,031	136,183
Stockholder s equity	104,743	107,956	115,983	93,594	122,095

---

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

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

**Overview**

We are a leading provider of medical devices in circulatory support and we offer a continuum of care in heart recovery to acute heart failure patients. 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. Our products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists and/or in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophylactically during high risk angioplasty procedures or who are in pre-shock, shock or profound cardiogenic shock. We believe heart recovery is the optimal clinical outcome by restoring the quality of life for patients. In addition, we believe heart recovery is the most cost-effective path for the healthcare system.

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. In December 2010, we announced the termination of the Protect II study based on a futility determination at the planned interim analysis regarding the primary end-point, which we view as likely to be due to how rotational atherectomy was used in the study. In April 2011, we announced final results from the Protect II study, including those patients enrolled post the initiation of the interim analysis, which showed a statistically significant reduction of 21% in major adverse events compared to the intra aortic balloon at 90 days per protocol. We received 510(k) clearance in April 2009 for our Impella 5.0 and Impella LD devices, which provide more blood flow than the Impella 2.5. In order for our manufacturing to meet the expected demand for our Impella 2.5 product, we have been implementing process improvements at our manufacturing facilities in Aachen, Germany, to increase the output that we can produce at the facility. In addition to process improvement programs designed to further increase yield and capacity levels, we plan to incrementally expand manufacturing capacity in Aachen and relocate selected Impella sub-assembly production to our manufacturing facility in Danvers, Massachusetts.

Revenues from our other heart recovery products, largely focused on the heart surgery suite, decreased in fiscal 2011 as we continued to strategically focus our sales and marketing efforts towards our Impella products in the cath lab. We expect that sales from our non-Impella products will continue to decline as we dedicate the majority of our focus and resources on our Impella products. 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 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. Our BVS product is 19 years old 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 our Impella 5.0 and LD products geared for the surgery suite. We expect our revenues from our non-Impella business during fiscal 2012 will continue to decrease as we continue to focus on our Impella products. We do not expect 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 on heart recovery for acute heart failure patients. We did not recognize any AbioCor revenue during fiscal 2009, 2010 or 2011.

We have incurred annual net losses since our inception, including net losses of \$11.8 million, \$19.0 million and \$31.6 million in fiscal years 2011, 2010 and 2009, 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, conduct clinical studies and registries on our products, and expand our commercial infrastructure.

Our financial condition was 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 fiscal year.

**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, 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. Revenue from product sales to new customers is deferred until all elements of the sale have been delivered. All costs related to product shipment are recognized at time of shipment. We do not provide for rights of return to customers on our product sales and therefore do not record a provision for returns.

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

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

#### *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 2011 as of October 31, 2010 and determined that no write-down for impairment of goodwill was required as the fair value of the reporting unit substantially exceeded the carrying value. The carrying amount of goodwill at March 31, 2011 was \$38.9 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, 2011 was \$1.6 million.

#### *Stock-Based Compensation*

We record stock-based compensation in our statements of operations based on the fair value method. This expense is determined after consideration of several significant judgments and estimates, including the probable outcome for awards with a performance condition or conditions. The fair value of stock option grants is estimated using the Black-Scholes option pricing model, which requires management to make certain assumptions with respect to selected model inputs. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on historical volatility of our stock. 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 historic forfeitures may not be indicative of forfeitures in the future. In addition, an expected dividend yield of zero is used in the option valuation model because we do not pay dividends and do not expect to pay any dividends in the foreseeable future.

The estimated fair value of all awards is recognized as compensation expense on a straight-line basis over the service period. Accruals of compensation cost for an award with a performance condition are based on the probable outcome of the performance conditions. The cumulative effects of changes in the probability outcomes are recorded in the period in which the changes occur.

### Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU No. 2009-13, which amended FASB Accounting Standard Codification Subtopic 605-25. This amended guidance requires an entity to allocate revenue to each unit of accounting in multiple deliverable arrangements based on the relative selling price of each deliverable. It also changes the level of evidence required to separate deliverables by requiring an entity to make its best estimate of the stand-alone selling price of the deliverables with more objective evidence if the selling price is not available. Previously we were required to have objective evidence of the undelivered items in order to have separate units of accounting for multiple element arrangements. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for us means no later than April 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than April 1, 2011, would have required us to apply this guidance retrospectively effective as of April 1, 2010 and required disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. We did not elect to early adopt this amended guidance and do not expect the adoption of this new guidance to have a material impact on our financial statements.

### 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,		
	2011	2010	2009
<b>Revenues:</b>			
Product	98.7%	98.9%	99.0%
Funded research and development	1.3	1.1	1.0
<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	21.7	26.3	27.9
Research and development	26.4	30.3	34.6
Selling, general and administrative	61.6	71.0	75.6
Amortization of intangible assets	1.4	1.7	2.2
<b>Total costs and expenses</b>	<b>111.1</b>	<b>129.3</b>	<b>140.3</b>
<b>Loss from operations</b>	<b>(11.1)</b>	<b>(29.3)</b>	<b>(40.3)</b>
<b>Other income (expense):</b>			
Investment income (expense), net		0.4	(1.9)
Gain on sale of WorldHeart stock	0.5	7.5	0.4
Other expense, net	(0.1)		(0.3)
	0.4	7.9	(1.8)
<b>Loss before income tax provision</b>	<b>(10.7)</b>	<b>(21.4)</b>	<b>(42.1)</b>
Income tax provision	0.9	0.8	1.0
<b>Net loss</b>	<b>(11.6)%</b>	<b>(22.2)%</b>	<b>(43.1)%</b>

*Fiscal Years Ended March 31, 2011 and March 31, 2010 ( fiscal 2011 and fiscal 2010 )*

## Revenue

Our revenues are comprised of the following:

	<b>Year Ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
	<b>(in \$000 s)</b>	
Impella products	\$ 77,747	\$ 57,799
Other products	22,090	26,966
<b>Total product revenues</b>	<b>99,837</b>	<b>84,765</b>
Funded research and development	1,314	948
<b>Total revenues</b>	<b>\$ 101,151</b>	<b>\$ 85,713</b>

Product revenues for fiscal 2011 increased by \$15.0 million, or 18%, to \$99.8 million from \$84.8 million for fiscal 2010. The increase in product revenue was primarily due to an increase in Impella revenue due to greater demand in the U.S. for the Impella 2.5 and 5.0, offset by a decrease in our other non-Impella revenue, primarily related to BVS and AB5000.

Impella product revenues for fiscal 2011 increased by \$19.9 million, or 34% to \$77.7 million from \$57.8 million for fiscal 2010. Most of our Impella revenue was from disposable product sales of Impella 2.5 as we focus on increasing utilization of Impella 2.5 through continued sales force and physician training. We have also generated sales of Impella 5.0 and Impella LD in the U.S. in fiscal 2011 through the expansion of these applications in the surgery suite following 510(k) clearance for these products received in April 2009.

Other product revenues for fiscal 2011 decreased by \$4.9 million or 18%, to \$22.1 million from \$27.0 million for fiscal 2010. 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 and AB5000 revenue will continue to decline in fiscal 2012 as we focus our sales efforts in the surgical suite on Impella 5.0 and LD.

## Cost of Product Revenue

Cost of product revenue for fiscal 2011 decreased by \$0.5 million or 2%, to \$22.0 million from \$22.5 million for fiscal 2010. Gross margin for fiscal 2011 was 78% compared to 74% for fiscal 2010. The increase in gross margin was primarily due to higher reorders of Impella product disposable pumps, improved manufacturing efficiency and a lower amount of console placements as we reduced the number of new site openings in fiscal 2011.

## Research and Development Expenses

Research and development expenses for fiscal 2011 increased by \$0.7 million, or 3%, to \$26.7 million from \$26.0 million in fiscal 2010. The increase in research and development expenses was primarily due to higher clinical trial activity expenditures. Research and development expenses for fiscal 2011 and 2010 included \$8.8 million and \$7.4 million, respectively, in clinical trial expenses primarily associated with our Impella 2.5 U.S. trials. We expect research and development spending to increase slightly in fiscal 2012 as we compile data and incur costs to close the Protect II trial and continue to invest in research on new products.

## Selling, General and Administrative Expenses

Selling, general and administrative expenses for fiscal 2011 increased by \$1.5 million, or 2%, to \$62.3 million from \$60.8 million in fiscal 2010. The increase was primarily due to investments in marketing initiatives and commercial infrastructure to support the expansion of the Impella platform.

We expect to continue to increase our expenditures on sales and marketing activities in fiscal 2012, 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 decreased by \$0.1 million, or 7%, to \$1.4 million from \$1.5 million for fiscal 2010. Amortization primarily relates to specifically identified assets from the Impella acquisition.



### Gain on Sale of WorldHeart Stock

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

### Income Tax Provision

During fiscal 2011 and 2010, we recorded a provision for income taxes of \$0.9 million and \$0.7 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. 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. The increase in income tax expense in fiscal 2011 was due to a lower refundable research and development credit received in fiscal 2011 as compared to fiscal 2010.

### Net Loss

During fiscal 2011, we incurred a net loss of \$11.8 million, or \$0.32 per share compared to a net loss of \$19.0 million, or \$0.52 per share, for the prior fiscal year. The decrease in the net loss in fiscal 2011 compared to fiscal 2010 was due primarily to increased Impella sales as a result of our focus on increasing Impella utilization in the U.S. 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 to bring enhancements to Impella and continue research on new products.

*Fiscal Years Ended March 31, 2010 and March 31, 2009 ( fiscal 2010 and fiscal 2009 )*

### Revenue

Our revenues are comprised of the following:

	Year Ended March 31,	
	2010	2009
	(in \$000 s)	
Impella products	\$ 57,799	\$ 36,364
Other products	26,966	36,148
Total product revenues	84,765	72,512
Funded research and development	948	698
Total revenues	\$ 85,713	\$ 73,210

Product revenues for fiscal 2010 increased by \$12.3 million, or 17%, to \$84.8 million from \$72.5 million for fiscal 2009. The increase in product revenue was primarily due to an increase in Impella revenue due to greater demand in the U.S. of the Impella 2.5, offset by a decrease in our other non-Impella revenue, primarily related to BVS and AB5000.

Impella product revenues for fiscal 2010 increased by \$21.4 million, or 59% to \$57.8 million from \$36.4 million for fiscal 2009. 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, as we focus on increasing utilization of Impella 2.5 through continued sales force and physician training. We have also generated sales of Impella 5.0 and Impella LD in the U.S. in fiscal 2010 following 510(k) clearance received in April 2009.

Other product revenues for fiscal 2010 decreased by \$9.1 million or 25%, to \$27.0 million from \$36.1 million for fiscal 2009. 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.

### Cost of Product Revenues

Cost of product revenues for fiscal 2010 increased by \$2.1 million or 10%, to \$22.5 million from \$20.4 million for fiscal 2009. This was due to shipments of higher volumes of Impella 2.5 disposable products in fiscal 2010. Gross margin for fiscal 2010 was 74% compared to 72% for fiscal 2009. The increase in gross margin was primarily due to higher reorders of Impella 2.5 disposables and lower amount of Impella and iPulse console placements.





---

### **Research and Development Expenses**

Research and development expenses for fiscal 2010 increased by \$0.7 million, or 3%, to \$26.0 million from \$25.3 million in fiscal 2009. The increase in research and development expenses was due to higher clinical trial activity and Impella program spending on product enhancements to Impella 2.5 during fiscal 2010. Research and development expenses for fiscal 2010 and 2009 included \$7.4 million and \$7.1 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, particularly Impella 2.5, across a clinical spectrum of circulatory care.

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

Selling, general and administrative expenses for fiscal 2010 increased by \$5.4 million, or 10%, to \$60.8 million from \$55.4 million in fiscal 2009. The increase is primarily due to investments in marketing initiatives and commercial infrastructure to support the launch and expansion of the Impella platform.

### **Amortization of Intangibles**

Amortization of intangible assets was \$1.5 million for fiscal 2010 compared to \$1.6 million for fiscal 2009. Amortization primarily relates to specifically identified assets from the Impella acquisition.

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

Investment income, net, was \$0.4 million for fiscal 2010, representing an increase of \$1.8 million from investment expense of \$1.4 million for fiscal 2009. The increase in investment income for fiscal 2010 was due to improvements in the fair value of our Columbia Fund investment that allowed us to recover a portion of the unrealized losses previously incurred on our investment in the Columbia Fund.

### **Gain on Sale of WorldHeart Stock**

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. In February and March 2010, we sold 2,543,496 shares of WorldHeart common stock, which resulted in a gain of \$6.4 million.

### **Income Tax Provision**

During fiscal 2010 and 2009, we recorded a provision for income taxes of \$0.7 million and \$0.8 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. 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. The decrease in income tax expense in fiscal 2010 is due to a refundable research and development tax credit we received in January 2010.

### **Net Loss**

During fiscal 2010, we incurred a net loss of \$19.0 million, or \$0.52 per share compared to a net loss of \$31.6 million, or \$0.91 per share, for the prior fiscal year. The decrease in the net loss in fiscal 2010 compared to fiscal 2009 is due primarily to increased Impella sales as a result of our focus on increasing Impella utilization in the U.S. and a \$6.4 million gain from the sale of WorldHeart stock in fiscal 2010.

### **Liquidity and Capital Resources**

At March 31, 2011, our cash, cash equivalents and short-term marketable securities totaled \$60.3 million, an increase of \$2.0 million compared to \$58.3 million in cash, cash equivalents and short-term marketable securities at March 31, 2010. 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 will be sufficient to fund our operations for at least the next twelve months.

Marketable securities at March 31, 2011 include \$54.5 million held in funds that invest solely in U.S. Treasury securities. We are not a party to any interest rate swaps, currency hedges or derivative contracts of any type and have no exposure to commercial paper or auction rate

securities markets. We continue to monitor our cash position closely with recent economic events and only invest excess cash in short term U.S. treasury securities.

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 commercial infrastructure in the U.S., increase our Impella manufacturing capacity, fund new product development, and general working capital needs. Through March 31, 2011, we have funded our operations principally from product sales 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 government funded research and development revenue.

Our operating activities during the year ended March 31, 2011 provided cash of \$1.6 million as compared to a use of cash of \$7.4 million during the prior year. Our net loss for the year ended March 31, 2011 was \$11.8 million and our accounts receivable and inventories increased by \$3.4 million during fiscal 2011. The uses of cash were offset by non-cash expenses of \$5.4 million related to stock-based compensation expense, \$3.9 million of depreciation and amortization, and \$2.8 million in write-downs of inventory during fiscal 2011. Additionally, accounts payable, accrued expenses, and deferred revenue increased by \$3.8 million in fiscal 2011.

Our investing activities during the year ended March 31, 2011 used cash of \$2.4 million as compared to \$8.8 million provided during the prior year. Cash used by investment activities for the year ended March 31, 2011 consisted primarily of \$1.8 million in cash expenditures for property and equipment primarily related to computer software projects and manufacturing equipment. We also had net purchases of \$1.0 million of short-term marketable securities in fiscal 2011 as we were able to primarily fund our activities from operating cash flows. Partially offsetting the use of cash was \$0.5 million in proceeds from the sale of WorldHeart stock in fiscal 2011.

Our financing activities during the year ended March 31, 2011 provided cash of \$1.4 million as compared to \$1.0 million during the prior year. Cash provided by financing activities for fiscal 2011 were attributable to the exercise of stock options and proceeds from our employee stock purchase plan.

Capital expenditures for fiscal 2012 are estimated to be \$3.0 to \$5.0 million, which relate primarily to our planned manufacturing capacity increases for Impella 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. At March 31, 2011, we had no debt outstanding.

#### ***Contractual Obligations and Commercial Commitments***

The following table summarizes our contractual obligations at March 31, 2011 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

	<b>Payments Due By Fiscal Year (in \$000 s)</b>				
	<b>Total</b>	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>More than 5 Years</b>
<b>Contractual Obligations</b>					
Operating lease commitments	\$ 5,512	\$ 1,639	\$ 2,322	\$ 1,551	\$
Contractual obligations (1)	5,416	168	1,344	2,904	1,000
<b>Total obligations</b>	<b>\$ 10,928</b>	<b>\$ 1,807</b>	<b>\$ 3,666</b>	<b>\$ 4,455</b>	<b>\$ 1,000</b>

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

We have no long-term debt, capital leases or other material commitments for open purchase orders and clinical trial agreements at March 31, 2011 other than those shown in the table above.

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

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

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

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

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

We have a lease for our European headquarters in Aachen, Germany. The lease payments are approximately 36,000 (Euro) (approximately U.S. \$50,000) per month and the lease term expires in December 2012.

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 was for a term of 25 years and one week, commencing on July 18, 2008. The monthly rent due under the lease agreement and payable monthly was 22,455.33 (Euro) (approximately U.S. \$30,000) per month through April 17, 2013.

We relocated the production equipment from our Athlone, Ireland manufacturing facility to our Aachen and Danvers facilities and fully vacated the Athlone facility in the first quarter of fiscal 2011. In March 2011, we terminated our lease agreement and paid a termination fee of approximately \$0.8 million as a result of the early termination.

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

We enter into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements at March 31, 2011.

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

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

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

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

### ***Primary Market Risk Exposures***

Our cash, cash equivalents and short-term marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at March 31, 2010, we believe the decline in fair market value of our investment portfolio would be immaterial. Marketable securities at March 31, 2011 consist of \$54.5 million in five funds that invest in U.S. Treasury securities and related interest.



---

**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, 2011, the result would have been a reduction of stockholders' equity of approximately \$4.1 million.

**Fair Value of Financial Instruments**

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

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of March 31, 2011. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2011, these disclosure controls and procedures were effective to provide reasonable assurance that material information required to be disclosed by us, including our consolidated subsidiaries, in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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

During the fourth quarter of our fiscal year ended March 31, 2011, 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, 2011.

**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.

Deloitte & Touche LLP, an independent registered public accounting firm that audited our financial statements for the year ended March 31, 2011, 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, 2011, 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, 2011, 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, 2011 of the Company and our report dated June 1, 2011 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

June 1, 2011



**ITEM 9B. OTHER INFORMATION**

Not applicable.

**PART III**

**ITEM 10. DIRECTOR, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

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

Proposal No. 1: Election of Directors,

Executive Officers and Directors,

Audit Committee Report,

Corporate Governance, and

Section 16(a) Beneficial Ownership Reporting Compliance.

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

**ITEM 11. EXECUTIVE COMPENSATION**

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

Executive Compensation

Compensation Discussion and Analysis,

Compensation Committee Interlocks and Insider Participation, and

Compensation Committee Report.

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

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

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

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.

## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) The financial statements from our Annual Report for our fiscal year ending March 31, 2011 are attached hereto.

<u>Report of Independent Registered Public Accounting Firm</u>	<b>Page</b>
<u>Consolidated Balance Sheets as of March 31, 2011 and 2010</u>	F-2
<u>Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2011, 2010, and 2009</u>	F-3
<u>Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended March 2011, 2010, and 2009</u>	F-4
<u>Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2011, 2010, and 2009</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6
	F-7

(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		Exhibit No.
		10-K	Form	Filing Date	
2.1	Share Purchase Agreement for the acquisition of Impella Cardio Systems AG, dated April 26, 2005.		8-K	May 16, 2005	2.1
3.1	Restated Certificate of Incorporation.		S-3	September 29, 1997	3.1
3.2	Restated By-Laws, as amended.		10-K	May 27, 2004	3.2
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock filed as Exhibit 3.3 to the 1997 Registration Statement.*		S-3	September 29, 1997	3.3
3.4	Amendment to the Company's Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000.		8-K	March 21, 2007	3.4
4.1	Specimen Certificate of common stock.		S-1	June 5, 1987	4.1
10.1*	Form of Indemnification Agreement for Directors and Officers.		S-1	June 5, 1987	10.13
10.2*	1992 Combination Stock Option Plan.		10-Q	October 27, 1995	10.2
10.3*	Amendment to 1992 Combination Stock Option Plan.		10-Q	October 14, 1997	10.2
10.4*	1988 Employee Stock Purchase Plan, as amended.		10-Q	February 8, 2005	10.11
10.5*	1989 Non-Qualified Stock Option Plan for Non-Employee Directors.		10-Q	October 27, 1995	10.1

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

10.6*	1998 Equity Incentive Plan.	10-Q/A	January 8, 1999	10
10.7*	2000 Stock Incentive Plan Agreement, as amended.	Schedule 14A	July 15, 2005	Appendix A
10.8*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Directors.	10-Q	February 9, 2006	10.16

Edgar Filing: ABIOMED INC - Form 10-K

Exhibit No.	Description	Filed with this Form		Incorporated by Reference		Exhibit No.
		10-K	Form	Filing Date		
10.9*	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
10.10*	Amended and Restated 2008 Stock Incentive Plan.	X				
10.11*	Form of Non-Statutory Stock Option Agreement for Employees and Consultants under 2008 Stock Incentive Plan.		8-K	August 18, 2008		10.1
10.12*	Form of Non-Statutory Stock Option Agreement for Non-Employee Directors under 2008 Stock Incentive Plan.		8-K	August 18, 2008		10.2
10.13*	Form of Restricted Stock Agreement under 2008 Stock Incentive Plan.		8-K	August 18, 2008		10.3
10.14*	Form of Change of Control Agreement.		8-K	August 18, 2008		10.4
10.15*	Employment Agreement of Michael R. Minogue dated April 5, 2004 (including Change in Control Agreement).		10-Q	August 9, 2004		10.10
10.16*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008.		10-Q	February 9, 2009		10.1
10.17*	Amendment to Change in Control Agreement with Michael R. Minogue dated December 31, 2008.		10-Q	February 9, 2009		10.1
10.18*	Inducement stock option granted to Michael R. Minogue dated April 5, 2004.		10-Q	August 9, 2004		10.11
10.19*	Restricted Stock Agreement between Abiomed, Inc. and Michael R. Minogue.		10-Q	October 9, 2005		10.15
10.20*	Offer Letter with Robert L. Bowen dated December 15, 2008.		8-K	December 22, 2008		99.2
10.21*	Offer letter with David Weber dated April 23, 2007		10-Q	August 9, 2007		10.1
10.22*	Separation agreement and release with Daniel J. Sutherby dated October 10, 2008.		10-Q	February 9, 2009		10.1
10.23*	Summary of Executive Compensation.	X				
10.24*	Summary of Director Compensation.		10-K	June 16, 2008		10.21
10.25*	Form of Employment, Nondisclosure and Non Competition Agreement.		10-K	June 14, 2006		10.20
10.26	Facility Lease dated January 8, 1999 for the premises at 22 Cherry Hill Drive.		10-Q	February 12, 1999		10
10.27	First Amendment to Lease Agreement dated June 27, 2008 between Abiomed, Inc. and Leo C. Thibeault, Jr., Trustee of The Thibeault Nominee Trust.		8-K	July 2, 2008		10.1
10.28	Lease Agreement dated as of July 18, 2008 by and among Abiomed, Inc., Abiomed Athlone Limited, and J.J. Rhatigan and Co.		10-K	June 8, 2010		10.29
10.29	Surrender of Lease dated as of March 8, 2011 by and among Abiomed, Inc., Abiomed Athlone Limited, and J.J. Rhatigan and Co.		8-K	March 11, 2011		10.1
11.1	Statement regarding computation of Per Share Earnings (see Note 2, Notes to Consolidated Financial Statements).	X				

Edgar Filing: ABIOMED INC - Form 10-K

Exhibit No.	Description	Filed with this Form		Incorporated by Reference		Exhibit No.
		10-K	Form	Filing Date		
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.

## 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 2, 2011

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.

SIGNATURE	TITLE	DATE
<i>/s/</i> MICHAEL R. MINOGUE  <b>Michael R. Minogue</b>	Chief Executive Officer, President and Chairman (Principal Executive Officer)	June 2, 2011
<i>/s/</i> ROBERT L. BOWEN  <b>Robert L. Bowen</b>	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	June 2, 2011
<i>/s/</i> W. GERALD AUSTEN  <b>W. Gerald Austen</b>	Director	June 2, 2011
<i>/s/</i> LOUIS E. LATAIF  <b>Louis E. Lataif</b>	Director	June 2, 2011
<i>/s/</i> DESMOND H. O. CONNELL, JR.  <b>Desmond H. O. Connell, Jr.</b>	Director	June 2, 2011
<i>/s/</i> DOROTHY E. PUHY  <b>Dorothy E. Puhly</b>	Director	June 2, 2011
<i>/s/</i> ERIC A. ROSE  <b>Eric A. Rose</b>	Director	June 2, 2011
<i>/s/</i> HENRI A. TERMEER  <b>Henri A. Termeer</b>	Director	June 2, 2011
<i>/s/</i> MARTIN P. SUTTER  <b>Martin P. Sutter</b>	Director	June 2, 2011
<i>/s/</i> PAUL THOMAS	Director	June 2, 2011

**Paul Thomas**

40



ABIOMED, INC.

Consolidated Financial Statements

Index

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of March 31, 2011 and 2010</u>	F-3
<u>Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2011, 2010, and 2009</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended March 2011, 2010, and 2009</u>	F-5
<u>Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2011, 2010, and 2009</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

---

**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, 2011, and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended March 31, 2011. 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, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of March 31, 2011, 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 1, 2011 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

June 1, 2011

## ABIOMED, INC. AND SUBSIDIARIES

## Consolidated Balance Sheets

(in thousands, except share data)

	March 31,	
	2011	2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,831	\$ 4,788
Short-term marketable securities	54,481	53,477
Accounts receivable, net	15,376	13,516
Inventories	7,505	9,211
Prepaid expenses and other current assets	1,544	1,676
Total current assets	84,737	82,668
Property and equipment, net	6,273	6,753
Intangible assets, net	1,632	2,979
Goodwill	38,946	37,170
Total assets	\$ 131,588	\$ 129,570
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,283	\$ 3,764
Accrued expenses	14,078	13,011
Deferred revenue	1,982	1,289
Total current liabilities	22,343	18,064
Long-term deferred tax liability	4,010	3,040
Other long-term liabilities	492	510
Total liabilities	26,845	21,614
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value		
Authorized 1,000,000 shares; Issued and outstanding none		
Common stock, \$.01 par value	377	375
Authorized 100,000,000 shares; Issued 37,756,719 shares at March 31, 2011 and 37,484,018 shares at March 31, 2010; Outstanding 37,705,765 shares at March 31, 2011 and 37,433,064 shares at March 31, 2010		
Additional paid in capital	379,218	372,425
Accumulated deficit	(274,770)	(263,015)
Treasury stock at cost 50,954 shares	(827)	(827)
Accumulated other comprehensive income (loss)	745	(1,002)
Total stockholders' equity	104,743	107,956
Total liabilities and stockholders' equity	\$ 131,588	\$ 129,570

See notes to consolidated financial statements

## ABIOMED, INC. AND SUBSIDIARIES

## Consolidated Statements of Operations

(in thousands, except per share data)

	Fiscal Years Ended March 31,		
	2011	2010	2009
<b>Revenue:</b>			
Product revenue	\$ 99,837	\$ 84,765	\$ 72,512
Funded research and development	1,314	948	698
	101,151	85,713	73,210
<b>Costs and expenses:</b>			
Cost of product revenue	21,977	22,529	20,437
Research and development	26,677	25,954	25,328
Selling, general and administrative	62,287	60,837	55,357
Amortization of intangible assets	1,395	1,469	1,606
	112,336	110,789	102,728
Loss from operations	(11,185)	(25,076)	(29,518)
<b>Other income (expense):</b>			
Investment income (expense), net	9	373	(1,404)
Gain on sale of WorldHeart stock	456	6,389	313
Other expense, net	(143)	(39)	(236)
	322	6,723	(1,327)
Loss before income tax provision	(10,863)	(18,353)	(30,845)
Income tax provision	892	671	752
Net loss	\$ (11,755)	\$ (19,024)	\$ (31,597)
Basic and diluted net loss per share	\$ (0.32)	\$ (0.52)	\$ (0.91)
Weighted average shares outstanding	37,167	36,875	34,882

*See notes to consolidated financial statements*

## ABIOMED, INC. AND SUBSIDIARIES

## Consolidated Statements of Stockholders Equity

(in thousands, except share data)

	Common Stock			Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Equity	Comprehensive Loss
	Number of shares	Par value	Additional Paid in Capital					
Balance, April 1, 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)
Comprehensive loss								(38,249)
Balance, March 31, 2009	36,685,889	367	362,097	(243,991)	(827)	(1,663)	115,983	
Common stock issued for milestone payment to Impella CardioSystems AG	663,535	7	3,820				3,827	
Restricted stock issued	50,000							
Stock options exercised	76,350	1	638				639	
Stock issued under employee stock purchase plan	61,380	1	339				340	
Stock issued to directors	17,223		165				165	
Cancellation of restricted stock	(121,313)	(1)	1					
Stock compensation expense			5,365				5,365	
Net loss				(19,024)			(19,024)	(19,024)
Foreign currency translation						661	661	661
Comprehensive loss								(18,363)
Balance, March 31, 2010	37,433,064	375	372,425	(263,015)	(827)	(1,002)	107,956	
Restricted stock issued	356,000	4	(4)					
Stock options exercised	126,460	1	1,060				1,061	
Stock issued under employee stock purchase plan	36,207		313				313	
Stock issued to directors	3,096							
Cancellation of restricted stock	(249,062)	(3)	3					
Stock compensation expense			5,421				5,421	
Net loss				(11,755)			(11,755)	(11,755)
Foreign currency translation						1,747	1,747	1,747
Comprehensive loss								\$ (10,008)
Balance, March 31, 2011	37,705,765	\$ 377	\$ 379,218	\$ (274,770)	\$ (827)	\$ 745	\$ 104,743	

See notes to consolidated financial statements

## ABIOMED, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

(in thousands)

	Fiscal Years Ended March 31,		
	2011	2010	2009
<b>Operating activities:</b>			
Net loss	\$ (11,755)	\$ (19,024)	\$ (31,597)
Adjustments required to reconcile net loss to net cash used for operating activities:			
Depreciation and amortization	3,948	4,898	5,016
Bad debt expense	139	22	438
Stock-based compensation	5,421	5,365	8,834
Write-down of inventory	2,781	3,536	1,444
Loss on disposal of fixed assets	29	54	165
Deferred tax provision	970	954	721
Change in unrealized loss on marketable securities		(342)	510
Gain on sale of WorldHeart common stock	(456)	(6,389)	(313)
Changes in assets and liabilities:			
Accounts receivable	(1,923)	2,210	(2,539)
Inventories	(1,508)	927	(1,598)
Prepaid expenses and other assets	161	(560)	992
Accounts payable	2,480	(1,387)	(2,402)
Accrued expenses	605	2,299	1,948
Deferred revenue	682	75	76
<b>Net cash provided by (used for) operating activities</b>	<b>1,574</b>	<b>(7,362)</b>	<b>(18,305)</b>
<b>Investing activities:</b>			
Purchases of short-term marketable securities	(8,004)	(11,869)	(60,180)
Proceeds from the sale and maturity of short-term securities	7,000	17,848	36,813
Proceeds from the sale of WorldHeart common stock	456	6,389	313
Contingent milestone payment on acquisition		(1,750)	
Expenditures for property and equipment	(1,804)	(1,800)	(3,751)
<b>Net cash (used for) provided by investing activities</b>	<b>(2,352)</b>	<b>8,818</b>	<b>(26,805)</b>
<b>Financing activities:</b>			
Issuance of common stock			41,970
Proceeds from the exercise of stock options	1,061	639	4,708
Payments in lieu of issuance of common stock for payroll taxes			(711)
Proceeds from employee stock purchase plan	313	340	263
<b>Net cash provided by financing activities</b>	<b>1,374</b>	<b>979</b>	<b>46,230</b>
Effect of exchange rate changes on cash	447	568	(1,377)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>1,043</b>	<b>3,003</b>	<b>(257)</b>
Cash and cash equivalents at beginning of year	4,788	1,785	2,042
<b>Cash and cash equivalents at end of year</b>	<b>\$ 5,831</b>	<b>\$ 4,788</b>	<b>\$ 1,785</b>
<b>Supplemental disclosures:</b>			
Taxes paid, net of refunds	\$	\$ 300	\$ 242
Common shares issued for business acquisition		3,827	5,574
Fixed assets in accounts payable	48	107	44

See note to consolidated financial statements

---

**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 provider of medical devices in circulatory support and offers a continuum of care in heart recovery to acute heart failure patients. 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 Company's products are used in the cardiac catheterization lab (cath lab) by interventional cardiologists and/or in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophelactically during high risk angioplasty procedures or who are in pre-shock, shock or profound cardiogenic shock.

**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.

**Cash Equivalents and Marketable Securities**

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

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

**Major Customers and Concentrations of Credit Risk**

Abiomed primarily sells its products to hospitals and distributors. No customer accounted for more than 10% of total product revenues in fiscal year 2011, 2010, or 2009. No customer had an accounts receivable balance greater than 10% of total accounts receivable at the end of fiscal years 2011 and 2010.

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.

---

ABIOMED, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

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

Financial instruments which potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and short-term 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.

**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.

**Impairment of Long-Lived Assets**

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 at that time records as expense the net capitalized amount of such patent application or patent.

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, 2010 and determined that no write-down for impairment was necessary.

**Financial Instruments**

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

**Accrued Expenses**

As part of the process of preparing its financial statements, the Company is required to estimate accrued expenses. This process involves identifying services that third parties have performed and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in its financial statements. Examples of estimated accrued expenses include contract service fees, such as amounts due to clinical research organizations, professional service fees, such as attorneys and accountants, and investigators in conjunction with clinical trials and third party expenses relating to marketing efforts associated with commercialization of the Company's





---

**ABIOMED, INC. AND SUBSIDIARIES**

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

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

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.

**Revenue Recognition**

The Company recognizes revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectibility is reasonably assured. Revenue from product sales to new customers is recognized when all elements of the sale have been delivered. 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 and therefore does not record a provision for returns.

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

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

**Product Warranty**

The Company provides a one-year warranty for certain products sold in which estimated contractual warranty obligations are recorded as an expense at the time of shipment and are included in accrued expenses in the accompanying consolidated balance sheets. The Company's products are subject to 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 income (loss) component of stockholders' equity. Currency transaction gains and losses are included as other income in the statements of operations.

**Net Loss 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, 2011, 2010 and 2009, 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.

Excluded from the calculation of diluted weighted average shares outstanding for the fiscal years ended March 31, 2011, 2010, and 2009 are stock options outstanding in the amount of 5,945,000, 5,557,000 and 4,583,000, respectively, and unvested shares of restricted stock for the fiscal years ended March 31, 2011, 2010, and 2009 in the amount of 407,000, 379,000, and 480,000, respectively.

**Comprehensive Loss**

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



---

ABIOMED, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

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

**Accounting for Stock-Based Compensation**

All share-based expense, including grants of employee stock options and restricted stock awards, are based on the grant-date fair value of those share-based payments, adjusted for expected forfeitures. The fair value of stock option grants is estimated using the Black-Scholes option pricing model. Use of the valuation model requires management to make certain assumptions with respect to selected model inputs. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on historical volatility of the Company's stock. The 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.

Management estimates the average expected life based on historical experience of the Company's 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 the Company does not pay dividends and does not expect to pay any cash dividends in the foreseeable future.

The estimated fair value of all awards is recognized as compensation expense on a straight-line basis over the service period. Accruals of compensation cost for an award with a performance condition are based on the probable outcome of the performance conditions. The cumulative effects of changes in the probability outcomes are recorded in the period in which the changes occur.

**Recent Accounting Pronouncements**

In October 2009, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, or ASU No. 2009-13, which amended FASB Accounting Standard Codification Subtopic 605-25. This amended guidance requires an entity to allocate revenue to each unit of accounting in multiple deliverable arrangements based on the relative selling price of each deliverable. It also changes the level of evidence required to separate deliverables by requiring an entity to make its best estimate of the stand-alone selling price of the deliverables with more objective evidence if the selling price is not available. Previously the Company was required to have objective evidence of the undelivered items in order to have separate units of accounting for multiple element arrangements. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for the Company means no later than April 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than April 1, 2011, would have required the Company to apply this guidance retrospectively effective as of April 1, 2010 and required disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. The Company did not elect to early adopt this amended guidance and does not expect the adoption of this new guidance to have a material impact on the Company's financial statements.

**Note 3. Fair Value Measurements**

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

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

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

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

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

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

## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

## Note 3. Fair Value Measurements (Continued)

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 Company's marketable securities were invested in the following:

	Level 1	Level 2 (in \$000 s)	Level 3	Total
At March 31, 2011:				
U.S. Treasury securities	\$ 54,481	\$	\$	\$ 54,481
At March 31, 2010:				
U.S. Treasury securities	\$ 53,477	\$	\$	\$ 53,477

The Company records these marketable securities at fair value and has classified all of its investments as Level 1 since quoted market prices in active markets are readily available.

## Note 4. Accounts Receivable

The components of accounts receivable are as follows:

	March 31, 2011      2010 (in \$000 s)	
Trade receivables	\$ 15,650	\$ 13,674
Allowance for doubtful accounts	(274)	(158)
	\$ 15,376	\$ 13,516

## Note 5. Inventories

The components of inventories are as follows:

	March 31, 2011      2010 (in \$000 s)	
Raw materials and supplies	\$ 2,784	\$ 2,759
Work-in-progress	3,689	3,344
Finished goods	1,032	3,108

Edgar Filing: ABIOMED INC - Form 10-K

\$ 7,505      \$ 9,211

The Company's inventories relate to its circulatory care product lines, primarily the AB5000, BVS 5000 and Impella product platforms. Finished goods and work-in-process inventories consist of direct material, labor and overhead. During the years ended March 31, 2011, 2010, and 2009, the Company recorded \$2.8 million, \$3.5 million, and \$1.4 million in write-downs of inventory.

F-11

## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

**Note 5. Inventories (Continued)**

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 Company had \$0.7 million and \$1.1 million in demo inventory at March 31, 2011 and March 31, 2010, respectively. Amortization expense related to demo inventory was \$0.6 million, \$1.2 million, and \$1.4 million for the years ended March 31, 2011, 2010, and 2009, respectively.

**Note 6. Property and Equipment**

The components of property and equipment are as follows:

	March 31,	
	2011	2010
	(in \$000 s)	
Machinery and equipment	\$ 11,996	\$ 11,104
Furniture and fixtures	489	494
Leasehold improvements	967	908
Construction in progress	870	515
<b>Total cost</b>	<b>14,322</b>	<b>13,021</b>
Less accumulated depreciation	(8,049)	(6,268)
	<b>\$ 6,273</b>	<b>\$ 6,753</b>

Depreciation expense related to property and equipment was \$1.9 million, \$2.5 million, and \$2.1 million for the years ending March 31, 2011, 2010, and 2009, respectively.

**Note 7. Intangible Assets and Goodwill**

The carrying amount of goodwill at March 31, 2011 and 2010 was \$38.9 million and \$37.2 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG, or Impella. The goodwill activity for the year ended March 31, 2011 is as follows:

	(in \$000 s)
Balance at March 31, 2009	\$ 31,295
Purchase price adjustments - milestone payment to Impella	5,583
Exchange rate impact	292
Balance at March 31, 2010	37,170
Exchange rate impact	1,776
Balance at March 31, 2011	\$ 38,946

The components of intangible assets are as follows:

	March 31, 2011		March 31, 2010
Cost		Cost	

Edgar Filing: ABIOMED INC - Form 10-K

		<b>Accumulated Amortization (in \$000 s)</b>	<b>Net Book Value</b>		<b>Accumulated Amortization (in \$000 s)</b>	<b>Net Book Value</b>
Patents	\$ 7,099	\$ 6,005	\$ 1,094	\$ 6,790	\$ 4,792	\$ 1,998
Trademarks and tradenames	361	299	62	345	236	109
Distribution agreements	690	584	106	659	463	196
Acquired technology	2,384	2,014	370	2,272	1,596	676
	\$ 10,534	\$ 8,902	\$ 1,632	\$ 10,066	\$ 7,087	\$ 2,979

Amortization expense for intangible assets was \$1.4 million, \$1.5 million, and \$1.6 million for the years ending March 31, 2011, 2010 and 2009, respectively. The Company's expected amortization expense will be \$1.4 million for fiscal 2012 and \$0.2 million for fiscal 2013.



## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

**Note 8. Stock Award Plans and Stock Based Compensation****Stock Option Plans**

The Company grants stock options and restricted stock awards to employees and others. Virtually all outstanding stock options of the Company as of March 31, 2011 were granted with an exercise price equal to the fair market value on the date of grant. For all 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.

The Company's 2008 Stock Incentive Plan (the "Plan") authorizes the grant of a variety of equity awards to the Company's officers, directors, employees, consultants and advisers, including awards of unrestricted and restricted stock, 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 5,508,688 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. Each share of stock issued pursuant to a stock option or stock appreciation right counts as one share against the maximum number of shares issuable under the Plan, while each share of stock issued pursuant to any other type of award counts as 1.58 shares against the maximum number of shares issuable under the Plan for grants made on or after August 11, 2010 (and as 1.5 shares for grants made prior to that date). At March 31, 2011, a total of 1,516,500 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, 2011, 2010, and 2009, were as follows:

	2011	March 31, 2010 (in \$000 s)	2009
Cost of product revenue	\$ 214	\$ 452	\$ 377
Research and development	1,001	744	1,808
Selling, general and administrative	4,206	4,169	6,649
	\$ 5,421	\$ 5,365	\$ 8,834

The stock-based compensation expense for the year ended March 31, 2011 includes \$3.8 million related to stock options and \$1.6 million related to performance-based restricted stock, as described below. The stock-based compensation expense for the year ended March 31, 2010 includes \$5.5 million related to stock options and a reversal of \$0.1 million related to performance-based restricted stock and the Company's Employee Stock Purchase Plan ("ESPP"). 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 ESPP.

The remaining unrecognized stock-based compensation expense for unvested stock option awards at March 31, 2011 was approximately \$5.7 million, net of forfeitures, and the weighted-average period over which this cost will be recognized is 1.7 years. Benefits of tax deductions in excess of recognized compensation cost are reported as a financing cash flow, rather than as an operating cash flow.

## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

## Note 8. Stock Award Plans and Stock Based Compensation (Continued)

## Stock Option Activity

The following table summarized stock option activity for the year ended March 31, 2011:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at beginning of year	5,557	\$ 10.56	6.62	
Granted	934	10.08		
Exercised	(126)	8.40		
Forfeited	(282)	13.19		
Expired	(138)	16.56		
Outstanding at end of year	5,945	\$ 10.27	6.30	\$ 25,418
Exercisable at end of year	3,910	\$ 10.80	5.18	\$ 15,829
Options vested and expected to vest at end of year	3,980	\$ 9.49		

The total intrinsic value of options exercised for fiscal years 2011, 2010, and 2009 was \$0.4 million, \$0.1 million and \$4.3 million, respectively. The total cash received from employees as a result of employee stock option exercises during the years ended March 31, 2011, 2010, and 2009 was approximately \$1.0 million, \$0.6 million and \$4.7 million, respectively. The total fair value of options vested in fiscal years 2011, 2010, and 2009 was \$4.5 million, \$5.4 million and \$6.6 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, 2011, 2010, and 2009 were calculated using the following weighted average assumptions:

	2011	2010	2009
Risk-free interest rate	2.04%	2.45%	2.77%
Expected option life (years)	5.30	5.24	5.10
Expected volatility	50.9%	53.9%	50.4%

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on the historical volatility of the Company's stock and adjustments for factors not reflected in historical volatility that may be more indicative of future volatility. The Company estimates the expected term 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, 2011, 2010, and 2009 was \$4.72, \$3.02, and \$6.71 per share, respectively.



## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

## Note 8. Stock Award Plans and Stock Based Compensation (Continued)

*Restricted Stock*

The following table summarizes restricted stock activity for the fiscal year ended March 31, 2011:

	Number of Shares (in thousands)	March 31, 2011	
			Grant Date Fair Value (per share)
Restricted stock awards at beginning of year	379	\$	15.93
Granted	356		10.00
Vested	(79)		12.05
Forfeited	(249)		18.63
Restricted stock awards at end of year	407	\$	9.84

The remaining unrecognized compensation expense for restricted stock awards at March 31, 2011 was \$2.8 million and the weighted-average period over which this cost will be recognized is 2.0 years.

*Performance Based Awards*

Included in the stock option and restricted stock activity discussed above are certain awards granted in fiscal years 2009, 2010 and 2011 that contain performance based vesting.

In August 2008, 406,250 shares of restricted common stock and options to purchase 93,750 shares of common stock were issued to certain executive officers and members of senior management of the Company, all of which would vest upon achievement of certain sales and profitability performance targets in fiscal years 2009 through 2011. In August 2009, 50,000 additional shares of restricted stock were issued to certain additional executive officers of the Company, which had the same vesting milestones based on fiscal 2010 and 2011 performance targets. In March 2009, the Company met one of the prescribed performance milestones and a portion of these shares and stock options vested.

During the fiscal years ended March 31, 2010 and 2011, the Company determined that it did not meet any of the prescribed performance targets for fiscal 2010 and 2011. Accordingly, 333,125 shares of restricted stock related to these awards were forfeited and 76,875 shares underlying stock options related to these awards failed to vest. There is no remaining compensation expense related to the August 2008 award performance targets as of March 31, 2011.

In June 2010, 311,000 shares of restricted stock and a performance award for the potential issuance of 45,000 shares of common stock were issued to certain executive officers and members of senior management of the Company, all of which could vest upon achievement of prescribed performance milestones. During the year ended March 31, 2011, the Company determined that it met the prescribed performance targets and a portion of these shares and stock options vested. As of March 31, 2011, the Company has determined that it is probable it will meet the remaining prescribed performance milestones for both of these awards.

During the year ended March 31, 2011, the Company has recorded \$1.0 million in stock-based compensation cost for shares and options in which the prescribed performance milestones have been achieved or are probable of being achieved. The remaining unrecognized compensation expense related to these shares and options at March 31, 2011 is \$2.3 million based on the Company's current assessment of probability of achieving the performance milestones.

## Note 9. 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.



## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

## Note 9. Income Taxes (Continued)

At March 31, 2011, the Company had federal and state net operating loss carryforwards, or NOLs, of approximately \$182.6 million and \$127.0 million, respectively, which expire in varying years from fiscal 2012 through fiscal 2031. Additionally, at March 31, 2011, the Company had federal and state research and development credit carryforwards of approximately \$9.3 million and \$4.7 million, respectively, which expire in varying years from fiscal 2012 through fiscal 2031. The Company acquired Impella, a German-based company, in May 2005. Impella had pre-acquisition net operating losses of approximately \$19.4 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 \$1.3 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. To date, there has been no challenge from the German tax authorities about the ability to use these German net operating losses.

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 completed a Section 382 study and analysis in fiscal 2008 to determine whether changes in the composition of its stockholders, including the Company's acquisition of Impella or the Company's public offering in August 2008, resulted in an ownership change for purposes of Section 382. The Company believes that all of its federal and state NOLs will be available for carryforward to future tax periods, subject to 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.

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

	2011	2010 (in \$000 s)	2009
<b>Loss before provision for income taxes:</b>			
United States	\$ (6,522)	\$ (7,698)	\$ (20,672)
Foreign	(4,341)	(10,655)	(10,173)
Loss before income taxes	\$ (10,863)	\$ (18,353)	\$ (30,845)
<b>Provision for income taxes:</b>			
<b>Current:</b>			
Federal	\$ (78)	\$ (361)	\$
State	81	78	32
Foreign			
Total current	3	(283)	32
<b>Deferred:</b>			
Federal	825	811	612
State	64	143	108
Foreign			
Total deferred	889	954	720
Total income tax provision	\$ 892	\$ 671	\$ 752



## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

## Note 9. Income Taxes (Continued)

Differences between the federal statutory income tax rate and the effective tax rates for the years ended March 31, 2011, 2010, and 2009 are as follows:

	2011	2010	2009
Statutory income tax rate	34.0%	34.0%	34.0%
Increase (decrease) resulting from:			
Change in valuation allowance	(33.8)%	(44.1)%	(41.2)%
State taxes, net	(14.1)		
Credits	8.4	9.0	8.6
Rate differential on foreign operations	(0.1)	(1.1)	(1.9)
Stock based compensation	(0.3)	(0.1)	(1.5)
Expiry of state NOL carryforwards	(2.6)		
Other, net	0.3	(1.4)	(0.4)
Effective tax rate	(8.2)%	(3.7)%	(2.4)%

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

	2011	March 31, 2010
	(in \$000 s)	
<b>Deferred tax assets</b>		
NOL carryforwards and tax credit carryforwards	\$ 82,588	\$ 75,677
Foreign NOL carryforwards	6,533	6,095
Stock-based compensation	9,455	8,038
Nondeductible reserves and accruals	2,798	3,067
Deferred revenue	764	515
Depreciation	441	460
Amortizable intangibles other than goodwill	4,757	5,018
Change in unrealized losses on marketable securities	294	710
Other, net	1,365	1,317
Capitalized research and development	11,726	16,150
	120,721	117,047
<b>Deferred tax liabilities</b>		
Indefinite lived intangibles	(4,010)	(3,040)
	(4,010)	(3,040)
Net deferred tax asset	116,711	114,007
Valuation allowance	(120,721)	(117,047)
Net deferred tax liability	\$ (4,010)	\$ (3,040)

The change in the valuation allowance was \$3.7 million and \$8.1 million for fiscal 2011 and 2010, respectively, and was primarily due to the impact of the annual operating losses without current tax benefit.



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

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.

F-17

---

ABIOMED, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements (Continued)

**Note 9. Income Taxes (Continued)**

As of March 31, 2011, the Company has accumulated a net deferred tax liability of \$4.0 million which is the result of the difference in accounting for the Company's goodwill, which is amortizable over 15 years for tax purposes but not amortized for book purposes. The net deferred tax liability cannot be offset against the Company's deferred tax assets since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period.

The Company accrues for the effects of uncertain tax positions and the related potential penalties and interest. At March 31, 2011, the Company had no unrecognized tax benefits. It is reasonably possible that the amount of the unrecognized tax benefit with respect to certain of the unrecognized tax positions will increase or decrease during the next 12 months; however, it is not expected that the change will have a significant effect on the Company's results of operations or financial position.

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

**Note 10. Commitments and Contingencies**

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

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

The Company enters into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. Abiomed has never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is immaterial. Accordingly, the Company has no liabilities recorded for these agreements as of March 31, 2011.

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

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

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

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

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

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

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

The Company has a lease for its European headquarters in Aachen, Germany. The lease payments are approximately 36,000 (Euro) (approximately U.S. \$50,000) per month and the lease term expires in December 2012.

F-18

## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

**Note 10. Commitments and Contingencies (Continued)**

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 was for a term of 25 years and one week, commencing on July 18, 2008. The monthly rent due under the lease agreement and payable monthly was 22,455 Euro (approximately U.S. \$30,000) per month through April 17, 2013. The Company relocated the production equipment from its Athlone, Ireland manufacturing facility to its Aachen and Danvers facilities and fully vacated the Athlone facility in the first quarter of fiscal 2011. In March 2011, the Company terminated the lease agreement. The Company paid a termination fee of approximately \$0.8 million as a result of the early termination of the lease.

Total rent expense for the Company's operating leases included in the accompanying consolidated statements of operations approximated \$2.7 million, \$2.2 million, and \$2.4 million for the fiscal years ended March 31, 2011, 2010, and 2009, respectively.

Future minimum lease payments under all significant non-cancelable operating leases as of March 31, 2011 are approximately as follows:

Fiscal Year Ending March 31,	Operating Leases (in \$000 s)
2012	\$ 1,639
2013	1,447
2014	875
2015	825
2016	726
Thereafter	
<b>Total future minimum lease payments</b>	<b>\$ 5,512</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 proceeding or claim which is 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, operations or statements of cash flows.

**Note 11. 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, 2011, 2010, and 2009 are reflected below:

	2011	March 31, 2010 (in \$000 s)	2009
Internally funded	\$ 25,735	\$ 25,434	\$ 24,849
Incurred under government contracts and grants	942	520	479
	<b>\$ 26,677</b>	<b>\$ 25,954</b>	<b>\$ 25,328</b>

## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

**Note 12. Accrued Expenses**

Accrued expenses consisted of the following:

	March 31, 2011                      2010 (in \$000 s)	
Salaries and benefits	\$ 7,416	\$ 7,652
Research and development	3,991	3,081
Professional, accounting and auditing fees	616	565
Warranty	537	482
Other	1,518	1,231
	\$ 14,078	\$ 13,011

**Note 13. Segment and Enterprise Wide Disclosures**

The Company operates in one business segment the research, development and sale of medical devices to assist or replace the pumping function of the failing heart. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results. Approximately 61% and 60% of the Company's total consolidated assets are located within the U.S. as of March 31, 2011 and 2010, respectively. Remaining assets are located in Europe, primarily related to the Company's Impella production facility in Germany, and include goodwill and intangibles of \$40.5 million and \$37.2 million at March 31, 2011 and 2010, respectively, associated with the Impella acquisition from May 2005. Total assets in Europe excluding goodwill and intangibles amounted to 8% and 9% of total consolidated assets at March 31, 2011 and 2010, respectively. International sales (sales outside the U.S. and primarily in Europe) accounted for 8%, 9%, and 14% of total product revenue during the fiscal years ended March 31, 2011, 2010, and 2009, respectively.

**Note 14. Quarterly Results of Operation (Unaudited)**

The following is a summary of the Company's unaudited quarterly results of operations for the fiscal years ending March 31, 2011 and 2010:

	Fiscal Years Ended March 31,				
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total Year
	(in thousands except per share data)				
<b>Fiscal Year 2011</b>					
Total revenues	\$ 22,002	\$ 23,376	\$ 27,244	\$ 28,529	\$ 101,151
Cost of product revenue	5,284	5,408	5,437	5,848	21,977
Other operating expenses	22,773	21,015	22,479	24,092	90,359
Other income (expense), net	318	88	34	(118)	322
Loss before income tax provision	(5,737)	(2,959)	(638)	(1,529)	(10,863)
Income tax provision	243	242	164	243	892
Net loss	\$ (5,980)	\$ (3,201)	\$ (802)	\$ (1,772)	\$ (11,755)
Basic and diluted net loss per share	\$ (0.16)	\$ (0.09)	\$ (0.02)	\$ (0.05)	\$ (0.32)

## ABIOMED, INC. AND SUBSIDIARIES

## Notes to Consolidated Financial Statements (Continued)

## Note 14. Quarterly Results of Operation (Unaudited) (Continued)

	Fiscal Years Ended March 31,				Total Year
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	
	(in thousands except per share data)				
<b>Fiscal Year 2010</b>					
Total revenues	\$ 19,913	\$ 20,022	\$ 22,799	\$ 22,979	\$ 85,713
Cost of product revenue	5,072	5,446	5,772	6,239	22,529
Other operating expenses	22,304	21,973	21,969	22,014	88,260
Other (expense) income, net	(71)	(35)	337	6,492	6,723
(Loss) income before income tax provision	(7,534)	(7,432)	(4,605)	1,218	(18,353)
Income tax provision (benefit)	226	242	(40)	243	671
Net loss (income)	\$ (7,760)	\$ (7,674)	\$ (4,565)	\$ 975	\$ (19,024)
Basic and diluted net (loss) income per share	\$ (0.21)	\$ (0.21)	\$ (0.12)	\$ 0.03	\$ (0.52)

ABIOMED, INC. AND SUBSIDIARIES

SCHEDULE II

Valuation and Qualifying Accounts

(in thousands)

Description	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Allowance for Doubtful Accounts				
Fiscal Year Ended March 31, 2009	\$ 153	\$ 384	\$ 353	\$ 184
Fiscal Year Ended March 31, 2010	184	270	296	158
Fiscal Year Ended March 31, 2011	158	262	146	274