ABIOMED INC
Form 10-K
June 16, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For fiscal year ended March 31, 2008

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	**04-2743260**
(State or Other Jurisdiction of Incorporation or Organization)	***(I.R.S. Employer Identification No.)***
22 Cherry Hill Drive	
Danvers, Massachusetts	**01923**
(Address of Principal Executive Offices)	***(Zip Code)***

(978) 646-1400

(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 x

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 x

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

Indicate by check mark 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 x

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

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

The aggregate market value of the registrant s common stock as of September 30, 2007, 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 $372,478,946.

As of June 09, 2008, 32,956,535 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 2008 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.

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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, including U.S. approval for our Impella products as well as for new products in development;

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

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

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

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

our business strategy;

our revenue growth expectations and our goal of achieving profitability; and

the sufficiency of our liquidity and capital resources.

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

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PART I

ITEM 1. ***BUSINESS***
Overview

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

Industry Background

Heart Disease Overview

According to the American Heart Association, or AHA, 2007 Heart Disease Update Report, there are an estimated 865,000 heart attack patients treated annually at U.S. hospitals. The AHA has also reported that coronary heart disease is the leading cause of death in the U.S. Coronary heart disease is a condition of the coronary arteries that causes reduced blood flow and insufficient oxygen delivery to the affected portion of the heart. Coronary heart disease leads to acute myocardial infarction, or AMI, commonly known as a heart attack, which may lead to heart failure, a condition in which the heart is unable to pump enough blood to the body s major organs. The AHA estimates that there are approximately 2.0 million hospital visits per year with coronary heart disease as the first-listed diagnosis and approximately 1.1 million hospital visits per year with congestive heart failure as the first-listed diagnosis. Approximately 267,000 women die each year in the U.S. from heart attacks, which is approximately six times as many as women who die from breast cancer annually.

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

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

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

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

An IAB is an inflatable balloon inserted via a catheter that is used as an initial line of therapy in the cath lab or the surgery suite for patients with diminished heart function. However, IABs typically provide only limited enhancement and depend on the patient s own heart to

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generate the majority of the patient s blood flow. In addition, IABs are often used in conjunction with inotropes or other drugs that stimulate heart muscle ejection but increase 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%. IABs have limited effectiveness in patients that are arrhythmic and /or in cardiogenic shock and published reports have indicated that IABs do not reduce mortality for patients in cardiogenic shock. However, there are an estimated 160,000 annual IAB procedures globally, with an estimated 110,000 IAB procedures annually in the U.S.

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

Recovery VADs are designed to enable the patient s heart to rest and potentially recover so that the patient can return home with his or her own heart. Because recovery is the goal, these devices are designed to minimize damage to heart tissue and be removed once the heart has recovered. If possible, recovery of one s own heart is generally preferred to transplantation or prolonged device implantation, both of which have significant side effects for the patient and increase the risk of mortality. Heart recovery as a preferred clinical outcome for the patient 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, therapeutic and immunosuppressant drugs and other related healthcare costs.

Bridge-to-transplant VADs are primarily used to support chronic heart failure patients eligible to receive a heart transplant. According to the United Network for Organ Sharing, there were only approximately 1,850 heart transplants in the U.S in 2006. As a result, about one third of the patients eligible for transplant must rely on bridge-to-transplant devices for an extended period while waiting for a heart transplant. During this time, these patients frequently experience significant medical complications, such as infection. Moreover, the implant of these devices generally requires the removal of a portion of the patient s heart tissue, significantly limiting the chance of recovery of the patient s heart.

Destination therapy generally involves the implantation of a mechanical support device as the last clinical alternative for a chronic patient with end-stage heart failure who is not eligible for transplantation. Destination VAD therapy only prolongs the end-stage disease, as the patient s heart condition is terminal and the patient s heart is not expected to recover. Furthermore, artificial replacement hearts, another destination therapy modality, may be suitable for end-stage heart failure patients requiring full support.

Our Solution

Our product portfolio is designed to provide a continuum of care in heart recovery to acute heart failure patients from the intensive care unit to the cath lab to the surgery suite to home discharge and to provide an array of choices for clinicians treating acute heart failure patients. Our products provide various levels of blood flow and are capable of supporting a patient from hours to months and longer to align with the clinical needs of the patient, whether in pre-shock or profound shock. Our cath lab products include an IAB and our catheter-based Impella® pumps for support of acute pre-shock patients or for prophylactic support of patients undergoing high-risk percutaneous coronary intervention. Our surgery suite products include our Impella pumps, our IAB, our BVS® 5000 blood pump and AB5000™ VAD, which 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.

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

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

Our Impella products are CE-marked in Europe. In June 2008, we received 510(k) clearance for our Impella 2.5 device for partial circulatory support for up to six hours. This clearance allows for immediate commercial shipment of the device to U.S. hospitals that purchase the device. Our Impella 2.5 device is also the subject of two U.S. pivotal studies comparing the Impella 2.5 to the IABP. Our Impella 5.0 device is currently in a U.S. study. Impella expands our product portfolio to include devices that address the larger population of heart attack

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

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

We recently announced that we have developed a new Portable Circulatory Support Driver, or Portable Driver, for both in-hospital and out-of-hospital patients. The Portable Driver is designed to support our AB5000 VAD. We received CE mark approval for our Portable Driver in March 2008 and beginning in our fiscal year 2009, we expect to sell the product commercially in Europe and other countries outside the U.S. that accept the CE mark designation. The Portable Driver is not yet approved by the FDA. In January 2008, we submitted for an Investigational Device Exemption, or IDE, to conduct a patient discharge study in the U.S. In May 2008, we received conditional approval for the Portable Driver for this IDE to conduct a U.S. patient discharge study at 20 hospitals for 30 patients.

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

In January 2008, we received Humanitarian Device Exemption, or HDE, supplement approval from the FDA for our engineering and product enhancements to our AbioCor® Implantable Replacement Heart or AbioCor, the first completely self-contained artificial heart. The AbioCor can be made available to a limited patient population, with no more than 4,000 patients receiving the technology under the limits of the HDE approval in the U.S. each year. The AbioCor gives chronic patients with biventricular heart failure who are not eligible for a transplant and whose sole alternative is death, the opportunity to extend life. The AbioCor has no wires piercing the skin and allows the patient improved quality of life outside the hospital. We began selling the AbioCor in the fourth quarter of fiscal 2008 in a controlled roll-out to a limited number of heart centers in the U.S.

Our Strategy

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

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

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

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

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

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Our Products

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

Product Name	Description of Use	Regulatory Status	
		US	CE Mark
Disposable Products for the Surgery Suite			
BVS 5000 Blood Pump	Provides temporary LVAD, RVAD or BiVAD support until recovery for cardiogenic shock from heart attack; post-cardiotomy cardiogenic shock; myocarditis, failed transplant and certain other clinical instances where the physician believes heart recovery is possible.	ü	ü
AB5000 Ventricle	Provides temporary LVAD, RVAD or BiVAD support until recovery for cardiogenic shock from heart attack: post-cardiotomy cardiogenic shock; myocarditis, failed transplant and certain other clinical instances where the physician believes heart recovery is possible; allows for full patient mobility.	ü	ü
Integrated Cannula System	Connects the BVS 5000 and AB5000 ventricle to the body and provides an option for the removal of the devices without re-opening the chest.	ü	Not yet submitted
Impella LD	Provides temporary LVAD support for recovery from post-cardiotomy hemodynamic instability where the physician believes heart recovery is possible Provides temporary LVAD support for recovery from cardiogenic shock.	IDE approved and pilot clinical trial in progress	ü
Disposable Products for the Cardiac Catheterization Lab and the Surgery Suite			
Impella 2.5	Miniature percutaneous heart pump providing up to 2.5 liters of blood flow per minute intended to support the heart while undergoing high-risk angioplasty procedures or for assisting the heart while in pre-shock for hemodynamic stabilization. Under 510(k) clearance, approved for partial circulatory support for up to six hours.	ü 510(k) clearance; IDE approved and pivotal studies in progress for high-risk PCI and AMI shock	ü
Impella 5.0	Percutaneous heart pump providing up to 5.0 liters of blood flow per minute for low cardiac output post-surgery patients intended to assist the heart while in pre-shock or profound shock for recovery.	IDE approved and pilot clinical trial in progress	ü
IAB	Percutaneous intra-aortic balloon used to support a wide variety of prophylactic, pre-shock and profound shock conditions.	ü	ü
Consoles			
AB5000 Console	Driver console for both BVS 5000 Blood Pump and AB5000 Ventricle.	ü	ü
Mobile Pump Console	Driver console for Impella products.	ü 510(k) clearance; IDE approved and pilot clinical trial in progress	ü
iPulse Console	Multi-purpose driver console for IAB, AB5000, BVS 5000 and other manufacturers IABs.	ü	ü
Portable Discharge Driver	Driver console for AB5000 for in-hospital and out-of-hospital patients; enables patient discharge while on support.	IDE received conditional approval in May 2008	ü
Disposable Implants			
AbioCor	Fully implantable replacement heart for severe biventricular heart failure when chronic patients are ineligible for a heart transplant.	HDE Approved	Not yet submitted

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IAB and iPulse

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

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

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

Impella 2.5, Impella 5.0, and Impella LD

Our Impella 2.5 and 5.0 catheters are percutaneous micro heart pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. These devices are designed for use by interventional cardiologists to support pre-shock patients in the cath lab who may not require as much support as patients in the surgery suite or first use in surgery for patients who may require assistance to maintain their circulation. Our Impella catheters are also designed to provide ventricular support for patients requiring hemodynamic stabilization or suffering from reduced cardiac output, and can aid in recovering the hearts of patients following a heart attack. These products increase flow to the heart and organs without the need for drugs such as inotropes while reducing the workload of the heart. Our Impella devices have CE mark approval in Europe, are approved in over 40 countries, have already been used to treat more than 1,500 patients in Europe and other countries outside the U.S. and have been the subject of over 40 peer-reviewed publications and other clinical presentations and publications.

These catheters can be quickly inserted via the femoral artery using a guide wire to reach the left ventricle of the heart where they are directly deployed to draw blood out of the ventricle and deliver it to the circulation, thereby reducing ventricular work (resting the heart) and providing flow to the rest of the organs. The Impella 2.5 is introduced with normal interventional cardiology procedures, while the Impella 5.0 is implanted via a small incision in the femoral artery in the groin. The Impella 2.5 can pump up to 2.5 liters of blood per minute and the Impella 5.0 can pump up to five liters of blood per minute. The Impella 5.0 has been used to treat patients in need of cardiac support resulting from post-cardiotomy cardiogenic shock, myocarditis, low cardiac output after a heart attack, or post-coronary intervention procedures, or as a bridge to other circulatory support devices, including our iPulse, AB5000 and BVS 5000 systems.

We are pursuing FDA approval for our Impella heart pumps through a pre-market approval, or PMA path, for our Impella 2.5 and 5.0 products. In August 2007, we received approval from the FDA to begin a high-risk PCI pivotal clinical trial for the Impella 2.5. This approval was based on the submission of the clinical results of the safety pilot clinical trial. The pivotal study will determine the safety and effectiveness of the Impella 2.5 as compared to optimal medical management with an IAB, during high-risk angioplasty procedures. The study inclusion criteria have been extended to include patients with triple vessel disease with low ejection fraction. The study is approved under category B2 status and the trial sites are eligible for full reimbursement from CMS. The randomized pivotal study, at up to 150 hospitals and 654 patients undergoing high-risk PCI procedure, is comprised of two arms comparing nearly equal number of Impella 2.5 supported patients and IAB supported patients during the procedure. Patients receiving the Impella 2.5 can be supported for up to five days as a left VAD. We have commenced shipments of Impella 2.5 disposables and Impella consoles to the enrolled pivotal sites. As of May 2008, 149 hospitals have signed a non-disclosure agreement and have started the investigational review board (IRB) approval process, 93 sites have submitted for IRB approval, and of those approximately 70 sites have received IRB approval. Currently, 31 of the 70 sites are open for enrollment and approximately 19 of the 31 centers have enrolled approximately 70 patients as of May 2008.

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

In March 2008, we received approval from the FDA to begin a second pivotal study for our Impella 2.5 in the U.S. under an IDE for hemodynamically unstable patients undergoing a PCI procedure due to acute myocardial infarction, or AMI, commonly referred to as heart attack. The AMI study will determine the safety and effectiveness of the Impella 2.5 as a left ventricular assist device for heart attack patients as compared to optimal medical management with an IAB. The study is approved under category B2 status and the trial sites are eligible for

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full CMS reimbursement. The randomized study, at up to 150 hospitals, is comprised of two arms; those patients that receive the Impella 2.5 for up to five days and patients that receive IAB therapy. The study will compare 192 Impella 2.5 patients to 192 IAB patients relative to a composite end point comparing safety and efficacy. The proposed primary endpoint will be a composite endpoint of major events assessed at 30 days post-AMI. These major events include but are not limited to: death, acute renal failure, and need for a major cardiovascular operation. The secondary endpoint will be a composite of cardiac function such as ejection fraction, requirement for inotropic support and cardiac power output. We plan to ship Impella 2.5 disposables and Impella consoles to enrolled sites. There are estimated to be approximately 100,000 AMI anterior infarct patients annually in the U.S. and these patients suffer failure of the left ventricle, the large main pumping muscle of the heart. Feasibility studies suggest that of heart attack patients, these are the patients that can be most helped by the Impella 2.5 technology.

As discussed above, our Impella 2.5 device received 510(k) clearance from the FDA in June 2008 for partial circulatory support for up to six hours, which allows for immediate commercial launch of our Impella 2.5 device to an estimated 14,000 interventional cardiologists at 1,900 hospitals in the U. S.

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

The Impella 5.0 is in a pilot clinical study that will enroll up to 20 patients at 15 U.S. sites including: the University of Maryland, Massachusetts General Hospital, Lankenau Hospital in Pennsylvania, Robert Wood Johnson Hospital in New Jersey, New York Presbyterian Hospital, Texas Heart Institute and Penn State Milton S. Hershey Medical Center in Pennsylvania. The study will include postcardiotomy patients who have been weaned from heart-lung machines and whose hearts require added support to maintain good blood flow. The study will enroll those patients that would typically need more flow and hemodynamic support than provided by an IAB.

AB5000 and BVS 5000

We manufacture and sell the AB5000 Circulatory Support System and the BVS 5000 Biventricular Support System for the temporary support of acute heart failure patients in profound shock, including patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock, or myocarditis. The AB5000 and BVS 5000 systems, which are implanted in the surgery suite, can assume the full pumping function of a patient s failing heart, allowing the heart to rest, heal and potentially recover. Both systems are designed to provide either univentricular or biventricular support. We believe the AB5000 and BVS 5000 systems are the only commercially available cardiac assist devices that are approved by the FDA for heart recovery for patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability.

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

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

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

Portable Driver

We recently announced that we have developed a new Portable Circulatory Support Driver for both in-hospital and out-of-hospital patients. The Portable Driver is designed to support our AB5000 VAD. The combination of our new Portable Driver and FDA-approved AB5000 VAD is designed to provide support of acute heart failure patients. In many cases, profound shock heart patients require biventricular support (both sides of the heart). The AB5000 can assume the pumping function of a patient s failing heart, allowing the heart to rest, heal and

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potentially recover. AB5000 is designed to provide either uni-ventricular or bi-ventricular support. Our recently received FDA labeling approval of one year bench reliability for our AB5000 VAD, is expected to complement the Portable Driver reliability. The Portable Driver is not yet approved by the FDA. We received CE mark approval for our Portable Driver in March 2008 and in January 2008 we submitted for an IDE to conduct a patient discharge study in the U.S. In May 2008, we received conditional approval for the Portable Driver for this IDE to conduct a U.S. patient discharge study at 20 hospitals for 30 patients.

Cannulae

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

AbioCor

Our AbioCor Implantable Replacement Heart is the first completely self-contained artificial heart. Designed to sustain the body s circulation, the AbioCor is intended for end-stage biventricular heart failure patients whose other treatment options have been exhausted. Patients with advanced age, impaired organ function or cancer are generally ineligible for a heart transplant and are potential candidates to receive the AbioCor implantable heart. The complete AbioCor system consists internally of a thoracic unit, a rechargeable battery, an electronics package and a power receiver coil, and externally, a power transmitter coil, power and battery pack, handheld alarm monitor, patient home electronics and an in hospital console. Once implanted, the AbioCor system does not penetrate the skin, reducing the chance of infection. This technology provides patients with mobility and remote diagnostics.

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

Research and Product Development

Over the last 27 years, we have gained substantial expertise in circulatory support while developing the BVS and the AB5000 systems and our AbioCor. Our current strategy is to develop a complete portfolio of products to treat acute heart failure patients with the goal of heart recovery. We have used this expertise to develop our IAB, iPulse and Portable Driver, and we intend to continue to use this experience to develop additional circulatory support products. Our research and development efforts are focused on developing a broader portfolio of products across the continuum of care in heart recovery, primarily focused in the area of circulatory care. In addition, we have a number of new products at various stages of development some of which integrate the Impella technology platform.

As of March 31, 2008, research and development staff consisted of 97 professional and technical personnel, including 33 engineers with advanced degrees, covering disciplines such as electrical engineering, mechanical engineering, computer science, reliability engineering, fluid mechanics, materials and physiology.

We expended $24.9 million, $22.3 million, and $16.7 million on research and development in fiscal years 2008, 2007, and 2006, respectively. Our research and development expenditures include costs related to clinical trials, including ongoing pilot and pivotal clinical trials for our Impella products.

Sales, Clinical Support, Marketing and Field Service

As of March 31, 2008, our worldwide sales, clinical support, marketing and field service teams included 99 full-time employees, 75 of whom are in the U.S. and 24 of whom are in Europe. Since March 31, 2004 when our sales, clinical support, marketing and field service teams totaled 17 employees, we have significantly increased the number of our direct sales and clinical support personnel covering the U.S., Germany, France and the UK.

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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 17%, 11% and 13% of total product revenue during the fiscal years ended March 31, 2008, 2007 and 2006, respectively.

Manufacturing

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

We believe our existing manufacturing facilities give us the physical capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months based on our revenue forecast. We have invested recently in capacity expansion in our Germany facility to meet anticipated future demand of our Impella 2.5 product in anticipation of the 510(k) clearance that we received in June 2008. We also continue to monitor market conditions and demand and are evaluating the potential need for expanded capacity in the future, including opportunities outside the U.S. for a high-throughput manufacturing facility. Both of our 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 2008 to 2026 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

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and sales and marketing resources and experience than we do. These competitors may develop superior products or products of similar quality at the same or lower prices. Moreover, improvements in current or new technologies may make them technically equivalent or superior to our products in addition to providing cost or other advantages. Other advances in medical technology, biotechnology and pharmaceuticals may reduce the size of the potential markets for our products or render those products obsolete.

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

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

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

Third-Party Reimbursement

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

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

Medicare payment may be made, in appropriate cases, for procedures performed in the in-patient hospital setting using our technology. Medicare generally reimburses the facilities in which the procedures are performed based upon prospectively determined amounts. For hospital in-patient stays, the prospective payment generally is determined by the patient s condition and other patient data and procedures performed during the in-patient stay, using a classification system known as diagnosis-related groups, or DRGs. Prospective rates are adjusted for, among other things, regional differences, co-morbidity, and complications. Hospitals performing in-patient procedures using our devices generally do not receive separate Medicare reimbursement for the specific costs of purchasing or implanting our products. Rather, reimbursement for these costs is bundled with the DRG-based payments made to hospitals for the procedures during which our devices are

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implanted, removed, repaired or replaced. Because prospective payments are based on predetermined rates and may be less than a hospital s actual costs in furnishing care, hospitals have incentives to lower their in-patient operating costs by utilizing products, devices and supplies that will reduce the length of in-patient stays, decrease labor or otherwise lower their costs.

Coverage and reimbursements for procedures to implant, remove, replace or repair the AB5000 and BVS 5000 are well-established in the U.S. market. For instance, Medicare covers the use of VADs, such as our AB5000 and BVS 5000 devices, when used for support of blood circulation post-cardiotomy, as a temporary life-support system until a human heart becomes available for transplant, or as therapy for patients who require permanent mechanical cardiac support. CMS recently increased Medicare reimbursement for patients that recover during an in-patient stay using external VADs, such as our AB5000 and BVS 5000 devices, to levels similar to those for patients who undergo heart transplants. Reimbursements for patients who do not recover remain at lower levels.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services when they perform surgeries to implant, remove, replace or repair our AB5000 or BVS 5000 devices. Physicians generally bill for such services using a coding system known as Current Procedural Terminology, or CPT, codes. Physician services performed in connection with the implantation, removal, replacement or repair of our AB5000 or BVS 5000 devices are billed using a variety of CPT codes. Generally, Medicare payment levels for physician services are based on the Medicare Physician Fee Schedule and are revised annually by CMS. Enrolling U.S. centers are approved for reimbursement for Impella procedures performed during the U.S. pivotal studies.

Coverage and reimbursement in the U.S. for our other products will depend upon, among other things, our ability to obtain the FDA approvals or clearances to market such products. Although certain costs associated with the use of our Impella 2.5 and 5.0 products in qualifying clinical trials are reimbursed, we cannot assure you that, if these products receive FDA approval or clearance, the commercial use of these products will also be reimbursed.

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

In general, third-party reimbursement programs in the U.S. and abroad, whether government-funded or commercially insured, are developing a variety of increasingly sophisticated methods of controlling healthcare costs, including prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, careful review of bills, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. These types of cost-containment programs, as well as legislative or regulatory changes to reimbursement policies, could limit the amount which healthcare providers may be willing to pay for our medical devices

Government Regulation

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

Premarket Regulation

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

In the U.S., medical devices are classified into one of three classes (Class I, II or III) based on the statutory framework described in the FFDCA. Class III devices, which are typically life-sustaining, life-supporting or implantable devices, or new devices that have been found not to be substantially equivalent to legally marketed devices, must generally receive premarket approval, or PMA, by the FDA to ensure their safety and effectiveness.

When clinical trials of a device are required in order to obtain FDA approval, the sponsor of the trial is required to file an IDE application before commencing clinical trials. The IDE application must be supported by data, which typically include the results of extensive device bench testing, animal testing performed in conformance with Good Laboratory Practices, and formal laboratory testing and documentation in accordance with appropriate design controls and scientific justification.

The FDA reviews and must approve an IDE before a study may begin in the U.S. In addition, the study must be approved by an Institutional Review Board, or IRB, for each clinical site. When all approvals are obtained, the study may be initiated to evaluate the device.

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The FDA, and the IRB at each institution at which a clinical trial is being performed, may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable health risk. All clinical studies of investigational devices must be conducted in compliance with FDA requirements. During a study, we are required to comply with the FDA s IDE requirements for investigator selection, trial monitoring, reporting, recordkeeping and prohibitions on the promotion of investigational devices or making safety or efficacy claims for them. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. Following completion of a study, we would need to collect, analyze and present the data in an appropriate submission to the FDA, either a 510(k) premarket notification or a PMA.

In the 510(k) process, the FDA reviews a premarket notification and determines whether or not a proposed device is substantially equivalent to predicate devices. In making this determination, the FDA compares the proposed device to predicate devices. If the intended use and safety and effectiveness are comparable to a predicate device, the device may be cleared for marketing. A device that raises a new question of safety or effectiveness is not eligible for the 510(k) clearance pathway and must undergo the PMA approval process. The FDA s 510(k) clearance pathway usually takes from 3 to 12 months, but it can last longer and clearance is never assured. In reviewing a premarket notification, the FDA may request additional information, including clinical data. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the agency can review any such decision. If the FDA disagrees with a manufacturer s decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Also, the manufacturer may be subject to significant regulatory fines or penalties.

Certain Class III devices that were on the market before May 28, 1976, known as preamendment Class III devices, and devices that are determined to be substantially equivalent to them, can be brought to market through the 510(k) process until the FDA, by regulation, calls for PMA applications for the devices. In addition, the FFDCA requires the FDA either to down-classify preamendment Class III devices to Class I or Class II or to publish a classification regulation retaining the devices in Class III. Manufacturers of preamendment Class III devices that the FDA retains in Class III must have PMA applications accepted by the FDA for filing within 90 days after the publication of a final regulation in which the FDA calls for PMA applications. Failure to meet the deadline can lead the FDA to prevent continued marketing of the device during the PMA application review period. Our IAB received 510(k) clearance as a preamendment Class III device. The Impella 2.5 for short duration use would also be a preamendment Class III device, if 510(k) clearance is obtained. 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 will conduct an inspection of the manufacturing facilities and the clinical sites where the supporting study was conducted. The facility inspection evaluates the company s compliance with the QSR. An inspection of clinical sites evaluates compliance with the IDE requirements. Typically, the FDA will convene an advisory panel meeting to seek review of the data presented in the PMA. The panel s recommendation is given substantial weight, but is not binding on the agency. If the FDA s evaluation is favorable, the PMA is approved and the device may be marketed in the U.S. The FDA may approve the PMA with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

By regulation, the FDA has 180 days to review a PMA application, during which time an advisory committee may evaluate the application and provide recommendations to the FDA. While the FDA has approved PMA applications within the allotted time period, reviews can occur over a significantly protracted period, usually 18 to 36 months but sometimes longer, and a number of devices have never been approved for marketing. This process is lengthy and expensive and there can be no assurance that FDA approval will be obtained.

Both a 510(k) and a PMA, if cleared or approved, may include significant limitations on the indicated uses for which a product may be marketed. FDA enforcement policy prohibits the promotion of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial marketing.

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

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HDE, if a device becomes available through the PMA process that addresses the same patient population as the HDE device, the HDE device may need to be withdrawn from the U.S. market. In January 2008 we received HDE supplement approval from the FDA for the AbioCor.

Our AB5000 and BVS 5000 systems are approved by the FDA for heart recovery for patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. In 1992, the FDA approved our PMA for the BVS 5000. In 1996 and 1997, the FDA approved the use of the BVS 5000 for additional indications, expanding its use to the treatment of all patients with potentially reversible heart failure. In April 2003, the AB5000 Circulatory Support System Console and AB5000 VAD were approved under PMA supplements. We received FDA clearance for our new IAB in December 2006. Our iPulse console was approved by the FDA under a PMA supplement in December 2007. Our Impella 2.5 device received 510(k) clearance in June 2008 for partial circulatory support for up to six hours. In May of 2008 we received conditional approval from the FDA for our AB5000 Portable Driver for an investigational device exemption (IDE) to conduct a U.S. patient discharge study at 20 hospitals for 30 patients. This product has CE Mark approval.

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 and manufacturing practices, labeling and record keeping, and manufacturers required reports of adverse experience and other information to identify potential problems with marketed medical devices. Among other FDA requirements, we must comply with the FDA s good manufacturing practice regulations. These QSR regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. We must also comply with Medical Devices Reporting, or MDR, which requires that a firm report to the FDA any incident in which its product may have caused or contributed to a death or serious injury, or in which its product malfunctioned and, if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. Labeling, advertising, and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

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

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

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

International Regulation

We are also subject to regulation in each of the foreign countries in which we sell our products. Many of the regulations applicable to our products in these countries are similar to those of the FDA. The European Union requires that medical devices such as ours comply with the Medical Device Directive or the Active Implantable Medical Device Directive, which includes quality system and CE certification requirements. To obtain a CE Mark in the European Union, defined products must meet minimum standards of safety and quality (i.e., the essential requirements) and then comply with one or more of a selection of conformity routes. A Notified Body assesses the quality management systems of the manufacturer and the product conformity to the essential and other requirements within the Medical Device Directive. In the European Community, we are also required to maintain certain International Organization for Standardization, or ISO, certifications in order to sell our products. Our BVS 5000, AB5000, Impella products, IAB, iPulse console and Portable Driver are CE marked and available for sale in the European Union.

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Fraud and Abuse Laws

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

Anti-Kickback Statute

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

Penalties for violating the federal Anti-Kickback Statute include substantial criminal fines and/or imprisonment, substantial civil fines and possible exclusion from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs and do not include comparable exceptions.

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

We have various arrangements with customers and physicians that may implicate these laws. For example, some physicians who use our products also provide medical advisory and other consulting and personal services. Some of these physician arrangements may not meet Anti-Kickback Statute safe harbor protections, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws. Additionally, we do not maintain a formal compliance plan concerning interactions with healthcare professionals nor have we formally adopted the recommendations issued by the OIG. The OIG may interpret the absence of such formal plan negatively in the case of an enforcement action, which could result in a material adverse effect on our financial condition and results of operations.

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

Federal False Claims Act

The federal False Claims Act prohibits the knowing filing or causing the filing of a false claim or the knowing use of false statements to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim. Private individuals can file suits under the False Claims Act on behalf of the government. These lawsuits are known as qui tam actions, and the individuals bringing such suits, sometimes known as relators or, more commonly, whistleblowers, may share in any amounts paid by the entity to the government 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.

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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, 2008, we had 377 full-time employees, including:

- 97 in product engineering, research and development, and regulatory;
- 99 in sales, clinical support, marketing and field service;
- 111 in manufacturing and quality control; and
- 70 in general and administration.

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

Our Corporate Information

We are a Delaware corporation and commenced operations in 1981. Our principal executive offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, and our telephone number is (978) 646-1400. Our web address is www.abiomed.com. 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.

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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 2009.

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 2009 and subsequent fiscal years for, among other things, the expansion of our global distribution network and ongoing product development, which we expect will result in losses in our fiscal year 2009 and potentially in future periods. These expenditures include costs associated with hiring additional personnel, performing clinical trials, continuing our research and development relating to our products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing activities. The amount of these expenditures is difficult to forecast accurately and cost overruns may occur. We also expect that we will need to make significant expenditures to begin to market and manufacture in commercial quantities our recently approved circulatory care products, and any other new products for which we may receive regulatory approvals or clearances in the future.

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

Medical devices such as ours are extensively regulated by the FDA in the U.S. and by other federal, state, local and foreign authorities. Governmental regulations relate to the testing, development, manufacturing, labeling, design, sale, promotion, distribution, importing, exporting and shipping of our products. In the U.S., before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we must generally first receive either a premarket approval, or PMA, or 510(k) clearance from the FDA. Both of these processes can be expensive and lengthy and entail significant expenses. The FDA s 510(k) clearance process usually takes from three to 12 months, but it can often last longer. The process of obtaining premarket approval is much more costly and uncertain than the 510(k) clearance process. It generally takes from one to three years, or even longer, from the time the PMA application is submitted to the FDA. We cannot assure you that any regulatory clearances or approvals, either foreign or domestic, will be granted on a timely basis, if at all. If we are unable to obtain regulatory approvals or clearances for use of our products under development, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of these products could be limited. The FDA may also limit the claims that we can make about our products.

For example, we are pursuing premarket approval for our Impella 5.0 products. We cannot assure you that we will receive any of these approvals. 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 and Japan. Approval processes differ among those jurisdictions and approval in the U.S. or any other single jurisdiction does not guarantee approval in any other jurisdiction. Obtaining foreign approvals could involve significant delays, difficulties and costs for us and could require additional clinical trials.

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

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

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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;
- 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.

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. Since 2004, we have experienced significant growth in the scope of our operations and the number of our employees, including the addition of our operations in Germany, France and the United Kingdom. This growth has placed significant demands on our management as well as our financial and operations resources. In order to achieve our business objectives, we will need to continue to grow. However, continued growth presents numerous challenges, including:

- developing our global sales and marketing infrastructure and capabilities;
- expanding manufacturing capacity, maintaining quality and increasing production;

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.

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

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

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

- limitations inherent in first-generation devices, and the potential failure to develop successive improvements, including increases in service life;
- the introduction by other companies of new treatments, products and technologies that compete with our products;
- the timing and amount of reimbursement for these products, if any, by third-party payers;
- the potential reluctance of clinicians to obtain adequate training to use our products or to use new products;
- the lifestyle limitations that patients will have to accept for our AbioCor and AbioCor II products; and
- the potential reluctance of physicians, patients and society as a whole to accept medical devices that replace or assist the heart or the finite life and risk of mechanical failure inherent in such devices.

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

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

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

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

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.

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

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

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

Our AB5000 and BVS 5000 are vulnerable to competitive pressures.

To date, we have derived most of our product revenues from sales of the AB5000 and BVS 5000. We believe that we will continue to rely heavily on these products in the near future until we obtain U.S. regulatory approval for new products. Moreover, we are relying and expect to rely increasingly on sales of the AB5000, as sales of the BVS 5000 have been declining. 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. For example, in the event of the expansion of technologies that allow heart surgical procedures to be performed without stopping the heart, a reduction in the market for these products could result. In addition, variations in the quantity and timing of sales of our consoles have a disproportionate effect on our revenues, because the price of a console is substantially greater than the price of our disposable blood pumps. The higher price of our consoles may limit sales of our consoles in the future by third-party payers. If we cannot maintain and increase our disposable revenues from our AB5000 and BVS 5000, our overall business and financial condition could be adversely affected.

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

To be successful, we believe we will need to increase our manufacturing capacity. We do not have experience in manufacturing our Impella products in the commercial quantities that might be required if we receive FDA approval or clearance of those products, nor do we have experience manufacturing our existing 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.

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

We manufacture our Impella heart pumps at our facility in Aachen, Germany and we manufacture our other products 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.

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

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

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

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

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

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

In addition, third-party payers are increasingly requiring evidence that medical devices are cost-effective. If we are unable to meet the standards of a third-party payer, that payer may not reimburse the use of our products, which could reduce sales of our products to healthcare providers who depend upon reimbursement for payment. We also cannot be sure that third-party payers will continue the current level of reimbursement to physicians and medical centers for use of our AB5000, BVS 5000, Impella products and iPulse consoles. Any reduction in the amount of this reimbursement could harm our business.

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

The Federal government has considered ways to change, and has changed, the manner in which healthcare services are provided and paid for in the U.S. Occasionally, the U.S. Congress passes laws that impact reimbursement for health care services, including reimbursement to hospitals and physicians. States may also enact legislation that impacts Medicaid payments to hospitals and physicians. In addition, the Centers for Medicare & Medicaid Services, the Federal agency responsible for administering the Medicare program, establishes payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. Future legislative and regulatory initiatives could be introduced that 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 future healthcare reforms.

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

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

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

- the Federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the

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furnishing, recommending, or arranging for, a good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid; and

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

We have various arrangements with customers that may implicate these laws. For example, some physicians who use our products also provide medical advisory and other consulting and personal services. Some of these physician arrangements may not meet Anti-Kickback Statute safe harbor requirements, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws. Additionally, we do not maintain a formal compliance plan concerning interactions with healthcare professionals nor have we formally adopted the recommendations issued by the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG. The OIG may interpret the absence of such formal plan negatively in the case of an enforcement action, which could result in a material adverse effect on our financial condition and results of operations.

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

If we cannot attract and retain the 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. For example, many of the members of our clinical staff are registered nurses with experience in the surgery suite or cath lab, only a limited number of whom seek employment with a company like ours. Competition for skilled and experienced management, scientific, clinical and sales personnel in the medical devices industry is intense. 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 all of our consoles other than final assembly and testing. Relying on third-party suppliers makes us vulnerable to component part failures and to interruptions in supply, either of which could impair our ability to conduct clinical tests or to ship our products to our customers on a timely basis. Using third-party vendors makes it difficult and sometimes impossible for us to test fully certain components, such as components on circuit boards, maintain quality control, manage inventory and production schedules and control production costs. Manufacturers of our product components may be required to comply with the FDA or other regulatory manufacturing regulations and to satisfy regulatory inspections in connection with the manufacture of the components. Any failure by a supplier to comply with applicable requirements could lead to a disruption in supply. Vendor lead times to supply us with ordered components vary significantly and often can exceed six months or more. Both now and as we expand our manufacturing capacity, we cannot be sure that our suppliers will furnish us required components when we need them. These factors could make it more difficult for us to manufacture our products effectively and efficiently and could adversely impact our results of operations.

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

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

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

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- the need to procure reimbursement for our products in each foreign market;
- the generally lower level of reimbursement available in foreign markets relative to the U.S.;
- longer sales cycles;
- limited protection of intellectual property rights;
- difficulty in collecting accounts receivable;
- fluctuations in the values of foreign currencies; and
- political and economic instability.

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

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

We rely on distributors to market and sell our products in parts of Europe, Asia, South America and Australia. Many of these distributors have the exclusive right to distribute our products in their territory. We may hire distributors to market our products in additional international markets. Our success in these markets will 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, particularly for our consoles, which are substantially more expensive than our disposable products;
- competitive changes, such as price changes or new product introductions that we or our competitors may make;
- the timing of regulatory actions, such as product approvals or recalls;
- costs we incur developing and testing our Impella heart pumps, IAB, Portable Driver, iPulse console, AbioCor, AbioCor II and any other product products;
- costs we incur in anticipation of future sales, such as inventory purchases, expansion of manufacturing facilities, or establishment of international sales offices;
- the effect of fluctuations in currency exchange rates on our results of operations;

economic conditions in the healthcare industry; and

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

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

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

At March 31, 2008, we had federal and state net operating loss (NOL) carryforwards of approximately $90.8 million and $42.8 million, respectively, which begin to expire in fiscal 2009. Additionally, at March 31, 2008, we had federal and state research and

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development credit carryforwards of approximately $6.6 million and $3.2 million, respectively, which begin to expire in fiscal 2009. We acquired Impella, a Germany-based company, in May 2005. Impella had pre-acquisition net operating losses of approximately $22.9 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 NOL s in each fiscal year since the acquisition. During fiscal 2008, we determined that approximately $1.5 million of pre-acquisition net operating losses could not be utilized. The utilization of pre-acquisition net operating losses of Impella in future periods is subject to certain statutory approvals and business requirements.

Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax assets and liabilities. Additionally, the future utilization of its NOL and research and development credit carry forwards to offset future taxable income may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to ownership changes that have occurred previously or that could occur in the future. Ownership changes, as defined in Section 382 of the Internal Revenue Code, can limit the amount of NOL s and research and development credit carry forwards that a company can use each year to offset future taxable income and taxes payable. We 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 recent 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 carry forwards, before they can be utilized, would reduce our gross deferred tax assets. We will monitor subsequent ownership changes, which could impose limitations in the future.

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

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

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.

Our short term marketable securities are subject to market risks and decreased liquidity.

Short-term marketable securities at March 31, 2008 consist of $28.8 million in the Columbia Fund, $7.3 million in four funds that invest in U.S. backed government securities and $0.1 million in interest receivable. In December 2007, the Columbia Fund ceased accepting redemption requests from new or current investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. As a result, we reclassified the securities in the Columbia Fund from cash equivalents to short-term marketable securities as the Columbia Fund was no longer expected to have a maturity of less than 90 days. We recorded a realized loss of $0.3 million and an unrealized loss of $0.9 million on short-term marketable securities in the statements of operations for the year ended March 31, 2008. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 97% of its carrying value. The Columbia Fund is being liquidated with distributions to us occurring and expected to be fully liquidated during calendar 2008. Since December 2007, we have received disbursements of approximately $20.7 million from the Columbia Fund. We expect conditions in the credit markets to remain uncertain for the foreseeable future. While it is our intent to liquidate securities in the Columbia Fund in future periods to reduce our exposure to future deterioration of these securities, we believe that operating results or cash flows could be affected significantly by fair value adjustments to the Columbia Fund. There can be no assurance that we will not have to take additional losses on the Columbia Fund.

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

Our intellectual property rights are and will continue to be a critical component of our success. A substantial portion of our intellectual property rights relating to the AB5000, BVS 5000, Impella products, AbioCor, AbioCor II and other products under development is in the

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

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

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

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

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

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

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

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

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

Future milestone payments relating to our acquisition of Impella could harm our financial position or result in dilution.

We may be required to make additional contingent payments of up to $11.2 million under the terms of our acquisition of Impella, based on our future stock price performance and milestones related to FDA approval of Impella s products. If we pay any milestone payment in

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shares of our common stock, our stockholders may experience dilution. If we use cash to make any such payment, our financial resources will be diminished and we may be unable to pursue other activities, such as research and development, the expansion of our sales force or the acquisition of other new products. In June 2008, we received 510(k) clearance of our Impella 2.5, triggering an obligation to pay $5.6 million of contingent payments in accordance with the May 2005 acquisition of Impella. These contingent payments may be made at our option with cash or stock or by a combination of cash or stock under circumstances described in the purchase agreement. It is our intent to satisfy this contingent payment through the issuance of shares of our common stock.

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

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

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

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

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, Ventracor, EvaHeart, Terumo Heart and several early-stage companies, that are developing permanent heart assist products, including implantable left ventricular assist devices and miniaturized rotary ventricular assist devices.

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

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

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced. We may be required to capitalize a significant amount of intangibles, including goodwill, which may lead to significant amortization charges. In addition, we may incur significant, one-time write-offs and amortization charges, such as our write-off of in-process research and development expenses in connection with the Impella acquisition in fiscal 2006. These amortization charges and write-offs could decrease our future earnings or increase our future losses.

Our strategic investment in WorldHeart Corporation, or WorldHeart, is subject to risk and we have recorded impairment charges against it.

In fiscal 2008, we invested $5.0 million in WorldHeart in the form of a convertible note and warrant. Our investment in WorldHeart is subject to a number of risks and uncertainties. WorldHeart currently is not profitable and has limited financial resources and we may lose

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some or all of our investment if WorldHeart is unable to pay back the loan we have made to it. WorldHeart may be unsuccessful in raising additional funds to finance its operations and may become insolvent as a result. In May 2008, WorldHeart filed a Form 8-K disclosing that it has limited cash available to continue operations and that if it is unable to secure additional funding, it will be forced to take extraordinary business measures which could include filing for bankruptcy, ceasing operations and liquidating assets. We have a security interest in WorldHeart s intellectual property and other assets under the terms of the loan agreements. However, in the event of insolvency or bankruptcy of WorldHeart, there may not be a market for these assets, in which case we may not be able to receive payment for our convertible note. We recorded an impairment charge of $5.0 million during fiscal 2008 related to our note receivable from WorldHeart and its associated derivative instruments.

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

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign currency exchange rates, primarily the Euro. The functional currency of our 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, 2007 to March 31, 2008 the price of our stock ranged from a high of $15.96 per share to a low of $9.95 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;
- future sales of shares of common stock in the public market; and
- market conditions in the industry and the economy as a whole.

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

The sale of additional shares of our common stock, or the exercise of outstanding options to purchase our common stock, could 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, in connection with our acquisition of Impella CardioSystems AG in 2005, we may be obligated to make certain milestone payments. These payments may be made in stock which 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.

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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 in 2010. This facility encompasses most of our U.S. operations, including research and development, manufacturing, sales and marketing and general and administrative departments. Under the terms of the lease, we have two five-year options to extend our lease term beyond 2010 at market rates. We terminated a short-term lease for office space in Washington, DC effective May 2008.

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 research and development and manufacturing operations for our Impella product line as well as the sales, marketing and general and administrative functions for most of our product lines sold in Europe and the Middle East.

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

In light of the recent 510 (k) clearance of our Impella 2.5 device and in advance of potential PMA approvals for our Impella 2.5 device, we are evaluating opportunities outside the U.S. for a high-throughput manufacturing facility.

ITEM 3. ***LEGAL PROCEEDINGS***

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

On January 4, 2008, St. Jude Medical, Inc. filed a Petition with the U.S. Trademark Trial and Appeal Board of the United States Patent and Trademark Office to cancel our registered trademark ABIOCOR. We plan to vigorously defend against this action.

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

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended March 31, 2008.

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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:

Fiscal Year Ended March 31, 2007	**High**	**Low**
First Quarter	$ 14.14	$ 11.48
Second Quarter	16.19	12.25
Third Quarter	15.65	12.07
Fourth Quarter	15.10	12.12

Fiscal Year Ended March 31, 2008	**High**	**Low**
First Quarter	$ 13.96	$ 10.50
Second Quarter	14.31	9.95
Third Quarter	15.96	11.68
Fourth Quarter	15.75	12.27

Number of Stockholders

As of June 4, 2008, we had approximately 690 holders of record of our common stock and there were approximately 9,380 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.

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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, 2003 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 ($)					
	3/31/2003	3/31/2004	3/31/2005	3/31/2006	3/31/2007	3/31/2008
ABIOMED, Inc.	100.00	210.00	271.28	330.77	350.26	336.92
Nasdaq Composite Index	100.00	148.69	149.07	174.46	180.56	169.93
Nasdaq Medical Equipment SIC Code 3840-3849	100.00	170.82	174.40	242.95	241.50	241.26

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.

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ITEM 6. ***SELECTED FINANCIAL DATA***

SELECTED CONSOLIDATED FINANCIAL DATA

(In thousands, except per share data)

	Fiscal Years Ended March 31,				
	2008	**2007**	**2006**	**2005**	**2004**
Statement of Operations Data:					
Revenue:					
Products	$ 58,322	$ 50,408	$ 43,322	$ 37,945	$ 25,070
Funded research and development	619	241	348	271	669
	58,941	50,649	43,670	38,216	25,739
Costs and expenses:					
Cost of product revenue excluding amortization of intangibles	15,065	12,012	11,685	9,366	7,591
Research and development	24,917	22,292	16,739	13,350	14,150
Selling, general and administrative	52,658	42,448	30,923	18,566	14,037
Arbitration decision	1,206				
Expensed in-process research and development		800	13,306		
Amortization of intangible assets	1,582	1,608	1,308	187	213
	95,428	79,160	73,961	41,469	35,991
Loss from operations	(36,487)	(28,511)	(30,291)	(3,253)	(10,252)
Other (expense) income:					
Investment income, net	1,625	1,045	1,194	801	634
Change in fair value of WorldHeart note receivable and warrant	(5,000)				
Other (expense) income, net	(541)	60	4	110	172
	(3,916)	1,105	1,198	911	806
Loss before provision for income taxes	(40,403)	(27,406)	(29,093)	(2,342)	(9,446)
Provision for income taxes	527	475	356		
Net loss	$ (40,930)	$ (27,881)	$ (29,449)	$ (2,342)	$ (9,446)
Basic and diluted net loss per share	$ (1.26)	$ (1.03)	$ (1.15)	$ (0.11)	$ (0.45)
Weighted average shares outstanding	32,465	27,124	25,649	21,845	21,153
Balance Sheet Data:					
Cash, cash equivalents, marketable securities and long-term investments	$ 38,299	$ 75,125	$ 30,835	$ 43,617	$ 45,483
Working capital	52,027	83,485	37,704	50,342	32,096
Total assets	118,031	136,183	78,537	61,061	59,161
Stockholder s equity	93,594	122,095	69,488	56,179	54,336
Dividends					

Note: Operating results include the operations attributable to Impella from the date of acquisition, May 10, 2005.

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

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

Overview

We are a leading provider of medical devices in circulatory support and we offer a continuum of care in heart recovery to acute heart failure patients. Our strategy is focused on establishing heart recovery as the goal for all acute cardiac attacks. Our products are designed to enable the heart to rest, heal and recover by improving blood flow and/or performing the pumping function of the heart. We believe we are the only company with commercially available cardiac assist devices approved for heart recovery from all causes by the U.S. Food and Drug Administration, or FDA and our products have been used to treat thousands of patients to date. Our products can be used in a broad range of clinical settings, including by heart surgeons for patients in profound shock and by interventional cardiologists for patients who are in pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab. We are focused on increasing awareness of heart recovery and establishing it as the goal for patients with failing but potentially recoverable hearts. We expect recovery awareness and utilization of our products will significantly increase the number of patients able to return home from the hospital with their own hearts. Since 2004, our executive team has focused our efforts on expanding our product portfolio and we have numerous circulatory care disposable products that have either been approved or cleared by the FDA or have received CE mark approval in Europe, as well as several additional circulatory care products in development.

Critical Accounting Policies and Estimates

Significant Estimates

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

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

Revenue Recognition

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

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

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

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Intangible Assets

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, 2008 was $6.9 million.

Goodwill

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 2008 as of October 31, 2007 and determined that goodwill was not impaired. The carrying amount of goodwill at March 31, 2008 was $31.6 million.

Allowance for Doubtful Accounts

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

Warranties

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

Inventories

We value our inventory of products held for sale at the lower of cost or current estimated market value. We regularly review inventory quantities on hand and write down to its net realizable value any inventory believed to be impaired. If actual demand or market conditions are less favorable than projected demand, additional inventory write-downs may be required that could adversely impact financial results for the period in which the additional excess or obsolete inventory is identified. We recorded write-downs of inventory in the amount of $1.0 million, $0.2 million, and $0.4 million for fiscal 2008, 2007 and 2006, respectively.

Accrued Expenses

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

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Stock-Based Compensation

In fiscal 2007, in accordance with Statements of Financial Accounting Standards (SFAS) No. 123(R) *Share-Based Payment*, we began recording stock-based compensation in our statements of operations based on the fair value method, rather than the intrinsic method. This expense is determined after consideration of several significant judgments and estimates. The fair value of each stock option we granted is estimated using the Black-Scholes option pricing model. Use of a valuation model requires us to make certain assumptions with respect to selected model inputs. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on historical volatility of our stock. The average expected life was estimated using the simplified method for stock option grants before January 1, 2008 as prescribed by SEC Staff Accounting Bulletin No. 107 *Share-based Payment*. The calculation of the fair value of the options is net of estimated forfeitures. Beginning with the quarter ended March 31, 2008, 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 cash dividends in the foreseeable future.

Prior to April 1, 2006, we accounted for stock-based compensation plans in accordance with the provisions of Accounting Principles Bulletin (APB) No. 25. We followed the disclosure-only alternative requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, we did not recognize compensation expense for the issuance of options with exercise prices at least equal to the fair market value at the date of the grant.

Income Taxes

As part of the process of preparing our consolidated financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. At March 31, 2008, we had federal and state net operating loss carryforwards, or NOLs, of approximately $90.8 million and $42.8 million, respectively, which begin to expire in fiscal 2009. Additionally, at March 31, 2008, we had federal and state research and development credit carryforwards of approximately $6.6 million and $3.2 million, respectively, which begin to expire in fiscal 2009. We acquired Impella, a German-based company, in May 2005. Impella had pre-acquisition net operating losses of approximately $22.9 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, we determined that approximately $1.5 million of pre-acquisition net operating losses could not be utilized. The utilization of pre-acquisition NOLs of Impella in future periods is subject to certain statutory approvals and business requirements.

Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation allowance of $96.2 million has been established to offset our net deferred tax assets and liabilities. In the event that we determine in the future that we will be able to realize all or a portion of our net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income in the period such a determination was made. Additionally, the future utilization of our NOL and research and development credit carry forwards to offset future taxable income may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to ownership changes that have occurred previously or that could occur in the future. Ownership changes, as defined in Section 382 of the Internal Revenue Code, can limit the amount of NOL carry forwards and research and development credit carry forwards that a company can use each year to offset future taxable income and taxes payable. We completed a Section 382 study and analysis in fiscal 2008 to determine whether changes in the composition of its stockholders, including our acquisition of Impella or our recent public offering, resulted in an ownership change for purposes of Section 382. We believe that all of our federal and state NOL s will be available for carryforward to future tax periods, subject to the statutory maximum carryforward limitation of any annual NOL. Any future potential limitation to all or a portion of the NOL or research and development credit carry forwards, before they can be utilized, would reduce our gross deferred tax assets. We will monitor subsequent ownership changes, which could impose limitations in the future.

In July 2006, the FASB issued FASB Interpretation No. 48 or FIN No. 48, *Accounting for Uncertainty in Income Taxes*, which we adopted effective April 1, 2007. FIN No. 48 addressed the determination of how tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under FIN No. 48, tax benefits from an uncertain tax position are recognized only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution.

Financial Instruments

We entered into a convertible note purchase agreement with World Heart Corporation, or WorldHeart, in December 2007. Under the agreement, we loaned $5.0 million to WorldHeart, with the note and accrued interest, at 8% per annum, convertible at our option into common stock of WorldHeart. We advanced $1.0 million of the loan in December 2007 with the remaining $4.0 million advanced in January

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2008. The conversion feature within the note is an embedded derivative instrument under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and, accordingly, is separately valued within the carrying value of the note receivable. We also received a warrant to purchase up to 3,400,000 shares of WorldHeart common stock.

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

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

We monitor our investment in the note receivable and warrant on a quarterly basis to determine whether any impairment is required. We consider available evidence, including the duration and extent to which the market value has been less than cost, if applicable, to evaluate the extent to which the decline is other-than-temporary. If the decline is considered other-than-temporary, the carrying value of the financial instruments will be written down to estimated realizable value.

In May 2008, WorldHeart filed a Form 8-K disclosing that it has limited cash available to continue operations and that if it is unable to secure additional funding, it will be forced to take extraordinary business measures which could include filing for bankruptcy, ceasing operations and liquidating assets. We have a security interest in WorldHeart s intellectual property and other assets under the terms of the loan agreements. However, in the event of insolvency or bankruptcy of WorldHeart, there may not be a market for these assets, in which case we may not be able to receive payment for our convertible note. Due to these events, we recorded an impairment charge of $5.0 million during fiscal 2008 related to our note receivable from WorldHeart and its associated derivative instruments. WorldHeart may be unsuccessful in raising additional funds to finance its operations and may become insolvent as a result. In the event of insolvency or bankruptcy of WorldHeart, there may not be a market for these assets, in which case the Company may not be able to receive payments for our convertible note.

Recent Accounting Pronouncements

SFAS No. 157

In September 2006, the Financial Accounting Standards Board, or FASB, issued SFAS No. 157, *Fair Value Measurements*. Among other requirements, SFAS No. 157 defines fair value and establishes a framework for measuring fair value and also expands disclosure requirements regarding fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. In February 2008, the FASB issued FASB Staff Position (FSP) FAS 157-2, *Partial Deferral of the Effective Date of Statement 157*. We do not expect the adoption of SFAS No. 157 to have a material impact on our financial position or results of operations.

SFAS No. 159

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which provides companies with an option to report selected financial assets and liabilities at fair value in an attempt to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. This Statement is effective as of the beginning of an entity s first fiscal year beginning after November 15, 2007. We do not expect the adoption of SFAS No. 159 to have a material impact on our financial position or results of operations.

EITF 07-3

In June 2007, the Emerging Issues Task Force, or EITF, reached a final consensus on Issue No. 07-3, or EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which requires that non-refundable advance payments for future research and development activities be capitalized until the goods have been delivered or related services have been performed. The adoption of EITF No. 07-3 is on a prospective basis for fiscal years beginning after December 15, 2007 and will only impact us if we enter into agreements which require non-refundable advance payments in fiscal year 2009.

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SFAS No. 141(R)

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

SFAS No. 160

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51.* SFAS No. 160 amends Accounting Research Bulletin, or ARB No. 51, to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It also amends certain of the consolidation procedures of ARB No. 51 for consistency with the requirements of FASB Statement No. 141(R). This statement is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The statement shall be applied prospectively as of the beginning of the fiscal year in which the statement is initially adopted. We are evaluating the impact that the adoption of SFAS No. 160 may have on our consolidated financial statements.

SFAS No. 161

In March 2008, the FASB issued FASB Statement No. 161, *Disclosures About Derivative Instruments and Hedging Activities*. This statement is intended to improve financial reporting about derivative instruments and hedging activities by enhanced disclosures to better understand their effects on a company s financial position, results of operation and cash flows. This standard is effective for interim and annual financial statements beginning after November 15, 2008. We are evaluating the impact that the adoption of SFAS No. 161 may have on our consolidated 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,		
	2008	**2007**	**2006**
Revenues:			
Products	98.9%	99.5%	99.2%
Funded research and development	1.1	0.5	0.8
Total revenues	100.0%	100.0%	100.0%
Costs and expenses:			
Cost of product revenue excluding amortization of intangibles	25.6%	23.7%	26.8%
Research and development	42.3	44.0	38.3
Selling, general and administrative	89.3	83.8	70.7
Arbitration decision	2.0		
Expensed in-process research and development		1.6	30.5
Amortization of intangible assets	2.7	3.2	3.0
Total costs and expenses	161.9	156.3	169.3
Loss from operations	(61.9)	(56.3)	(69.3)
Other (expense) income:			
Investment income, net	2.8	2.1	2.7
Change in fair value of WorldHeart note receivable and warrant	(8.5)		
Other (expense) income, net	(0.9)	0.1	
	(6.6)	2.2	2.7
Loss before provision for income taxes	(68.5)	(54.1)	(66.6)
Provision for income taxes	0.9	0.9	0.8

Net loss	(69.4)%	(55.0)%	(67.4)%

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

Revenues

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

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

Total console revenue for fiscal 2008 decreased $1.0 million, or 12%, due to declines in AB5000 console revenues, partially offset by sales outside the U.S. of iPulse and Impella consoles. Our new iPulse combination console (combination driver for our IAB, BVS blood pump and AB5000 ventricular assist device) is approved under CE-mark in Europe and was approved by the FDA under a PMA supplement approval in late December 2007.

The increase in revenue for fiscal 2008 as compared to fiscal 2007 is primarily due to the effects of our strategy to increase global distribution and our ongoing efforts to increase recovery awareness globally in hospitals, open heart centers and transplant centers. Our sales and clinical teams are focused on stimulating demand for our products by educating surgeons and cardiologists about both the clinical benefits of recovery and the increased reimbursement available for our heart recovery products. We expect to continue to increase our marketing, service and training, investments throughout fiscal 2009 with particular focus on expertise in the cath lab to support the efforts of the sales and clinical teams to drive recovery awareness and revenue growth globally.

The BVS product was launched over 15 years ago and revenue from this product has been declining as AB5000, our next-generation product for heart recovery, is designed to provide a longer duration of support than the BVS 5000 and facilitates patient mobility in the hospital. We expect revenue from BVS to continue to decline as our AB5000 disposable revenue grows and also as our new Impella products are introduced in the U.S.

The Impella 2.5 has been approved by the FDA for two pivotal studies in the U.S. In June 2008, we received 510(k) clearance for our Impella 2.5 device for partial circulatory support for up to six hours. This clearance allows for immediate commercial shipment of the device to U.S. hospitals that purchase the device. The Impella 2.5, Impella 5.0 and Impella LD are approved in Europe under CE-mark and are now approved in over 40 countries. During the U.S. pivotal studies for the Impella 2.5, we are generating revenue from the sale of Impella 2.5 disposables.

Cost of Product Revenues

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

Research and Development Expenses

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

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Selling, General and Administrative Expenses

Selling, general and administrative expenses for fiscal 2008 increased by $10.3 million, or 24%, to $52.7 million from $42.4 million in fiscal 2007. The increase is due to increased investments in our global distribution of sales and clinical representatives with headcount up approximately 17% as compared to fiscal 2007, and is also due to our increased investments in our marketing initiatives. We continue to invest in our European operations to generate revenue growth in that region and recently opened sales offices in France and the United Kingdom. We are investing in our global distribution to generate revenue growth of products that are approved by the FDA and other global regulatory authorities today and also in advance of potential FDA approvals of our Impella products to maximize our market penetration and revenue growth following regulatory approval or clearance.

We expect to continue to increase our expenditures on sales and marketing activities throughout fiscal 2009, with particular investments in clinical personnel with cath lab expertise and also plan to increase our marketing, service and training investments to support the efforts of the sales and clinical teams to drive recovery awareness for acute heart failure patients globally.

Arbitration Decision

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

Amortization of Intangibles

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

Change in Fair Value of WorldHeart Note Receivable and Warrant

We mark to market the fair value of the conversion feature on the note receivable and warrant associated with the WorldHeart transaction. In May 2008, WorldHeart filed a Form 8-K disclosing that it has limited cash available to continue operations and that if it is unable to secure additional funding, it will be forced to take extraordinary business measures which could include filing for bankruptcy, ceasing operations and liquidating assets. We have a security interest in WorldHeart s intellectual property and other assets under the terms of the agreement. Due to these events, we recorded an impairment charge of $5.0 million during fiscal 2008 related to our note receivable from WorldHeart and its associated derivative instruments. WorldHeart may be unsuccessful in raising additional funds to finance its operations and may become insolvent as a result. In the event of insolvency or bankruptcy of WorldHeart there may not be a market for these assets, in which case we may not be able to receive payments for our convertible note.

Investment Income, net

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

Other (Expense) Income

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

Provision for Income Taxes

During fiscal 2008 and 2007, we recorded a provision for income taxes of $0.5 million in each year. The income tax provision is primarily due to a deferred tax related to a difference in accounting for our goodwill, which is amortizable over 15 years for tax purposes but