ABIOMED INC Form 10-K June 14, 2006

## **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, 2006

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 (Address of Principal Executive Offices)

01923

(Zip Code)

(978) 777-5410

(Registrant s Telephone Number, Including Area Code)

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

Title of Each Class
None

Name of Each Exchange on Which Registered None

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

## Common Stock, \$.01 par value

## **Preferred Stock Purchase Rights**

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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer " Accelerated filer x Non-accelerated filer "

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, 2005, 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 \$237,213,633.

As of June 13, 2006, 26,532,524 shares of the registrant s common stock, \$.01 par value, were outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement for its 2006 Annual Meeting of Stockholders, which is scheduled to be filed within 120 days after the end of the registrant s fiscal year, are incorporated by reference in Part III (Items 10, 11, 12, 13 and 14) of this Report.

#### INTRODUCTORY NOTE

This report, including the documents incorporated by reference in this report, includes forward-looking statements. 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, will, 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:

the outcome of our FDA submission to the U.S. Food and Drug Administration (FDA) for limited market approval under a Humanitarian Device Exemption (HDE) for our AbioCor Implantable Replacement Heart;

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 currently 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 currently exist or could develop for our products and products under development;

the potential comparative long-term patient cost of permanent heart replacement as compared to heart transplantation;

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, ItemIA and elsewhere in this Report. We are not obligated to update or revise these forward-looking statements to reflect new events or circumstances.

#### PART I

# ITEM 1. BUSINESS Overview

ABIOMED is a Delaware corporation, incorporated in 1981, with its principal executive offices located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923. We commenced operations in 1981. Our telephone number is (978) 777-5410 and our web address is www.abiomed.com. We make available free of charge through the Investor section of our website, all reports filed with the Securities and Exchange Commission (SEC). We include our website address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website. The Company is a leading provider of medical products and services in the area of circulatory care. The Company s strategy is centered around establishing recovery as the standard of care for acute patients. The two products of the Company designed for heart recovery, and approved by the FDA, following acute events are the AB5000 and BVS 5000. The Company s Impella products are CE marked in Europe and are discussed in more detail in this Overview section. Our AB5000 Circulatory Support System is a heart assist product designed to provide enhanced patient mobility within and between medical centers, to facilitate patient ambulation and to provide enhanced features and ease of use for caregivers. The AB5000 console serves as a platform for ongoing and future blood pump product line enhancements expected to meet patient needs across a broader spectrum of temporary heart assist applications. Our AB5000 marketing efforts were initially focused on introducing the system in the largest cardiothoracic surgical centers through sales of consoles and blood pumps. It is our intention to seek expansion of the current approved indications for use of the AB5000 in order to allow support of expanded patient populations for longer periods of support.

The BVS and AB5000 systems each consist of single-use external blood pumps and cannulae and a reusable pneumatic drive and control console. Both are capable of assuming the full pumping function of a patient s failing heart, and are designed to provide either univentricular or biventricular support. Both are currently approved by the FDA for temporary use while the patient s heart is allowed to rest, heal and recover. The AB5000 console is capable of controlling both the BVS and the AB5000 blood pumps and ventricles and a patient can be switched from a BVS VAD to an AB 5000 VAD without surgery due to the compatible design of the cannulae used with the products.

Our AbioCor is a battery-powered totally implantable replacement heart system, designed to operate without wires or any other material penetrating the patient s skin. The Company applied for initial FDA market approval for the AbioCor to treat a defined subset of irreversible end-stage heart failure patients under a Humanitarian Device Exemption (HDE). This would allow implantation of the AbioCor in up to 4,000 U.S. patients a year. As of June 13, 2006, the Company is awaiting an FDA decision on its HDE application.

In May 2005, we completed the acquisition of Impella CardioSystems AG (Impella), located in Aachen, Germany. Impella manufactures, sells and supports the world s smallest, minimally invasive, high performance micro blood pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. Impella s Recover System pumps are designed to provide ventricle support for patients requiring hemodynamic stabilization, or suffering from reduced cardiac output and can potentially aid in recovering the hearts of patients suffering from acute myocardial infarction (AMI or Heart Attack). Impella has CE marks for four of its devices and currently markets them throughout Europe. We intend to seek FDA approval to sell the Impella Recover System blood pumps in the United States, as well as regulatory approval in other countries in order to address wider market opportunities for circulatory care. In May 2006, the FDA granted approval for the Company to commence its pilot clinical trial immediately in the United States for the Impella 2.5 minimally invasive ventricular assist device (VAD). The approval is conditioned on submitting additional information to the FDA by early July, 2006.

The indication for use is support during high-risk angioplasty for up to five days as a left ventricular assist device. Angioplasty, performed in the catheterization lab, is the insertion of a catheter-guided balloon and is used

to open a narrowed coronary artery. A stent (a wire-mesh tube that expands to hold the artery open) is usually placed at the narrowed section. High-risk angioplasty is defined as patients undergoing angioplasty on an unprotected left main coronary artery lesion, or the last patent coronary conduit, and poor cardiac function.

As used herein, ABIOMED includes ABIOMED, Inc., together with our subsidiaries. ABIOMED and ABIOCOR are trademarks of ABIOMED, Inc., and are registered in the U.S.A. and certain foreign countries. BVS is a trademark of ABIOMED, Inc. and is registered in the U.S.A. AB5000 is a trademark of ABIOMED, Inc. IMPELLA and RECOVER are trademarks of Impella CardioSystems GmbH, a subsidiary of ABIOMED, Inc., and are registered in the U.S.A. and certain foreign countries. This Report may also include trademarks of companies other than ABIOMED.

## **Industry Overview**

#### Heart Disease

Heart disease is the number one cause of death in the U.S., annually claiming more than 700,000 lives in the U.S. Internationally, heart disease accounts for nearly one third of all deaths, killing 16.7 million people annually (according to World Health Organization estimates), including more than 4 million in Europe alone. Illnesses and deaths from heart disease create an immense burden to many individuals and their families. Patients frequently experience extended suffering, and the economic cost can be substantial. While a number of therapies exist for the treatment of patients in early stages of heart disease, limited therapies exist today for most patients with severe end-stage heart failure.

The majority of deaths from heart disease can be attributed to coronary heart disease and congestive heart failure. Other types of heart disease include rhythm disorders and diseases of the valves.

Coronary heart disease is a disease of the coronary arteries causing reduced blood flow and insufficient oxygen delivery to the affected portion of the heart. Coronary heart disease can lead to a heart attack, also known as acute myocardial infarction (AMI), and may result in permanent damage to the heart muscle. In severe heart attacks, death can occur suddenly or gradually over days and weeks. Each year, approximately 865,000 people in the U.S. experience AMI. Of these cases, 7% to 10% suffer from cardiogenic shock, preventing blood flow from the heart. Cardiogenic shock is the leading cause of mortality for patients hospitalized with AMI, resulting in death in up to 50% of cases.

Congestive heart failure is a condition resulting from the progressive deterioration of the heart over extended periods of time. The patient s heart cannot provide adequate blood flow and oxygen to meet the needs of the body. Congestive heart failure may be initiated and aggravated by a variety of factors, including high blood pressure, defective heart valves, coronary heart disease, infections of the heart muscle or the valves and problems resulting from heart defects. Due to the progressive nature of congestive heart failure, medical interventions often take place over periods of months or years.

In general, heart failure is progressive. While over 60% of all heart failure patients experience sudden death as a result of cardiac arrest, the remaining patients who die from heart failure typically do so in hospitals or long-term care facilities.

## Prevalence, Incidence and Mortality

The American Heart Association reports in the 2005 update on *Heart Disease and Stroke Statistics* that a total of 70.1 million people in the United States live with some form of cardiovascular disease, including 65.0 million with high blood pressure. Of those, 13.0 million were diagnosed with coronary heart disease, 4.9 million with congestive heart failure. Thus, coronary heart disease patients outnumbered congestive heart failure patients by approximately 2.7:1. For patients newly diagnosed within 2002, however, the ratio of coronary

heart disease to congestive heart failure patients was 2.2:1, indicating that congestive heart failure is becoming relatively more important as time goes on. We believe this trend is primarily attributable to the aging of the population. Congestive heart failure is primarily a condition of the elderly.

According to the National Center for Health Statistics, approximately 700,000 people died of heart disease in the U.S. in 2002. According to the same source, nearly 371,000 of these deaths were attributable to coronary (ischemic) heart disease, approximately 42,000 were attributable to congestive heart failure, and approximately 287,000 were attributable to other diagnoses. We believe that a close examination of the various categories included in those other diagnoses reveals that many of those deaths may have been attributable to congestive heart failure related conditions.

## Therapies for Heart Disease

A broad spectrum of treatment is available for heart disease patients. Treatments include drug therapies, cardiac interventions, including closed chest procedures (angioplasty and stents) and rhythm management therapies, or surgical corrections, such as coronary bypass surgery and valve replacement. These therapies are sometimes successful in slowing the progression of heart disease, extending life, and/or improving the quality of life for some period of time. For patients with end-stage heart disease, however, these treatments are typically inadequate. Patients with the most severe heart disease, those at identifiable risk of death, frequently are in need of mechanical circulatory support or heart replacement. Because the supply of available donor hearts is limited, with fewer than 2,200 per year available in the U.S., heart assist and replacement treatments have been and continue to be developed with the goal of extending and improving the lives of these patients.

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

At present, due to the stage of technological development, circulatory support devices are typically used only after other, less-invasive therapies have been found to be inadequate. The appropriate reference group from which to begin analysis of the potential market for these devices are the patients who die each year of heart disease: approximately 700,000 in the U.S. and the estimated 16.7 million around the globe. In the future, when devices have matured and become less invasive, more durable and reliable, and surgical and patient management techniques have improved, these devices may become appropriate choices for less emergently ill patients and the potential addressable market may be much larger.

Not all of the patients who die each year of heart disease are addressable by circulatory support devices. Many patients not classifiable as coronary heart disease or congestive heart failure patients are not suitable candidates for circulatory support. In addition, more than 60% of all cardiac deaths occur suddenly, outside of the hospital or in the Emergency Room, and therefore cannot be reached by this therapy. Some suffer significant comorbidities that might rule out device implantation, and many are simply too frail to withstand the rigors of device implantation and surgical recovery. As a result, we estimate that the total number of patients addressable today by mechanical circulatory support devices ranges from 60,000 to 100,000 patients per year in the U.S.

This and any other estimate of market size should be viewed as dynamic and subject to change on account of a variety of factors. For example, both the percentage of heart disease patients who are unreachable because they die suddenly and the percentage of patients who are untreatable because of frailty are important determinants of the total circulatory support device market. Both of those variables are susceptible to change over time as technology improves and patient management techniques mature. The total size of the market will also be affected by demographic trends, most particularly by the aging of the so-called baby boom generation. That generation is just approaching the age at which heart disease becomes a major medical problem, and it is reasonable to postulate that the pool of heart disease patients will increase as the baby boom generation ages.

## **ABIOMED Products and Products Under Development**

ABIOMED is building a global suite of cardiac assist solutions for physicians and clinicians. Our cardiac assist products support patients along the entire care pathway to heart recovery. Today, ABIOMED manufactures the smallest circulatory assist devices in the market. The Impella Recover 2.5 and 5.0 are minimally invasive, high-performance micro blood pumps designed for use by cardiologists in the cardiac catheterization lab. These pumps can be inserted percutaneously to provide ventricular support to patients suffering cardiogenic shock or undergoing a high risk procedure. Currently, the Impella Recover devices, the 5.0, 2.5 and RD each have the CE mark. The 5.0 and the RD are not yet approved by the FDA for sale in the U.S. The conditional approval of the 2.5 for initial clinical trials in the U.S. is conditioned on submitting additional information to the FDA by early July, 2006.

Patients presented to the surgery suite may be supported with the ABIOMED BVS 5000. The BVS 5000 was the first FDA approved heart assist device capable of assuming the pumping function of the heart, allowing the patient s heart to rest, heal and recover. Since 1992, thousands of patients have been supported, and the BVS system was considered the standard of care for patients with acute shock, supporting either the right, left or both ventricles.

Acute shock of the heart can occur in many situations including immediately following heart surgery, a virus attacking the heart or a heart attack. Published data demonstrates that recovery from a heart attack complicated by shock requires on the average 30 days of cardiac support. This latest data supports the need for a recovery device, such as ABIOMED s AB5000, which provides longer support durations, ambulation and ease of explant post recovery.

The AB5000 heart assist system was FDA approved for recovery and commercial distribution during fiscal 2004. Since its introduction, the AB5000 has supported more than 400 patients globally, increasing the recovery and survival rates for all potentially recoverable indications. There is growing acceptance of the AB5000 around the world. It is quickly being recognized as the device preference for surgical patients.

In May 2005, we completed the acquisition of Impella CardioSystems AG (Impella), located in Aachen, Germany. Impella manufactures, sells and supports the world s smallest, minimally invasive, high performance micro blood pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. Impella s Recover System pumps are designed to provide ventricle support for patients requiring hemodynamic stabilization, or suffering from reduced cardiac output and can potentially aid in recovering the hearts of patients suffering from acute myocardial infarction (AMI or Heart Attack). Impella has CE marks for its devices and currently markets them throughout Europe. We intend to seek FDA approval to sell the Impella products in the United States as well as regulatory approval in other countries in order to address wider market opportunities for circulatory care.

The AbioCor and the Company s next generation AbioCor II are battery-powered totally implantable replacement heart systems, designed to operate without wires or any other material penetrating the patient s skin. As of June 13, 2006, we are awaiting an FDA decision on our HDE application for AbioCor. The AbioCor II is 30% smaller than the AbioCor, incorporates key design elements of the Penn State Heart technology acquired in 2000, and has a Company reliability goal of five years of operation.

## **Research and Product Development**

As of May 31, 2006, our research and development staff, including those employees who joined us from Impella, consisted of 86 professional and technical personnel, including many engineers with advanced degrees, covering disciplines such as electronics, mechanical engineering, software, reliability engineering, fluid mechanics, physics, materials and physiology.

Our research and development efforts are focused on developing a broader portfolio of products across a clinical spectrum of care, primarily focused in the area of circulatory care.

We expended \$14.2 million, \$13.4 million and \$16.7 million on research and development in fiscal 2004, 2005 and 2006, respectively. We expect research and development expenditures of approximately \$16 million to \$20 million in fiscal year 2007, which includes certain estimated expenses for the U.S. FDA trials for certain Impella products, as well as costs associated with the development of new technologies and improvements to existing technologies.

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

As of May 31, 2006, our worldwide sales, clinical support, marketing and field service teams included 73 full-time employees, 53 in the United States and 20 in Europe. In the fiscal year ahead, we plan to increase our sales and clinical support personnel by approximately two to four individuals per quarter to enhance our global distribution and generate recovery awareness to establish recovery as the standard of care for acute patients worldwide.

As of May 31, 2006, we have signed international sales and distribution agreements in Japan, China, Australia, Canada, and Latin America. We also utilize distributors throughout Europe and the Middle East in those countries in which we have not chosen to sell directly to medical centers. In fiscal 2006, fiscal 2005 and fiscal 2004, approximately 13%, 8% and 8%, respectively, of our product revenues were derived from international sales.

#### Manufacturing

We manufacture our products in Danvers, Massachusetts and Aachen, Germany. Our United States operations manufacture the BVS, AB5000, AbioCor and other products under development. Our Aachen, Germany facility manufactures all of our Impella products.

We believe our existing manufacturing facilities give us the physical capacity to produce sufficient quantities of products to meet market demand for the foreseeable future. However, we will continue to monitor market conditions and demand and evaluate capacity expansion requirements as deemed necessary in the future. Our U.S. manufacturing facility is ISO9001 certified and operates under the FDA s good manufacturing practice requirements set forth in the current quality system regulations, known as QSR.

#### Proprietary Rights, Patents and Know-How

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, gain access to our trade secrets or disclose such technology without our approval.

A substantial portion of our intellectual property rights relating to the AbioCor, the Penn State Heart, the BVS and the AB5000 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 that our trade secrets will not become known to or be independently developed by our competitors.

As of June 8, 2006, we own or have rights to 70 U.S. patents and at least 87 foreign patents. Our overall patent portfolio is comprised of 70 U.S. patents, of which 17 are related to the AbioCor Implantable Replacement Heart, two are related to the BVS 5000 Bi-Ventricular Support System, and 17 are related to Impella products. Our portfolio also includes ten patents related to the Penn State Heart to which we have an exclusive worldwide license. Our 70 U.S. patents have expiration dates ranging from July 11, 2006, to January 25, 2025. The remaining 87 patents are foreign patents issued in a variety of countries and related to 21 distinct patent families, of which one is related to the BVS 5000 Bi-Ventricular Support System and 84 are related to Impella

products. Our 87 foreign patents have expiration dates ranging from April 4, 2016, to November 16, 2021. We also own or have rights to certain pending U.S. and foreign patent applications. We believe patents will issue pursuant to such applications. However, neither the timing of the issuance, the scope of protection, nor the actual issue date of these pending applications can be forecasted with precision at this point in time. In certain instances, we may be required to pay royalties to maintain certain patent rights.

Our patents may not provide us with competitive advantages. They may also be challenged by third parties. Our pending or future patent applications may not be approved. The patents of others may render our patents obsolete 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 proprietary information.

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. 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 to design around the patented or otherwise proprietary technology.

The 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 (subject to a non-exclusive, non-transferable, royalty-free license to the government), provided we follow prescribed procedures.

#### 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 developing or marketing cardiovascular products that have substantially greater or broader financial, product development, sales and marketing resources and experience than ABIOMED. 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 BVS and AB 5000 systems can assume the full pumping function of the heart. The FDA approved these systems as bridge-to-recovery devices for the treatment of all patients with potentially reversible heart failure. They 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 for post-cardiotomy support. The Thoratec device was originally approved for bridge-to-transplant and bridge-to-transplant continues to be the primary use of the device. In addition, the BVS and AB 5000 compete with other blood pumps, such as intra-aortic balloon pumps (Datascope, Arrow International) and centrifugal pumps, that are used in medical centers for a variety of applications but which 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 bridge-to-recovery. We are aware of one other company, Levitronix, that is conducting clinical trials in the U.S. with a device that may compete with our current heart assist products in some applications. Approval by the FDA of products that compete directly with our products could increase competitive pricing and other pressures. We believe that we can compete with such products based on cost, clinical utility and customer relations.

No fully implantable replacement heart is commercially available today. We are aware of other heart replacement device research efforts in the U.S., Canada, Europe and Japan, but 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. In March 2004, the FDA s Circulatory Systems Devices Panel recommended approval of 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. The FDA approved the recommendation in October of 2004. Unlike our AbioCor, the CardioWest heart is not fully implantable. In addition, there are a number of companies including Thoratec Corporation, World Heart Corporation, MicroMed Technology, and Ventracor which are developing permanent heart assist products, including implantable 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**

ABIOMED s products and services are generally purchased by healthcare institutions that rely on third party reimbursement to cover the costs of related patient care. Third parties may include government healthcare plans such as the U.S. Medicare program (CMS), private insurers or managed care organizations. The type of coverage and amount of payment for patients supported by ABIOMED technology varies by country, medical procedure, hospital, outcome, cost and third party. Reimbursement for the AB5000 and BVS 5000 are well established in the U.S. market and most major global markets. Effective October 1, 2005 CMS increased reimbursement under DRG 103 for ABIOMED s recovery VADs to an average of \$140,000 per patient, up approximately 70% from historical CMS reimbursement levels. Commercial insurance carriers in the U.S. generally reimburse approximately \$165,000 per patient and are not subject to CMS reimbursement regulations. New products and services such as certain Impella products and AbioCor are actively reviewed for coverage and payment amounts with major third party payers.

## **Government Regulation**

*U.S. Clinical Use Regulations*. In the United States, our AB5000 and BVS 5000 heart assist systems are classified as Class III medical devices under FDA rules, as is the AbioCor. In the U.S., medical devices are classified into one of three classes (i.e., Class I, II or III) based on the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness. 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 pre-market approval (PMA) by the FDA to ensure their safety and effectiveness.

The FDA also provides that certain devices can be distributed under a Humanitarian Device Exemption (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 currently 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. If clinical trials of a device are required in order to obtain FDA approval, the sponsor of the trial is required to file an Investigational Device Exemption, known as an IDE, application prior to

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.

In November 1992, the FDA approved our PMA for the BVS. In 1996 and 1997, the FDA approved the use of the BVS 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 was approved under a PMA Supplement, and in September 2003 a PMA supplement for the AB5000 blood pump was approved. The AbioCor is classified as a Class III device and therefore is subject to a stringent regulatory approval and monitoring process. In January 2001, the FDA granted an IDE providing us with regulatory permission to commence the initial clinical trial of the AbioCor.

In September, 2003, a Humanitarian Use Device ( HUD ) designation was approved by the Office of Orphan Product Development, paving the way for our HDE submission in September, 2004. In June, 2005, the Circulatory Support Panel considered our HDE application for the AbioCor and provided feedback to the FDA. We are currently awaiting an FDA decision on our HDE application.

*U.S. Manufacturing and Sales Regulation.* Any devices, including the AB5000, BVS 5000 and AB5000 circulatory assist systems, which we manufacture or distribute pursuant to FDA clearances or approvals, are subject to continuing regulation by the FDA and other regulatory authorities. Manufacturers of medical devices for marketing in the U.S. are required to adhere to QSR requirements and 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 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.

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 the BVS and AB5000 comply with the Medical Device Directive, which includes quality system and CE certification requirements. The BVS, AB5000 and certain Impella Recover temporary cardiac assist products comply with the Medical Devices Directive, are CE marked and available for sale in the European Union.

## **Employees**

As of May 31, 2006 we had approximately 300 full-time employees, including:

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

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

100 in manufacturing and quality control; and

## 41 in general and administration.

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

#### ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. Current and prospective investors should carefully consider each of the risks and uncertainties described in this section and all of the other information in this Report. Our business, financial condition and results of operations could be severely harmed by any of the following risks. The trading price of our common stock could decline if any of these risks and uncertainties develop into actual events.

## We do not operate at a profit and cannot be assured of future profitability.

We have had net losses in each of the past three fiscal years. We are committed to making large expenditures in fiscal 2007 and subsequent fiscal years for our new products under development, including those acquired in connection with our recent acquisition of Impella CardioSystems, AG, (now Impella CardioSystems GmbH, a Division of ABIOMED) which may result in losses in future periods. These expenditures include costs associated with performing clinical trials, continuing our research and development relating to our new products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing. The amount of these expenditures is difficult to forecast accurately, and cost overruns may occur. We plan to fund a portion of these expenditures from our existing financial resources and revenues from AB5000, BVS and Impella product sales. 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. In the event that we are unable to obtain the necessary funding to develop and commercialize our products, our business may be adversely affected.

## Our operating results may fluctuate unpredictably.

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

costs we incur developing and testing the AbioCor, AbioCor II and other new products or product enhancements;

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

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

the timing of customer orders and deliveries;

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

economic conditions in the health care industry and the state of cost containment efforts, including reimbursement policies. We believe that period-to-period comparisons of our historical and future results will not necessarily be meaningful, and that investors should not rely on them as an indication of 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.

Our principal products and current primary source of revenues, the AB5000, BVS 5000 and Impella circulatory assist products, are vulnerable to competitive pressures, disruptions in sales, continuing review and extensive regulatory requirements.

All of our product revenues to date have come from sales of the AB5000, BVS 5000 and Impella products. We believe that we will continue to rely heavily on these products for at least the next several years until we

obtain regulatory approval for new products. In the event that a competitor were to introduce new treatments, products and technologies which compete with our products, add new features to their existing products or reduce their prices to make their products more financially attractive to customers, our revenue from our AB5000, BVS 5000 and Impella products could decline. For example, in the event of the expansion of technologies, which allow heart surgical procedures to be performed without stopping the heart, a reduction in the market for the AB5000 and BVS 5000 products could potentially result. Further, the AB5000 and BVS 5000 products are subject to stringent and continuing FDA and other regulatory requirements, including compliance with the QSR, adverse event reporting, prohibitions on promoting the products for unapproved uses, and continued inspection and market surveillance by the FDA. If our products are recalled or otherwise withdrawn from the market, our revenues would likely decline, which would hurt our business. In addition, variations in the quantity and timing of sales of our new AB5000 consoles have a disproportionate effect on our revenues, because the price of the console is substantially greater than the price of our disposable blood pumps. If we cannot maintain and increase our disposable blood pump revenues from our AB5000 and BVS 5000 product line, our overall business and financial condition could be adversely affected.

Our product revenues increased in fiscal 2006 by 14% in comparison to fiscal 2005 and in fiscal 2005 our product revenues increased by 51% in comparison to fiscal 2004. To maintain or increase revenues from sales of our current products, we may be required to adopt new sales and marketing strategies, some of which may require expending additional capital resources, or execute on existing strategies. The new strategies we may adopt or execute on include:

regularly introducing enhancements and product line extensions;

product expansion within our markets through the acquisition of existing companies whose products may require additional development or clinical analysis for regulatory approval;

expanding sales of our AB5000, BVS 5000 and Impella products within international markets, some of which require separate regulatory approvals; and

seeking new categories of patients to support with our technology platform. In the event that we are unsuccessful in carrying out these new strategies, our revenues may decline.

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

limited protection of intellectual property rights;

We are seeking to expand our international sales of the AB5000, BVS and Impella circulatory assist systems by recruiting direct sales and support teams for selected countries in Europe. Our international operations will be subject to a number of risks, which may vary from the risks we experience in the U.S., including:

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 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 profitability would be adversely affected.

Sales of medical products largely depend on the reimbursement of patients medical expenses by government health care programs and private health insurers. The cost of our AB5000 and BVS 5000 systems is substantial, and we anticipate that the cost of implanting the AbioCor in a patient will also be substantial. Without the financial support of the government reimbursement for CMS patient care 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 third party payors will reimburse sales of our products now under development, or enable us to sell them at profitable prices. We also cannot be sure that third party payors will continue the current level of reimbursement to physicians and medical centers for use of the AB5000 and BVS 5000 products. Any reduction in the amount of this reimbursement could harm our business.

The federal government and private insurers have considered ways to change, and have changed, the manner in which health care services are provided and paid for in the U.S. In the future, it is possible that the government may institute price controls and further limits on Medicare and Medicaid spending. These controls and limits could affect the payments we collect from sales of our products. Internationally, medical reimbursement systems vary significantly, with some medical centers having 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 health care 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.

Prior to approving coverage for new medical devices, most third party payors require evidence that the product has received FDA approval, is not experimental, and is medically necessary for the specific patient. Increasingly, third party payors require evidence that the devices being used are cost-effective. Our Impella, AbioCor and other products under development may not meet these or future criteria, which could hurt our ability to market and sell these products.

If we fail to achieve and maintain the high manufacturing standards that our products require or if we are unable to develop additional manufacturing capacity, we will not be successful.

Our products require precise, high quality manufacturing. 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 not able to manufacture the AB5000, BVS 5000 and Impella Recover products in accordance with necessary quality standards, our business and results of operations may be negatively affected.

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

The manufacture of our products is and will continue to be complex and costly, requiring a number of separate processes and components. Achieving precision and quality control requires skill and diligence by our

personnel. Further, to be successful, we believe we will need to increase our manufacturing capacity. We may experience difficulties in scaling up manufacturing of our new 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.

## 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 certain components used in our existing and other products under development. 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. Vendor lead times to supply us with ordered components vary significantly and 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 with required components when we need them. These factors could make it more difficult for us to effectively and efficiently manufacture our products, and could adversely impact our results of operations.

Some suppliers may be the only source for a particular component, which makes us vulnerable to cost increases and supply interruptions. Vendors may decide to limit or eliminate sales of certain products 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. 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. If we cannot obtain a necessary component, we may need to find, test and obtain regulatory approval 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 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, competition could force us to lower our prices, which could hurt our profitability.

Our intellectual property rights are and will continue to be a critical component of our success. A substantial portion of our intellectual property rights relating to the AB5000, BVS 5000, Impella products, AbioCor, AbioCor II and other products under development is in the form of trade secrets, rather than patents. In order to preserve certain proprietary information as trade secrets, we are required to restrict disclosure of information intended to constitute trade secrets to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. Certain of our consultants and third parties with whom we have business relationships 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 may seek employment with, and become employed by, our competitors. We cannot assure that confidentiality agreements with our employees, consultants and third parties will not be breached, 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 the AB5000, BVS 5000, Impella products, AbioCor or AbioCor II could adversely affect our business prospects.

Our business position will also depend in part on our ability to defend our existing and future patents and rights and conduct our business activities free of infringement claims by third parties. We intend to seek

additional patents, but our pending and future patent applications may not be approved, may not give us a competitive advantage, and could be challenged by others. Patent proceedings in the U.S. and in other countries may be expensive and time consuming. 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.

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

## If we cannot attract and retain the management, 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. Competition for skilled and experienced business management, scientific personnel 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.

We expect to grow rapidly if our products under development advance through the approval process. The expansion of personnel and facilities will strain our management and our financial and other resources. If we cannot manage this growth successfully, our business will likely suffer.

## Product liability claims could damage our reputation and hurt our financial results.

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

Many patients supported by our products do not survive. There are many factors beyond our control that could result in patient death, including the condition of the patient prior to use of the product, the skill and reliability of physicians and hospital personnel using and monitoring the product, and product maintenance by customers. However, the failure of the life support products we distribute for clinical test or sale could give rise to product liability claims and negative publicity.

The risk of product liability claims will increase as we introduce new products that are intended to support a patient until the end of life. For example, the AbioCor will have a finite life and could cause unintended complications to other organs and may not be able to successfully support all patients. Its malfunction could give rise to product liability claims whether or not it has extended or improved the quality of the patient s life. We cannot be sure that we can obtain liability insurance to cover the AB5000, BVS 5000, Impella products, AbioCor or other new products at a reasonable cost, if at all. If we have to pay product liability claims in excess of our insurance coverage, our financial condition will be adversely affected.

## Failure of our Impella acquisition to achieve its potential benefits could harm our business and operating results.

The acquisition of our Impella division may not achieve its anticipated benefits for a variety of reasons, including:

our inability to obtain FDA approval and market acceptance for Impella s products;

problems in successfully coordinating our research and development efforts;

difficulty in integrating sales, support and product marketing;

costs and delays in implementing common systems and procedures, including financial accounting systems; and

the inability to retain and integrate key management, research and development and customer support personnel. Further, we cannot assure you that we will realize any of the anticipated benefits and synergies of the acquisition. Any one or all of the factors identified above could cause increased operating costs, lower than anticipated financial performance, or the loss of customers, employees or business partners. The failure to integrate Impella successfully would have a material adverse effect on our business, financial condition and results of operations.

## The substantial costs of our Impella acquisition could harm our financial results.

In connection with our acquisition of Impella, we incurred substantial costs. These include fees to legal counsel, independent accountants and consultants. We may also be required to make additional contingent payments under the terms of the acquisition, in an amount of up to approximately \$28.2 million, based on our future stock price performance and milestones related to FDA approval and unit sales of Impella s products. If the benefits of the acquisition do not exceed the associated costs, including any dilution to our stockholders resulting from the issuance of shares of our common stock in the transaction, our financial results, including earnings per share, could suffer, and the market price of our common stock could decline.

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

In the future, we may pursue new acquisitions to obtain complementary businesses, products or technologies. Any such acquisition may not produce the revenues, earnings or business synergies that we anticipated, and an acquired business, product or technology might not perform as we expected. If we pursue an additional acquisition, our management could spend a significant amount of time and effort in identifying and completing the acquisition. If we complete an additional acquisition, we may encounter significant difficulties and incur substantial expenses in integrating the operations and personnel of the acquired company into our operations while preserving 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 is relationships with employees and customers.

Any of these outcomes could prevent us from realizing the anticipated benefits of our additional acquisitions. 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 our 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. These amortization charges and write offs could decrease our future earnings or increase our future losses.

Our rights distribution, 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.

Our rights distribution and provisions of our certificate of incorporation and of the 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. Our rights distribution and 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.

Our future success is strongly dependent on development of new assist products and implantable replacement heart devices. Our development efforts may not be successful.

We are currently devoting our major research and development and regulatory efforts, and significant financial resources, to the development of the AbioCor and AbioCor II, product extensions of existing commercial products and new products, such as the Impella Recover 2.5 and 5.0 micro blood pumps. The development of assist and replacement heart devices such as the AbioCor, AbioCor II, Impella blood pumps and other new products, 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. Specifically, for many years, we and other parties have been attempting to develop a heart replacement device. We cannot be sure that we will be successful in our development efforts, and in the event that we are unable to commercialize the AbioCor and AbioCor II, our business and financial condition could be adversely affected.

## The markets for our products under development are unproven.

Even if our products are successfully developed and approved by the FDA and corresponding foreign regulatory authorities, they may not enjoy commercial acceptance or success, which would adversely affect our business and results of operations. Several factors could limit our success, including:

our need to create a market for our new products: AB5000, AbioCor, AbioCor II, Impella products and possible limited market acceptance among physicians, medical centers, patients and third party payers;

the need for surgeons and cardiologists to develop or be trained in new surgical techniques or non-invasive procedures in order to use our products effectively;

limitations on the number of patients who may have access to physicians and medical centers with adequate training, equipment and personnel to make use of our products;

limitations inherent in first generation devices, and the potential failure to develop successive improvements, including increases in service life, which would reduce the addressable market for our products;

the lifestyle limitations that patients will have to accept;

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

the introduction by other companies of new treatments, products and technologies which compete with our products, and may reduce their market acceptance, or make them obsolete;

the reluctance, due to ethical considerations, of physicians, patients and society as a whole to accept significant medical devices that replace or assist the heart; and

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

The commercial success of the AB5000, AbioCor, AbioCor II, Impella Recover 2.5 and 5.0 micro blood pumps and other heart assist products will require acceptance by cardiovascular surgeons and interventional and heart failure cardiologists, a limited number of whom significantly influence medical device selection and purchasing decisions. We may achieve our business objectives only if our other products are accepted and recommended by leading physicians, which is likely to be based on a determination by these physicians that our products are safe, cost-effective and represent acceptable methods of treatment. Although we have developed relationships with leading cardiac surgeons and cardiologists, we cannot assure that these existing relationships and arrangements can be maintained or that new relationships will be established in support of our products. If cardiovascular surgeons and cardiologists do not consider our products to be adequate for the treatment of our target cardiac patient population or if a sufficient number of physicians recommend and use competing products, it would seriously harm our business.

Testing of our new products will involve uncertainties and risks which could delay or prevent new product introductions, require us to incur substantial additional costs or result in our failure to bring our products to market.

Development and testing of design changes to the AbioCor, AbioCor II, Impella 2.5 and 5.0 micro blood pumps and other products under development is often extensive, expensive and time consuming. Some of the tests for our products may require months or years to perform, and we could be required to begin these tests again if we modify one of our products to correct a problem identified in testing. Even modest changes to certain components of our products can take months or years to complete and test. If results of pre-clinical or clinical testing of our products under development indicate that design changes are required, such changes could cause serious delays that would adversely affect our results of operations. 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 the event that we suffer setbacks in the pre-clinical or clinical testing of our heart assist and replacement products, these products may be delayed, require further funding, and possibly may not be brought to market.

If we fail to obtain approval from the FDA and/or from foreign regulatory authorities, we cannot market and sell the affected products currently under development in the U.S. and/or other countries.

If we cannot demonstrate through clinical testing on humans or other means that the AbioCor or other new products under development and testing are safe and effective, we will not be able to obtain regulatory approvals in the U.S. or other countries for the commercial sale of these products. We cannot assure that the FDA or any other regulatory authority will act quickly or favorably on our requests for this product approval, or that the FDA or any other regulatory authority will not require us to provide additional data that we do not currently anticipate in order to obtain product approvals. If we are successful in obtaining FDA approval for an HDE for the AbioCor, the initial approval is likely to include conditions or limitations to particular indications that would limit the available market for these products. If we are not able to obtain regulatory approvals for use of the AbioCor or our other 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.

We intend to market our new products in international markets, including the European Union and Japan. We must obtain separate regulatory approvals in order to market our products in other jurisdictions. The approval

process may differ among those jurisdictions and approval in the U.S. or in any other jurisdiction does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties and costs for us, and require additional trials and additional expense.

If we obtain regulatory approval of our new products, the products will be subject to continuing review and extensive regulatory requirements, which could affect the manufacturing and marketing of our products.

The FDA continues to review products even after they have received initial approval. If and when the FDA approves the Impella and AbioCor devices, or our other products under development, the manufacture and marketing of these products will be subject to continuing regulation, including compliance with QSR, adverse event reporting requirements and prohibitions on promoting a product for unapproved uses.

We will also be required to obtain additional approvals in the event we significantly modify the design of an approved product or the product s labeling or manufacturing process. Modifications of this type are common with new products, and 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. If we are not able to obtain regulatory approval of modifications to our current and future products, the commercial success of these products would be limited.

We and our third-party suppliers of product components are also subject to inspection and market surveillance by the FDA for QSR and other requirements. Enforcement actions resulting from failure to comply with government requirements could result in fines, suspensions of approvals, recalls of products, operating restrictions and criminal prosecutions, and affect the manufacture and marketing of our products. The FDA 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.

The cost of developing and manufacturing the AbioCor, AbioCor II, Impella micro blood pumps and other planned new products is substantial for a company of our size and might exert a strain on our available resources.

Spending on our AbioCor, AbioCor II, Impella micro blood pumps and other products under development will remain significant for some time. We expect that we will also need to make significant expenditures to begin to manufacture and market the AbioCor and our other planned new products in commercial quantities for sale in the U.S. and other countries, if and when we obtain regulatory approval. We cannot be sure that our estimates of capital expenditures for the development of our new products will be accurate. We could have significant cost overruns, which could reduce our ability to commercialize our products. Any delay or inability to commercialize our products under development could adversely affect our business prospects and results of operations.

ITEM 1B. UNRESOLVED STAFF COMMENTS Not applicable.

## ITEM 2. PROPERTIES

Our headquarters are in an industrial office park located 22 miles north of Boston. This facility, located at 22 Cherry Hill Drive in Danvers, Massachusetts, consists of approximately 80,000 square feet of space under an operating lease that expires in 2010. This facility houses all of our U.S. operations, including research and development, manufacturing, sales and marketing and general and administrative departments. The lease contains options to extend twice in five-year increments beyond 2010 at market rates.

Our European operations are located in Aachen Germany in a 30,000 square foot leased facility that expires in August 2008. The building houses all 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 all ABIOMED product lines sold in Europe and the Middle East.

#### ITEM 3. LEGAL PROCEEDINGS

On May 15, 2006 Richard A. Nazarian, as Selling Stockholder Representative, filed a Demand for Arbitration (subsequently amended) with the Boston office of the American Arbitration Association, seeking 600,000 shares of unrestricted Abiomed stock for an alleged breach of our obligation to fund development of the Penn State Heart program and an alleged cancellation of the Penn State Heart development project. The Company intends to vigorously defend against the claims asserted.

As of March 31, 2006, we were not party to any material pending legal proceedings.

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

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended March 31, 2006.

#### 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 National 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 National Market for our two most recent fiscal years:

Fiscal Year Ended March 31, 2005	High	Low
First Quarter	\$ 14.63	\$ 7.80
Second Quarter	12.64	8.63
Third Quarter	17.70	8.88
Fourth Quarter	15.97	9.92
Fiscal Year Ended March 31, 2006	High	Low
Fiscal Year Ended March 31, 2006 First Quarter	<b>High</b> \$ 11.91	Low \$ 7.75
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First Quarter	\$ 11.91	\$ 7.75

#### Number of Stockholders

As of May 31, 2006, we estimate there are less than 1,000 holders of record 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. We estimate that there are approximately 11,000 beneficial holders who hold our common stock in street name.

## **Dividends**

We have never declared or paid any cash dividends on our capital stock and do not plan to pay any cash dividends in the foreseeable future. Our current policy is to retain all of our cash flows and future earnings to finance future growth.

## **Sales of Unregistered Securities**

No sales of unregistered securities occurred during our fourth quarter ended March 31, 2006.

## **Transfer Agent and Rights Agent**

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

ITEM 6. SELECTED FINANCIAL DATA
SELECTED CONSOLIDATED FINANCIAL DATA

(In thousands, except per share data)

	2002	Fiscal Y 2003	ears Ended Ma 2004	2006	
Statement of Operations Data:				2005	
Revenues:					
Products	\$ 24,747	\$ 23,127	\$ 25,070	\$ 37,945	\$ 43,322
Funded research and development	2,214	183	669	271	348
Total revenues	26,961	23,310	25,739	38,216	43,670
Costs and expenses:					
Cost of product revenues	7,925	7,501	7,591	9,366	11,685
Research and development	26,970	20,206	14,150	13,350	16,739
Selling general and administrative	16,005	14,667	14,037	18,566	30,923
Expensed in-process research and development					13,306
Amortization of intangibles	199	427	213	187	1,308
Total costs and expenses	51,099	42,801	35,991	41,469	73,961
Loss from operations	(24,138)	(19,491)	(10,252)	(3,253)	(30,291)
Interest and other income, net	2,945	1,320	806	911	1,198
	(21,193)	(18,171)	(9,446)	(2,342)	(29,093)
Tax provision					356
Net loss	\$ (21,193)	\$ (18,171)	\$ (9,446)	\$ (2,342)	\$ (29,449)
Basic and diluted net loss per share	\$ (1.02)	\$ (0.87)	\$ (0.45)	\$ (0.11)	\$ (1.15)
Weighted average shares outstanding	20,869	20,994	21,153	21,845	25,649
	2002	2003	March 31, 2004	2005	2006
Balance Sheet Data:					
Cash, cash equivalents, marketable securities and long-term investments	\$ 71,321	\$ 54,449	\$ 45,483	\$ 43,617	\$ 30,835
Working capital	74,127	56,987	32,096	50,342	37,650
Total assets	89,176	68,516	59,161	61,061	78,537
Long-term liabilities					
Stockholders equity					
- ·	79,868	62,090	54,336	56,179	69,488
Dividends	N/A	N/A	N/A	N/A	N/A

Note: Fiscal year 2006 data includes Impella from the date of acquisition in May, 2005.

#### 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

The Company is a leading provider of medical products and services in the area of circulatory care. The Company is strategy is centered around establishing recovery as the standard of care for acute patients. The two products of the Company designed for heart recovery, and approved by the FDA, following acute events are the AB5000 and BVS 5000. The Company is Impella products are CE marked in Europe and are discussed in more detail in this Overview section. Our AB5000 Circulatory Support System is a heart assist product designed to provide enhanced patient mobility within and between medical centers, to facilitate patient ambulation and to provide enhanced features and ease of use for caregivers. The AB5000 console serves as a platform for ongoing and future blood pump product line enhancements expected to meet patient needs across a broader spectrum of temporary heart assist applications. Our AB5000 marketing efforts were initially focused on introducing the system in the largest cardiothoracic surgical centers through sales of consoles and blood pumps. It is our intention to seek expansion of the current approved indications for use of the AB5000 in order to allow support of expanded patient populations for longer periods of support.

The BVS and AB5000 systems each consist of single-use external blood pumps and cannulae and a reusable pneumatic drive and control console. Both are capable of assuming the full pumping function of a patient s failing heart, and are designed to provide either univentricular or biventricular support. Both are currently approved by the FDA for temporary use while the patient s heart is allowed to rest, heal and recover. The AB5000 console is capable of controlling both the BVS and the AB5000 blood pumps and ventricles and a patient can be switched from a BVS VAD to an AB 5000 VAD without surgery due to the compatible design of the cannulae used with the products.

Our AbioCor is a battery-powered totally implantable replacement heart system, designed to operate without wires or any other material penetrating the patient s skin. The Company applied for initial FDA market approval for the AbioCor to treat a defined subset of irreversible end-stage heart failure patients under a Humanitarian Device Exemption (HDE). This would allow implantation of the AbioCor in up to 4,000 U.S. patients a year. As of June 13, 2006, the Company is awaiting an FDA decision on its HDE application.

In May 2005, we completed the acquisition of Impella CardioSystems AG (Impella), located in Aachen, Germany. Impella manufactures, sells and supports the world s smallest, minimally invasive, high performance micro blood pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. Impella s Recover System pumps are designed to provide ventricle support for patients requiring hemodynamic stabilization, or suffering from reduced cardiac output and can potentially aid in recovering the hearts of patients suffering from acute myocardial infarction (AMI or Heart Attack). Impella has CE marks for four of its devices and currently markets them throughout Europe. We intend to seek FDA approval to sell the Impella Recover System blood pumps in the United States as well as regulatory approval in other countries in order to address wider market opportunities for cardiac assist, recovery and replacement.

Our operating results reflect the dual activities of commercial operations and investments in the research and development of new technologies.

#### **Critical Accounting Policies**

The Company s discussion and analysis of its financial condition and results of operations are based on its consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our estimates and judgments, including those related to revenue recognition, bad debts, warranty obligations, inventory valuations and income taxes. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition. SEC Staff Accounting Bulletin No. 104 ( SAB 104 ) provides guidance on the recognition, presentation and disclosure of revenue in financial statements. SAB 104 establishes the SEC s view that it is not appropriate to recognize revenue until all of the following criteria are met: (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the seller s price to the buyer is fixed or determinable, and (4) collectibility is reasonably assured. Further, SAB 104 requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. In addition to SAB 104, we follow the guidance of EITF 00-21, Revenue Arrangements with Multiple Deliverables.

We derive our revenues primarily from product sales, including maintenance service agreements. The great majority of our product revenues are derived from shipments of our AB5000 and BVS 5000 product lines to fulfill customer orders for a specified number of consoles and/or blood pumps for a specified price. We recognize revenues and record costs related to such sales upon product shipment.

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.

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

Intangibles. The Company estimates 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. Actual cash flows arising from a particular intangible asset could vary from projected cash flows which could imply different carrying values and annual amortization expense from those established at the dates of acquisition. The net book value of intangible assets at March 31, 2006 was approximately \$8.2 million.

Goodwill. The Company periodically evaluates goodwill for impairment 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 the company s analysis could materially affect projected cash flows and the company s evaluation of goodwill for impairment. Should the fair value of the company s goodwill decline because of reduced operating performance, market declines, or other indicators of impairment, or as a result of changes in the discount rate, charges for impairment of goodwill may be necessary. The carrying amount of goodwill at March 31, 2006 was \$19.1 million.

Allowance for Doubtful Accounts. We continuously 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. While 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. While we engage in extensive product quality programs and processes, including monitoring and evaluating the quality of component suppliers, our warranty obligation is affected by product failure rates and product recalls. Our operating results could be adversely affected if the actual cost of 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. The inventory balances at March 31, 2005 and March 31, 2006, are net of accumulated impairment write-downs of \$887,000 and \$413,000, respectively. All of our inventories are related to our heart assist product line. We will not capitalize any costs related to AbioCor inventory until we receive regulatory approval to begin commercial sales.

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. In addition, as of March 31, 2006, the Company had federal and state tax net operating loss carryforwards of approximately \$67.9 million and \$24.1 million, respectively, that begin to expire in fiscal 2007. At March 31, 2006, the Company also had foreign net operating loss carryforwards of approximately \$24.8 million that can be carried forward indefinitely. The Company also has federal and state research and development credit carryforwards of approximately \$5.6 million and \$3.8 million, respectively, that begin to expire in fiscal 2007. We have recorded a valuation allowance of \$68.5 million as an offset against these otherwise recognizable net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that we determine in the future that the Company will be able to realize all or a portion of its net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income in the period such a determination was made.

Stock-Based Compensation. In December 2004 the FASB issued a revised Statement of Financial Accounting Standard (SFAS) No. 123, Share-Based Payment (FAS 123(R)). FAS 123(R) requires public entities to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award and recognize the cost over the period during which an employee is required to provide service in exchange for the award. The requirements of SFAS 123(R) are effective for annual fiscal periods beginning after June 15, 2005. Through its fiscal year ended March 31, 2006, the Company has followed APB No.25 which does not require the recognition of compensation expense relating to the issuance of stock options so long as the quoted market price of the Company s stock at the date of grant is less than or equal to the amount an employee must pay to acquire the stock. The original FAS 123 requires footnote disclosure only of proforma net income as if a fair-value-based method had been used. The Company is transitioning on a modified prospective basis, and the adoption of SFAS 123(R) effective with the fiscal quarter ended June 30, 2006 is expected to have a material impact on the Company s consolidated financial statements, although management is still evaluating the exact impact.

Recent Accounting Pronouncements. In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 151, Inventory Costs (FAS 151), which adopts wording from the International Accounting

Standards Board s (IASB) Standard No. 2, Inventories, in an effort to improve the comparability of international financial reporting. The statement is effective for the Company beginning in the first quarter of fiscal year 2007 and is not expected to have a material impact on the Company s results of operations, financial position or cash flows.

## **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,		
	2004	2005	2006	
Revenues:				
Products	97.4%	99.3%	99.2%	
Funded research and development	2.6	0.7	0.8	
Total revenues	100.0	100.0	100.0	
Costs and expenses:				
Cost of product revenues	29.5	24.5	26.8	
Research and development	55.0	34.9	38.3	
Selling, general and administrative	54.5	48.6	70.7	
Expensed in-process research and development			30.5	
Amortization of intangibles	0.8	0.5	3.0	
Total costs and expenses	139.8	108.5	169.3	
Loss from operations	(39.8)	(8.5)	(69.3)	
Other income, net	3.1	2.4	2.7	
Loss before income taxes	(36.7)	(6.1)	(66.6)	
Tax provision			0.8	
Net loss	(36.7)	(6.1)	(67.4)%	

Fiscal Years Ended March 31, 2006 and March 31, 2005 (fiscal 2006 and fiscal 2005)

## PRODUCT REVENUES

Product revenues for the fiscal year ended March 31, 2006 increased by \$5.4 million or 14% to \$43.3 million from \$37.9 million for the fiscal year ended March 31, 2005. The increase is primarily the result of the addition of Impella product revenues since its acquisition in May 2005 and increased sales of consoles and ventricles in the fiscal year ended March 31, 2006 compared to the prior year.

Revenues for fiscal year 2006 from consoles, disposables, and service/other programs increased 14%, 13% and 26%, respectively compared to the same period of 2005. Revenues from disposables, service and other programs comprised approximately 86% of total revenues for fiscal year 2006. The higher revenue during fiscal 2006 compared to fiscal 2005 is due to the effects of the increased global distribution during fiscal 2006 versus fiscal 2005 as the Company s sales and clinical team headcount was 45 at the end of fiscal 2006, up nearly 70% since the end of fiscal 2005. These sales and clinical teams have been focused on increasing recovery awareness in the hospitals and open heart centers globally. The increase in revenue during fiscal 2006 is a result of the increased global distribution and the recovery awareness programs with hospitals and centers merging clinical outcomes and reimbursement education to fuel demand for the Company s products. On October 1, 2005, the Centers for Medicare and Medicaid Services (CMS) increased reimbursement for the Company s recovery VADs to an average of \$140,000, an increase of 70% from prior levels, and now at the same level of reimbursement as transplant VADs (products sold by other device companies other than ABIOMED). The Company believes that

this change in reimbursement, an increase in published recovery data using the Company s products together with the increased global distribution teams generated the increase in revenues in fiscal 2006 compared to fiscal 2005. The Company expects to increase sales and clinical headcount in fiscal 2007 by two to four individuals per quarter and also plans to increase its service, marketing and training programs to continue to increase recovery awareness globally.

#### COST OF PRODUCT REVENUES

Cost of product revenues as a percentage of product revenues was 27% or \$11.7 million for the fiscal year ended March 31, 2006 versus 25% or \$9.4 million in fiscal 2005. The increase year over year is due primarily to inclusion of Impella product cost of product revenues in fiscal year 2006 and increased costs of product revenues for our AB 5000 and BVS as we sold more of these products in fiscal 2006 compared to fiscal 2005. Additionally, during fiscal 2006 the Company recorded a non-cash charge of approximately \$423,000 primarily as a result of determining that certain inventory had no future net realizable value.

#### RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses increased by \$3.3 million or 25% to \$16.7 million in fiscal 2006, from \$13.4 in fiscal 2005. The increase is primarily the result of including Impella s research and development expense since its acquisition in May 2005 and also reflects our efforts to expand and enhance our product lines across a clinical spectrum of care in the cath lab and surgery suite. During fiscal 2006, the Company invested in new product development to broaden its portfolio of products in the circulatory care markets.

## SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses increased by \$12.3 million, or 67%, to \$30.9 million in the fiscal year ended March 31, 2006, from \$18.6 million in fiscal 2005. The increase is primarily due to the inclusion of Impella expenses during fiscal year 2006 and also due to the Company's strategy to increase its global distribution, specifically its global sales, service, marketing and clinical specialists organizations. Total global sales and clinical headcount at the end of fiscal year 2006 was 45 compared to 27 at the end of fiscal 2005, representing an increase of 67%.

## EXPENSED IN-PROCESS RESEARCH AND DEVELOPMENT

The Company recorded a \$13.3 million non-cash charge to in-process research and development expense during the quarter ended June 30, 2005 in connection with the Company s acquisition of Impella on May 10, 2005. This charge relates to costs to acquire in-process research and development projects and technologies, which have not reached technological feasibility at the date of the business acquisition and have no alternative future use, and are expensed as incurred.

## OTHER INCOME

Other income consists primarily of interest earned on our cash and investments, foreign exchange gains, and other miscellaneous income. Other income was \$1.2 million for fiscal 2006 compared to \$0.9 million for fiscal 2005. This increase was primarily due to higher investment income.

## TAX PROVISION

In 2005, the Company had no tax provision as it was in a loss position and it was more likely than not that the Company would not recognize the benefit of the net operating losses. As part of the Impella acquisition in May of 2005, the Company obtained tax deductible goodwill amounting to \$13.9 million. The difference

between tax and financial statement cumulative amortization on tax deductible goodwill gives rise to a long-term deferred tax liability of \$310,000. This deferred tax liability cannot be used as a source of taxable income in the determination of the valuation allowance. Valuation allowances for deferred tax assets are established when necessary to reduce deferred tax assets to the amount expected to be realized. Based on expected future operating results, we believe that it is more likely than not that we will not realize the benefits of our deferred tax assets.

#### **NET LOSS**

During the fiscal year ended March 31, 2006 we incurred a net loss of \$29.4 million, or \$1.15 per share. This compares to a net loss of \$2.3 million or \$0.11 per share for the prior fiscal year. The \$27.1 million change in the net loss in fiscal 2006 compared to fiscal 2005 is due primarily to: a \$13.3 million non-cash in-process research and development charge; increased SG&A expenses of \$12.3 million as we expanded our global distribution; and an increase of \$3.3 million in research and development expenses as we drive a strategy to expand our product portfolio across a clinical spectrum.

We expect to continue to incur net losses for the foreseeable future as we plan to invest in expanding our global distribution and also expect to incur costs to bring new products to market.

Fiscal Years Ended March 31, 2005 and March 31, 2004 (fiscal 2005 and fiscal 2004)

## PRODUCT REVENUES

Product revenues increased by \$12.8 million, or 51%, from \$25.1 million in fiscal 2004 to \$37.9 million in fiscal 2005. The improvement is attributable to increased sales of both our AB5000 consoles and ventricles and our BVS 5000 disposable blood pumps. A majority of the increased product sales were derived from our delivering a record number of AB5000 systems and reorder ventricles during the fiscal year ended March 31, 2005 as a result of the product continuing to gain market acceptance as patient outcomes continued to improve with its wider use. Higher average unit selling prices for both products also contributed to approximately half the increased revenue performance during the past fiscal year. Our former European subsidiary, ABIOMED B.V., set a company record for revenues during the fiscal year ending March 31, 2005 by increasing product revenues by 56%, or \$0.7 million, over the prior year. International product revenue from sources outside of Europe also increased by 10% during the fiscal year ended March 31, 2005 as a result of our efforts to establish and strengthen international distribution channels. Of the \$37.9 million in product revenues for the fiscal year ended March 31, 2005, approximately 80% was derived from sales of AB5000 Ventricles and BVS disposable blood pumps. As of March 31, 2005, we have a sales backorder and deferred revenues of approximately \$0.6 million, primarily as a result of our multi-year customer service support contracts.

International sales accounted for 8% of total product revenue during the fiscal years ended March 31, 2005 and 2004.

## COST OF PRODUCT REVENUES

Our costs of product revenues as a percentage of product revenue improved for the fiscal year 2005 as compared to fiscal 2004 due to higher volumes of product sold, specifically our AB5000 and BVS products. Cost of product revenues as a percentage of product revenues was 25%, or \$9.4 million, for fiscal 2005 compared to 30%, or \$7.6 million, in fiscal 2004. Approximately 80% of the improvement in margin is the result of higher average unit selling prices for our AB 5000 and BVS pumps in comparison to the prior fiscal year with the remainder in improvement coming from increased productivity in our manufacturing processes.

## RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses decreased by \$0.8 million, or 6%, from \$14.2 million in fiscal 2004 to \$13.4 million in fiscal 2005. Research and development expenses were 35% of total revenues for fiscal 2005 and

55% of total revenues in fiscal 2004. The decrease is primarily as a result of shifting our labor and other costs to commercial BVS and AB5000 manufacturing activities offset by increased development efforts on potential new products.

## SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses increased by \$4.6 million, or 32%, from \$14.0 million in the prior year to \$18.6 million in fiscal year ended March 31, 2005. The increases are primarily the result of labor, recruiting and relocation expenses incurred in connection with our adding new senior management earlier this fiscal year and expenses in connection with the Sarbanes-Oxley 404 compliance. In addition, sales and marketing expenses increased significantly as a result of our efforts to expand our commercial operations both domestically and internationally.

#### OTHER INCOME

Other income consists primarily of interest earned on our investment balances, net of expenses and foreign exchange gains or losses. Other income was \$0.9 million in fiscal 2005, an increase of \$0.1 million from \$0.8 million in fiscal 2004. This increase was primarily due to interest income representing better yields on investments offset by a reduction of the foreign translation gain.

#### **NET LOSS**

Net loss for the fiscal year ended March 31, 2005 was approximately \$2.3 million, or \$0.11 per share. This is a 75% reduction from the net loss of approximately \$9.4 million, or \$0.45 per share, in the prior fiscal year.

## **Liquidity and Capital Resources**

As of March 31, 2006, our cash and investments totaled \$30.8 million compared to \$43.6 million in cash and investments at March 31, 2005 representing cash consumption of \$12.8 million. This compares to \$1.9 million consumed for the year ended March 31, 2005. The cash utilization during fiscal 2006 was driven by our strategy to expand our product portfolio and global distribution.

During the fiscal year ended March 31, 2006, cash used by operating activities was \$9.3 million, as compared to \$5.2 million used by operations during the fiscal year ended March 31, 2005. The increased use of cash for the period is primarily driven by the net loss for the fiscal year of \$29.4 million. This compares to a net loss of \$2.3 million in the prior fiscal year. The net loss was offset by various non-cash expenditures such as \$2.7 million for depreciation and amortization and a \$0.4 million write-down of inventory primarily related to Impella operations. We also had a one-time non-cash expense of \$13.3 million for in-process research and development related to the acquisition of Impella. The change in assets and liabilities was \$2.8 million, this net operating source of cash was primarily related to increases in accounts payable of \$1.3 million, accrued expenses of \$0.8 million and deferred revenues of \$0.4 million. Net cash flows from investing activities were \$7.4 million as net proceeds from the maturities of securities of \$13.0 million were offset by purchases of property and equipment of \$2.9 million and cash used to acquire Impella including acquisition costs of approximately \$2.6 million, net of cash acquired. We benefited from \$2.2 million in cash proceeds as a result of employee stock option exercises and employee participation in our stock purchase plan.

We believe that our revenue from product sales together with existing resources will be sufficient to fund our planned operations, including funding the operating capital needs of Impella, funding potential contingent cash payments to Impella s former shareholders in accordance with the Impella purchase agreement, the planned expenditures for our AbioCor and AbioCor II implantable replacement hearts, and development and continued commercialization efforts for the BVS, AB5000 and Impella products, for at least the next twelve months. During fiscal 2007, the Company expects to spend approximately \$16 million to \$20 million in research and development expenses, and expects capital expenditures to be approximately \$2 million to \$3 million. The

U.S. phase of our ERP (SAP) implementation is expected to be completed during our fiscal year ended 2007 at a total estimated cost of \$1.5 million, of which the Company has already spent approximately \$0.9 million in fiscal 2006. We may need additional funds for possible strategic acquisitions of businesses, products or technologies complementary to our business, including their subsequent integration into our operations. If additional funds are required and available in the debt and equity markets, we may raise such funds from time to time through public or private sales of equity or from borrowings.

## **Contractual Obligations and Commercial Commitments**

The following table (in thousands) summarizes our contractual obligations at March 31, 2006 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

		Payments Due By Fiscal Year			
Contractual Obligations	TOTAL	2007	2008	2009	2010
Operating Lease Obligations	\$ 4,819	\$ 1,703	\$ 1,371	\$ 1,035	\$710
Other Obligations	600	200	200	200	
-					
Total Obligations	\$ 5,419	\$ 1,903	\$ 1,571	\$ 1,235	\$ 710

The Company has no long-term debt or material commitments at March 31, 2006 other than those shown in the table above.

In May 2005, the Company acquired all the shares of outstanding capital stock of Impella CardioSystems, a company headquartered in Aachen, Germany. The aggregate purchase price was approximately \$45.1 million, which consisted of \$42.2 million of our common stock, \$1.6 million of cash paid to certain former shareholders of Impella, and \$1.3 million of transaction costs, consisting primarily of fees paid for financial advisory and legal services. We may make additional contingent payments to Impella s former shareholders based on our future stock price performance and additional milestone payments related to FDA approvals and unit sales of Impella products. These contingent payments range from zero dollars to approximately \$28 million and, if necessary, may be made in a combination of cash or stock under circumstances described in the purchase agreement. If any contingent payments are made, they will result in an increase to the carrying value of goodwill.

In November 2002, the Financial Accounting Standards Board (FASB) issued FASB Interpretation (FIN) No. 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57, and 107 and Rescission of FASB Interpretation No. 34.* This interpretation expands the disclosure requirements of guarantee obligations and requires the guarantor to recognize a liability for the fair value of the obligation assumed under a guarantee. In general, FIN No. 45 applies to contracts or indemnification agreements that contingently require the guarantor to make payments to the guaranteed party based on changes in an underlying instrument that is related to an asset, liability, or equity security of the guaranteed party. We apply the disclosure provisions of FIN 45 to agreements that contain guarantee or indemnification clauses. These disclosure provisions expand those required by SFAS No. 5, *Accounting for Contingencies*, by requiring that guarantors disclose certain types of guarantees, even if the likelihood of requiring the guarantor s performance is remote. The following is a description of arrangements in which we are a guarantor.

Product warranties We routinely accrue for estimated future warranty costs on our product sales at the time of sale. The AB5000 and BVS products are subject to rigorous regulation and quality standards. While we engage in extensive product quality programs and processes, including monitoring and evaluating the quality of component suppliers, our warranty obligations are affected by product failure rates. Operating results could be adversely effected if the actual cost of product failures exceeds the estimated warranty provision.

Patent indemnifications In many sales transactions, the Company indemnifies customers against possible claims of patent infringement caused by our products. The indemnifications contained within sales contracts

usually do not include limits on the claims. The Company has never incurred any material costs to defend lawsuits or settle patent infringement claims related to sales transactions. Under the provisions of FIN No. 45, intellectual property indemnifications require disclosure only.

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

While we do not invest for speculative purposes, we are exposed to market risk related to changes in interest rates. Our investment portfolio consists mainly of U.S. Treasury notes, federal agency obligations, state and municipal bonds, and corporate bonds with maturities of one year or less and ratings of at least AA by Moody s or Standard & Poor s. These securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at March 31, 2006, we believe the decline in fair market value of our investment portfolio would be immaterial. We believe, however, that we have the ability to hold our fixed income investments until maturity and therefore we would not expect our operating results or cash flows to be affected by a change in market interest rates on our securities portfolio.

## **Currency Exchange Rates**

Our Impella subsidiary s functional currency is the Euro. Therefore, our investment in Impella is sensitive to fluctuations in currency exchange rates. The effect of a change in currency exchange rates on our net investment in international subsidiaries is reflected in the accumulated other comprehensive items component of shareholders equity. Had a 10% depreciation in the Euro occurred relative to the U.S. dollar as of March 31, 2006, the result would have been a reduction of shareholders equity of \$3.0 million.

### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Consolidated Financial Statements and Supplementary Data are provided under Part IV, Item 15, in this Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE Not Applicable.

### ITEM 9A. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and our Chief Financial Officer, and all members of the senior management team held a Disclosure Committee meeting on May 22, 2006 and after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) have concluded that, based on such evaluation as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that material information relating to the Company, including our consolidated subsidiaries, was made known to them by others within those entities.

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

During the fourth quarter of our fiscal year ended March 31, 2006, there were no changes in our internal control over financial reporting that have affected, or are reasonably likely to affect, materially our internal control over financial reporting.

### Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of March 31, 2006.

Management has excluded the Impella CardioSystems GmbH operations in Aachen, Germany from its assessment of internal control over financial reporting as of March 31, 2006 because it was acquired during the fiscal year ending March 31, 2006 in a purchase business combination. This business is a wholly-owned subsidiary of the Company. The consolidated assets and total revenues of Impella represent 6% and 6%, respectively, of the related consolidated financial statement amounts as of and for the fiscal year ended March 31, 2006. Excluded from the total assets of Impella as of March 31, 2006 were goodwill and intangible assets recorded as a result of the Company s acquisition of Impella in May, 2005.

Our management s assessment of the effectiveness of our internal control over financial reporting as of March 31, 2006 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

### Important Considerations

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in

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

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

ITEM 9B. OTHER INFORMATION

Not applicable.

### PART III

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this Item 10 is hereby incorporated by reference to the information under the heading Executive Officers and Directors and Section 16(a) Beneficial Ownership Reporting Compliance in our definitive proxy statement to be filed within 120 days after the close of our fiscal year.

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

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is hereby incorporated by reference to the information under the heading Executive Compensation in our definitive proxy statement to be filed within 120 days after the close of our fiscal year. Such incorporation by reference shall not be deemed to specifically incorporate by reference the information referred to in Item 402(a)(8) of Regulation S-K.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is hereby incorporated by reference to the information under the heading Securities Beneficially Owned by Certain Persons in our definitive proxy statement to be filed within 120 days after the close of our fiscal year.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this Item 13 is hereby incorporated by reference to the information under the heading Certain Transactions, if any, in our definitive proxy statement to be filed within 120 days after the close of our fiscal year.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The Information required by this Item 14 is hereby incorporated by reference to the information under the heading Principal Accountant Fees and Services in our definitive proxy statement to be filed within 120 days after the close of our fiscal year.

### PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

(1) The financial statements from our Annual Report for our fiscal year ending March 31, 2006 are attached hereto.

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Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Stockholders Equity	F-5
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(2) Consolidated financial statement schedule Schedule II: Valuation and qualifying accounts

- (3) Unaudited Quarterly Results of Operations, as previously reported for each of the fiscal quarters in the fiscal years ending March 31, 2006 and 2005. Except for the schedule of unaudited Quarterly Results of Operations and Schedule II: Valuation and Qualifying Accounts, other schedules are not provided because the required information is given in the financial statements or notes thereto.
- (4) Exhibits
  - (2.1) Share Purchase Agreement for the acquisition of Impella Cardio Systems AG, dated April 26, 2005 filed as Exhibit 2.1 to our Form 8-K filed on May 16, 2005.\*
  - (3.1) Restated Certificate of Incorporation filed as Exhibit 3.1 to our Registration Statement on Form S-3 (Registration No. 333-36657) (the 1997 Registration Statement ).\*
  - (3.2) Restated By-Laws, as amended filed as Exhibit 3.2 to our Annual Report on Form 10-K for the fiscal year ended March 31, 2005.\*
  - (3.3) Certificate of Designations of Series A Junior Participating Preferred Stock filed as Exhibit 3.3 to the 1997 Registration Statement.\*
  - (3.4) Amendment to the Company s Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000 filed in conjunction with the Company s 2000 definitive proxy statement.\*
  - (4.1) Specimen Certificate of common stock filed as Exhibit 4.1 to our Registration Statement on Form S-1 (Registration No. 33-14861) (the 1987 Registration Statement ).\*
  - (4.2) Description of Capital Stock (contained in the Restated Certificate of Incorporation filed as Exhibit 3.1 to the 1997 Registration Statement and in the Certificate of Designations of Series A Junior Participating Preferred Stock filed as Exhibit 3.3 to the 1997 Registration Statement).\*
  - (4.3) Rights Agreement between ABIOMED and its transfer agent, as Rights Agent dated as of August 13, 1997 (including Form of Rights Certificate attached thereto as Exhibit A) filed as Exhibit 4 to our Current Report on Form 8-K, dated August 13, 1997.\*

(10.1)

Form of Indemnification Agreement for Directors and Officers  $\,$  filed as Exhibit 10.13 to the 1987 Registration Statement.\*

(10.2) 1992 Combination Stock Option Plan, as amended filed as Exhibit 10.2 to our Form 10-Q for the fiscal quarter ended September 30, 1997.\*\*\*

(10.3)	1988 Employee Stock Purchase Plan, as amended filed as Exhibit 10.11 to our Form 10-Q for the quarter ended December 31, 2004.***
(10.4)	1989 Non-Qualified Stock Option Plan for Non-Employee Directors filed as Exhibit 10.1 to our Form 10-Q for the fiscal quarter ended September 30, 1995.***
(10.5)	Facility Lease dated January 8, 1999 for the premises at 22 Cherry Hill Drive filed as Exhibit 10 to our Form 10-Q for the fiscal quarter ended December 31, 1998.*
(10.6)	1998 Equity Incentive Plan filed as Exhibit 10 to our Form 10-Q/A for the fiscal quarter ended September 30, 1998.***
(10.7)	Form of Change of Control Agreement filed as Exhibit 10 to our Form 10-Q for the fiscal quarter ended September 30, 1999.***
(10.8)	Schedule related to Change of Control Agreement filed as Exhibit 10 to our Form 10-Q for the fiscal quarter ended September 30, 1999.***
(10.9)	2000 Stock Incentive Plan Agreement, as amended filed as Appendix A to our 2005 Proxy Statement filed on July 15, 2005.***
(10.10)	Employment Agreement of Michael R. Minogue dated April 5, 2004 filed as Exhibit 10.10 to our Form 10-Q for the quarter ended June 30, 2004.***
(10.11)	Inducement stock option granted to Michael R. Minogue dated April 5, $2004$ as filed as Exhibit 10.10 to our Form 10-Q for the quarter ended June 30, $2004.***$
(10.12)	Registration Rights and Stock Restriction Agreement between ABIOMED, Inc. and Stockholders of Impella CardioSystems AG as filed as Exhibit 10.1 to our Form 8-K filed on May 16, 2005.*
(10.13)	Consulting Agreement between ABIOMED, Inc. and Dr. David M. Lederman dated October 17, 2005 as filed as Exhibit 10.1 to our Form 8-K filed on October 21, 2005.*
(10.14)	Restricted Stock Agreement between ABIOMED, Inc. and Michael R. Minogue dated April 28, 2005 as filed as Exhibit 10.15 to our Form 10-Q for the fiscal quarter ended September 30, 2005.***
(10.15)	Offer letter with Daniel Sutherby dated December 13, 2005 as filed as Exhibit 10.15 to our Form 10-Q for the fiscal quarter ended December 31, 2005.***
(10.16)	Form of ABIOMED, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Directors as filed as Exhibit 10.16 to our Form 10-Q for the fiscal quarter ended December 31, 2005.***
(10.17)	Form of ABIOMED, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Employees or Consultants as filed as Exhibit 10.17 to our Form 10-Q for the fiscal quarter ended December 31, 2005.***
(10.18)	Summary of Executive Compensation $$ as filed as Exhibit 10.18 to our Form 10-Q for the fiscal quarter ended December 31, 2005.***
(10.19)	Summary of Director Compensation as filed as Exhibit 10.19 to our Form 10-Q for the fiscal quarter ended December 31, 2005.***
(10.20)	Form of Employment Agreement, Nondisclosure and Non Competition Agreement.**
(10.21)	Software License Agreement between ABIOMED, Inc. and AnswerThink, Inc. dated November 30, 2005 as filed as Exhibit 10.20 to our Form 10-Q for the fiscal quarter ended December 31, 2005.*

(10.22)	Consulting Agreement between ABIOMED, Inc. and AnswerThink, Inc. dated December 5, 2005 as filed as Exhibit 10.21 to our Form 10-Q for the fiscal quarter ended December 31, 2005.*
(11.1)	Statement regarding computation of Per Share Earnings see Note 2(j), Notes to Consolidated Financial Statements.
(21.1)	Subsidiaries of the Registrant.
(23.1)	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
(31.1)	Rule 13a 14(a)/15d 14(a) certification of principal executive officer
(31.2)	Rule 13a 14(a)/15d 14(a) certification of principal accounting officer
(32.2)	Section 1350 certification

<sup>\*</sup> In accordance with Rule 12b-32 under the Securities Exchange Act of 1934 reference is made to the documents previously filed with the Securities and Exchange Commission, which documents are hereby incorporated by reference.

<sup>\*\*</sup> Management contract or compensatory plan or arrangement

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### ABIOMED, Inc.

Dated: June 14, 2006

By: /s/ Daniel J. Sutherby

Daniel J. Sutherby

Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)

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

SIGNATURE	TITLE	DATE
/s/ Michael R. Minogue	Chief Executive Officer, President and Chairman (Principal Executive Officer)	June 14, 2006
Michael R. Minogue		
/s/ Daniel J. Sutherby	Chief Financial Officer (Principal Financial Officer and	June 14, 2006
Daniel J. Sutherby	Principal Accounting Officer)	
/s/ W. Gerald Austen	Director	June 14, 2006
W. Gerald Austen		
/s/ Ronald W. Dollens	Director	June 14, 2006
Ronald W. Dollens		
/s/ David Gottlieb	Director	June 14, 2006
David Gottlieb		
/s/ Louis E. Lataif	Director	June 14, 2006
Louis E. Lataif		
/s/ John F. O Brien	Director	June 14, 2006
John F. O Brien		
/s/ DESMOND H. O CONNELL, JR.	Director	June 14, 2006
Desmond H. O Connell, Jr.		
/s/ Dorothy E. Puhy	Director	June 14, 2006
Dorothy E. Puhy		

/s/ Henri A. Termeer Director June 14, 2006

Henri A. Termeer

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### **Consolidated Financial Statements**

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### Report of Independent Registered Public Accounting Firm

### To the Board of Directors and Stockholders of ABIOMED, Inc.:

We have completed integrated audits of ABIOMED Inc. s 2006 and 2005 consolidated financial statements and of its internal control over financial reporting as of March 31, 2006, and an audit of its 2004 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

Consolidated financial statements and financial statement schedule

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a) (1) present fairly, in all material respects, the financial position of ABIOMED, Inc. and its subsidiaries at March 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2006 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

### Internal control over financial reporting

Also, in our opinion, management s assessment, included in Management s Report on Internal Control over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of March 31, 2006 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2006, based on criteria established in *Internal Control Integrated Framework* issued by the COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and on the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable

assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. As described in Management s Report on Internal Control over Financial Reporting, management has excluded Impella Cardiosystems GmbH from its assessment of internal control over financial reporting as of March 31, 2006 because it was acquired by the Company in a purchase business combination during the year ended March 31, 2006. We have also excluded Impella Cardiosystems GmbH from our audit of internal control over financial reporting. Impella Cardiosystems GmbH is a wholly-owned subsidiary whose total consolidated assets and total consolidated revenues represent 6% and 6%, respectively, of the related consolidated financial statement amounts as of and for the year ended March 31, 2006.

PricewaterhouseCoopers LLP

Boston, Massachusetts

June 12, 2006

### **Consolidated Balance Sheets**

### (in thousands, except share data)

		March 31,		
		2005	,	2006
Assets				
Current Assets:	Φ.	= <10	Α.	= 000
Cash and cash equivalents	\$	7,618	\$	7,832
Short-term marketable securities		33,887		23,003
Accounts receivable, net of allowance for doubtful accounts of approximately \$64 and \$211 at March 31,		0.605		0.000
2005 and 2006, respectively		8,635		8,880
Inventories		3,877		4,868
Prepaid expenses and other current assets		1,207		1,860
Total current assets		55,224		46,443
Long-term Investments		2,112		
Property and Equipment, net of accumulated depreciation of \$10,867 and \$12,077 at March 31, 2005 and				
2006, respectively		2,804		4,824
Intangible Assets, net		418		8,164
Goodwill				19,106
Other Assets		503		
Total Assets	\$	61,061	\$	78,537
LIABILITIES AND STOCKHOLDERS EQUITY				
Current Liabilities:				
Accounts payable	\$	1,132	\$	3,070
Accrued expenses		3,623		5,185
Deferred revenue		127		484
Total current liabilities		4,882		8,739
Deferred Income Taxes				310
beloned medine Takes				510
Total Liabilities		4,882		9,049
Commitments and Contingencies				
Stockholders Equity:				
Class B Preferred Stock, \$.01 par value				
Authorized 1,000,000 shares; Issued and outstanding No shares				
Common Stock, \$.01 par value				
Authorized 100,000,000 shares;				
Issued 22,079,311 shares at March 31, 2005 and 26,474,270 at March 31, 2006				
Outstanding 22,079,311 shares at March 31, 2005 and 26,468,091 at March 31, 2006		221		265
Additional paid-in capital		170,095		214,666
Deferred stock-based compensation		(278)	)	(171)
Accumulated deficit	(	113,859		(143,308)
Treasury stock, at cost; 6,179 shares at March 31, 2006				(66)
Accumulated other comprehensive loss				(1,898)
Total stockholders equity		56,179		69,488

\$ 61,061

\$ 78,537

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

### **Consolidated Statements of Operations**

(in thousands, except per share and share data)

		2004	Fiscal Years Ended March 31, 2005	2006		
Revenues:						
Products	\$	25,070	\$ 37,945 \$	43,322		
Funded research and development		669	271	348		
		25,739	38,216	43,670		
Costs and Expenses:						
Cost of product revenues, (excluding amortization)		7,591	9,366	11,685		
Research and development		14,150	13,350	16,739		
Selling, general and administrative		14,037	18,566	30,923		
Acquired in-process research and development				13,306		
Amortization of intangibles		213	187	1,308		
		35,991	41,469	73,961		
Loss From Operations		(10,252)	(3,253)	(30,291)		
Other Income, net:						
Investment income		634	801	1,194		
Foreign exchange gain(loss)		156	91	(116)		
Other		16	19	120		
		806	911	1,198		
			, , ,	2,223		
Loss Before Provision for Income Taxes		(9,446)	(2,342)	(29,093)		
Provision for Income Taxes		(2,110)	(2,3 12)	356		
110 Vision for income Taxes				330		
Net Loss	\$	(9,446)	\$ (2,342) \$	(29,449)		
Net Loss	φ	(3,440)	$\varphi$ (2,342) $\varphi$	(29,449)		
Basic and Diluted Net Loss per Share:	\$	(0.45)	\$ (0.11) \$	(1.15)		
•	Ψ	(0.43)	φ (0.11) φ	(1.13)		
Weighted Average Shares Outstanding:	21	1,153,014	21,844,759	25,649,038		

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

### 

(in thousands, except share data)

	Common					Accumulated						
				umulated Deferred						Comprehensive		
	Number	Par	Paid-in	Stock-based A							ncome	
	of Shares	Value		Compensation		Stock	Income		Equity		(Loss)	
Balance, March 31, 2003	21,047,918		\$ 163,951		\$ (102,071)	\$	\$	\$	62,090			
Stock options exercised	295,272	3	1,452	2					1,455			
Stock issued under employee stock												
purchase plan	28,837	1	133						134			
Stock issued to directors	14,892		88	3					88			
Deferred compensation related to												
employee stock option grants			72	( , )								
Amortization of deferred compensation				15					15			
Net loss					(9,446)				(9,446)			
Balance, March 31, 2004	21,386,919	214	165,696	(57)	(111,517)				54,336			
Stock options exercised	665,437	7	3,919		(111,517)				3,926			
Stock issued under employee stock	000,107	•	2,717						5,720			
purchase plan	21,287		161						161			
Stock issued to directors	5,668		60						60			
Deferred compensation related to	3,000		00						00			
employee stock option grants			259	(259)								
Amortization of deferred compensation			23,	38					38			
Net loss				30	(2,342)				(2,342)			
1101 1035					(2,342)				(2,342)			
Balance, March 31, 2005	22,079,311	221	170,095	(278)	(113,859)				56,179			
Stock issued to acquire Impella												
CardioSystems AG	4,029,004	40	42,160	)					42,200			
Restricted stock	24,000	1		86					87			
Stock options exercised	313,628	3	1,952	?					1,955			
Stock issued under employee stock												
purchase plan	23,970		204						204			
Stock issued to directors	4,357		56	, )					56			
Amortization of deferred compensation			(9	)) 21					12			
Stock compensation related to stock												
options			208	3					208			
Treasury stock acquired from Business												
acquisition escrow at cost	(6,179)					(66)	)		(66)			
Net loss					(29,449)				(29,449)	\$	(29,449)	
Foreign currency translation							(1,89	3)	(1,898)		(1,898)	
Comprehensive loss										\$	(31,347)	
Balance, March 31, 2006	26,468,091	\$ 265	\$ 214,666	\$ (171)	\$ (143,308)	\$ (66)	) \$ (1,89	8) \$	69,488			

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

### **Consolidated Statements of Cash Flows**

### $(in\ thousands)$

		Fiscal Years Ended March 31 2004 2005		
Cash Flows from Operating Activities:	2004	2005	2006	
Net loss:	\$ (9,446)	\$ (2,342)	\$ (29,449)	
Adjustments to reconcile net loss to net cash used in operating activities:	Ψ (>,110)	Ψ (2,3 12)	Ψ (25,115)	
Depreciation and amortization	1,388	1,240	2,742	
Bad debt expense (recovery)	35	(67)	193	
Loss on abandonment of patents	55	49	-,-	
Write-downs of inventory	465	36	423	
Increase in deferred taxes			310	
Stock-based compensation	103	98	371	
Acquired in-process research and development			13,306	
Changes in assets and liabilities, net of acquisition:				
Accounts receivable	(587)	(2,563)	258	
Inventories	(267)	(1,202)	(177)	
Prepaid expenses, other current assets and other assets	(347)	(465)	173	
Accounts payable	314	(238)	1,326	
Accrued expenses	(887)	355	827	
Deferred revenue	(864)	(65)	358	
Net cash used in operating activities	(10,038)	(5,164)	(9,339)	
Cash Flows from Investing Activities:				
Proceeds from the maturity of short and long-term securities	10,197	42,169	42,016	
Purchases of short and long-term securities	(38,968)	(39,520)	(29,021)	
Cost of acquisition, net of cash acquired			(2,573)	
Proceeds from disposal of equipment	12		11	
Additions to patents	(41)	(36)	(133)	
Purchases of property and equipment	(429)	(697)	(2,931)	
Net cash (used in) provided by investing activities	(29,229)	1,916	7,369	
Cash Flows from Financing Activities:				
Proceeds from exercise of stock options and stock issued under employee stock purchase plan	1,589	4,087	2,159	
Purchase of treasury stock			(66)	
Net cash provided by financing activities	1,589	4,087	2,093	
Net (Decrease) Increase in Cash and Cash Equivalents	(37,678)	839	123	
Exchange rate effect on cash	(59)	(56)	91	
Cash and Cash Equivalents, excluding marketable securities, at beginning of fiscal year	44,572	6,835	7,618	
, , , , , , , , , , , , , , , , , , , ,	,	,		
Cash and Cash Equivalents, excluding marketable securities, at end of fiscal year	\$ 6,835	\$ 7,618	\$ 7,832	
Supplemental Disclosures:				