ABIOMED INC
Form 10-K/A
June 17, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K/A

(Amendment No. 1)

(Mark One)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For fiscal year ended March 31, 2005

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 0-20584

ABIOMED, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(978) 777-5410

(Registrant s Telephone Number, Including Area Code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**

None 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: (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 ý No o

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. o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2) Yes ý No o

The aggregate market value of the voting stock held by non-affiliates of the registrant as of September 30, 2004 was $148,479,760 based on the closing price of $8.85 on that date as reported on the Nasdaq National Market. As of June 3, 2005, 26,153,672 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 2005 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.

EXPLANATORY NOTE

We are filing this 10-K/A solely to update our disclosures set forth in the first paragraph on page 29 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 of our existing products in the U.S. and internationally 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 health care programs and private issuers;

our ability to integrate our recently acquired Impella subsidiary into our existing operations;

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, Item7 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 leading developer, manufacturer and marketer of medical products designed safely and effectively to assist, recover or replace the pumping function of the failing heart. ABIOMED s BVS 5000 Biventricular Support System is the most widely used advanced heart assist device for the treatment of all patients with failing but potentially recoverable hearts in the U.S. Our newer AB5000 Circulatory Support System incorporates a number of advanced features to facilitate patient mobility and transport and to better meet the needs of physicians and hospitals treating heart assist patients. The AB5000 is also designed to provide an adaptable common platform for a family of blood pumps, which in the future, subject to FDA approval, will be able to support a broader population of patients for longer periods of time. Our AbioCor Implantable Replacement Heart, the world s first battery-powered implantable replacement heart system, was submitted to the FDA for limited commercial approval under an HDE in September 2004. The FDA has subsequently announced that it will convene a special expert panel of cardiovascular surgeons and cardiologists on June 23, 2005 to review and potentially to decide whether a recommendation should be made for the groundbreaking technologies and clinical trial data behind the AbioCor. The AbioCor, the development of which follows decades of fundamental and applied research, development and testing, is intended to extend life and provide an improved quality of life for end-stage acute and chronic heart failure patients. Another area of focused effort involves adaptation and development of the AbioCor II Heart, based on technology acquired in 2000 from The Pennsylvania State University. The AbioCor II Heart has a drive mechanism that is different than the AbioCor design, and is the only implantable heart system other than the AbioCor to survive the rigor of the replacement heart development program funded by the U.S. National Heart Lung and Blood Institute (NHLBI). We are also engaged in significant research and development related to other devices to assist, recover or replace the pumping function of the heart and we continue to investigate enhancements to our exiting product line in order to serve more patients who require mechanical heart assistance.

In May 2005, we completed our 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 has CE marks for each of its devices and currently markets them throughout Europe. The Company acquired all of the outstanding capital stock of Impella in exchange for approximately $1,600,000 in cash and 4,029,004 shares of ABIOMED common stock. The agreement also provides for a contingent payments in cash, ABIOMED stock, or a combination of both, based on the Company s future stock price performance and additional milestone payments related to FDA approvals and unit sales of Impella products.

Our BVS is a bridge-to-recovery device that can temporarily assume the pumping function of the heart for patients with potentially reversible heart failure. It is intended for use in patients whose hearts can recover within a period of a few weeks. In 1992, the BVS became the first heart assist device capable of providing full circulatory support to be approved by the FDA. The BVS is the most widely used FDA-approved temporary heart assist device, and to date has been used to support thousands of patients at over 600 medical centers worldwide. The BVS primarily consists of single-use external blood pumps and cannulae, and a drive and control console.

In April 2003, we received FDA approval to market the AB5000 Circulatory Support System Console, and in September 2003 we received approval to market the AB5000 Ventricle, an advanced circulatory support blood pump. The AB5000 console can drive and control either BVS or AB5000 blood pumps, and provides an upgradeable platform for continued circulatory assist product line enhancements. The AB5000 was introduced with the same indications for use as the BVS, but it is our intention to seek FDA approval for expanded indications of use for the AB5000 to encompass broader patient populations and lengthened periods of patient support.

Our AbioCor is a heart replacement device that replaces the failing ventricles of the heart and takes over the heart s blood pumping function. It is designed for use in patients at risk of imminent death due to irreparably heart damage, but whose other vital organs remain viable. We believe the AbioCor will provide a much-needed treatment option for those patients in the U.S. for whom no effective therapy is currently available. This is the first completely self-contained artificial heart ever to come before the FDA for review.

We are also conducting animal studies on our second-generation artificial heart, AbioCor II. The AbioCor II is approximately 30% smaller and is expected to function more than three times longer than the present AbioCor, providing the capability to serve many more patients while increasing the quality of life for these patients.

Our focused research and development related to these products has provided us with the proprietary technology, know-how and experience that we are using to develop additional products. We believe we are the only company in the world with technical background and expertise in the full range of technology to support and replace the pumping function of the heart with a total artificial heart. We believe that there are many opportunities to apply our expertise to address the needs of heart failure patients. We seek to be first to market with high-quality and cost-effective technologies for heart failure patients who currently lack adequate therapies.

ABIOMED is a Delaware corporation 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 Relations section of our web site all reports filed with the Securities and Exchange Commission (the SEC). We include our web site 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 web site. As used herein, ABIOMED includes ABIOMED, Inc., together with our subsidiaries. ABIOMED, the ABIOMED logo, BVS, ABIOCOR and ANGIOFLEX are our registered U.S. trademarks. ABIOFIT and AB5000 are trademarks of ABIOMED, Inc. 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 (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 approximately 63% 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, cardiological 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.

Current penetration of the potential market for circulatory support devices, measured by number of devices implanted annually, is low but is expected to increase fairly rapidly in the next few years. An independent report by Health Research International, published in March 2004, estimated the total value of advanced mechanical circulatory support sales in 2004 in the U.S. to be $145.9 million, and projected a compound annual growth rate of 43.1% from 2003 through 2008.

Temporary Heart Assist. Candidates for temporary heart assist devices include patients with severe but potentially reversible heart failure and patients whose hearts need help pumping blood while they await transplantation or other therapies. Temporary heart assist devices typically consist of a specialized pump that is attached to a patient s heart and driven by a console or powered by an external battery pack. Such devices are intended to be removed from a patient s body once the patient s heart has had the opportunity to recover its normal function, or when the patient receives the next appropriate therapy. Temporary heart assist devices can be grouped into three categories:

Bridge-to-Recovery. Bridge-to-recovery devices are used to support patients with potentially reversible heart failure. These devices are most frequently used to support patients whose hearts suffer shock following open-heart surgery and who cannot be weaned off the heart-lung machine. Of the patients who experience such complications, many who die each year could potentially be saved with a temporary assist device as a bridge to recovery. Bridge-to-recovery devices temporarily assume the pumping function of the heart, while allowing the heart to rest, heal and recover its normal function. These devices can also be used for patients who have not undergone surgery but whose lives are threatened by viral infections that attack the heart muscle. In addition, bridge-to-recovery devices may prove beneficial to certain patients who have suffered from a recent heart attack and their heart has gone into shock. This younger patient population may need support for 2 to 3 times longer for their hearts to recover.

The number of patients who might be candidates for a bridge-to-recovery device on account of post-cardiotomy shock each year is a function of the number of patients who undergo open-heart surgery and the percentage of such surgeries that result in shock. There are approximately 400,000 open heart operations annually in the United States, a number that has steadily been trending down as medical practice shifts toward less-invasive options. According to the Society of Thoracic Surgeons National Adult Cardiac Surgery Database, 3.4% of coronary artery bypass operations in 1999 resulted in cardiogenic shock, yielding a potential bridge-to-recovery market of approximately 13,000 patients. In 2002, the Society of Thoracic Surgeons reported that the cardiogenic shock rate had dropped to 1.9 %, yielding an estimated market of approximately 7,500 patients in the U.S. per year. According to the 2005 update of the American Heart Association heart disease and stroke statistics, 865,000 patients will suffer a new or recurrent heart attack. Of these, 7 to 10% will suffer cardiogenic shock and up to 60,000 patients will need some type of cardiac support.

Bridge-to-Transplant. Bridge-to-transplant devices are used to support patients who have experienced life-threatening heart disease and are awaiting heart transplantation. We believe that the market for this

category of device is limited by the size of the transplant waiting list. In the U.S., approximately 3,000 patients are added to the transplant list each year, and approximately 2,200 patients receive a human heart transplant annually. We estimate that the potential U.S. bridge-to-transplant market is, therefore, something less than 3,000 patients per year.

Bridge-to-Bridge. These staging devices are used to support patients before or during application of other therapies and to support patients with failing hearts being transported to other facilities. At present, for reasons of specialized care, patients are transported between medical centers with the assistance of such devices under hospital guidelines. In other cases, patients initially placed on mechanical support for bridge-to-recovery are moved to a bridge-to-transplant or destination therapy device. In addition, there are less invasive, percutaneous devices which can provide short-term support while clinicians assess a patient s heart and determine the appropriate therapeutic strategy. In the future, staging devices could potentially be used to support and stabilize heart failure patients during a course of therapy and assessment leading to potential implantation of a permanent heart assist device or a heart replacement. In addition, while bridge-to-recovery devices are approved and used today to assist heart transplant patients when rejection occurs, in the future staging devices may be used with transplant patients who have rejected their donor heart and need life support before receiving an implantable replacement heart.

At present, there are two potential therapies other than transplant to which patients might be bridged in the reasonably near term: a permanent heart assist device, typically referred to as ventricular assist device (VAD) or a permanent heart replacement device. The first FDA approval of a left ventricular assist device, referred to as an LVAD, for destination therapy occurred in November 2002. No replacement heart has yet been approved by the FDA for commercial use. There is, therefore, little empirical basis for estimating what proportion of destination circulatory support device patients will require a bridge device prior to implantation of a destination device. Our estimates of this potential market in the U.S. range from 20,000 to 40,000 patients per year.

Destination Therapy. Devices intended to be within or attached to patients for their remaining lives are classified as destination therapies. Destination therapy devices consist of replacement hearts and permanent assist devices, including devices that provide partial support to the heart on a permanent basis.

Heart Replacement. The goal of heart replacement, whether with a donor heart or a mechanical device, is to replace the failing human heart with a viable alternative. Patients with irreparably damaged hearts who are facing imminent death are potential candidates for heart replacement provided that their other vital organs remain viable. The supply of human donor hearts is extremely limited and unlikely to increase meaningfully, and no device is yet approved for use in these patients. The AbioCor is the first permanent heart replacement device to commence clinical trials for this purpose. We believe that tens of thousands of patients per year might eventually benefit from an implantable replacement heart once it is proven safe, effective and reliable. We filed with the FDA in September 2004 for approval of AbioCor under a Humanitarian Device Exemption. A recommendation is expected from an FDA panel in late June, 2005.

Permanent Heart Assist. Permanent assist devices are being developed to supplement the function of the diseased heart or to stop or slow the progression of the disease, while leaving the diseased heart in place. These devices contrast with replacement hearts, which are intended to replace a severely and irreversibly damaged heart. A number of companies

are developing permanent heart assist devices, some of which are in clinical trials in the U.S. and overseas. Certain of these assist devices are in advanced stages of clinical testing and pursuing regulatory approval. One implantable left ventricular assist device, or LVAD, has been approved in the U.S. for commercial use as a destination device.

We estimate the U.S. market for all destination therapy circulatory support devices is approximately the same as the total device market of between 60,000 and 100,000 patients. The distribution of those patients between assist devices and replacement devices is subject to debate among clinicians and cannot be definitively determined until both types of devices are clinically available and considerable clinical experience has been gained. Major variables include the percentage of congestive heart failure patients in the group who would require long term biventricular support, and would therefore require a replacement heart,

and the percentage of the coronary heart disease patients in the group who have isolated left-side damage and therefore might be adequately treated with an LVAD. At least two different registries from different manufacturers of temporary ventricular assist devices in commercial use over a period of more than ten years indicate an incidence of approximately 50% biventricular support and 50% univentricular support. If and when the technology advances to the point where, in addition to safety and efficacy, implanted patients can live without constant awareness that their heart has been replaced or is being permanently assisted, then the potential use of these devices could increase significantly.

ABIOMED Products and Products Under Development

Our current commercial heart assist product line consists of the BVS and AB5000 models. Our primary products under development are the AbioCor system, a second generation replacement heart, the AbioCor II, incorporating elements of the Penn State Heart technology, and enhancements to our heart assist product line. In May 2005, we acquired Impella CardioSystems AG, based in Aachen, Germany. Impella develops, manufactures and markets minimally invasive cardiovascular support systems for numerous indications in the fields of cardiology and cardiac surgery. Each of these systems consists of various component elements. Impella has the CE mark for each of its products and currently markets them throughout Europe.

Heart Assist: The BVS 5000 Biventricular Support System and the AB5000 Circulatory Support System

The BVS was the first heart assist device capable of assuming the pumping function of the heart to be approved by the FDA, and is the most widely used heart assist device today, with thousands of patients supported to date. It is a bridge-to-recovery device designed to provide a patient s failing heart with full circulatory assistance while allowing the heart to rest, heal and recover its function. The BVS can support the left, right or both ventricles of the heart. The average age of patients supported with the BVS is 53; however the BVS has been used to support patients as young as 8 and as old as 86 years old.

The BVS is most frequently used in patients whose hearts fail to recover function immediately following heart surgery. The FDA approved the BVS for use with these post-surgical patients in November 1992. In 1996, the FDA approved use of the BVS for all other categories of post-surgical patients with potentially reversible heart failure. In 1997, the FDA approved use of the BVS on patients who, prior to BVS insertion, are non-surgical patients with abrupt heart failure as a result of viral attack of the heart or certain heart attacks, expanding its use to the temporary treatment of all patients with potentially reversible heart failure. We market and sell the BVS system in Europe under a CE mark and in 2001 we received regulatory approval to market and sell the BVS in Japan.

The AB5000 is a new heart assist product approved for commercial distribution during fiscal 2004. It incorporates a number of features to facilitate temporary patient mobility within the hospital, patient transport between hospitals, and improved ease of use for caregivers. These features include a smaller and more mobile control console incorporating computer-based technology, a blood pump geometry and design that allows paracorporeal placement, and a simpler and more intuitive user interface. In addition, the AB5000 console is designed to serve as a flexible and upgradeable platform for future blood pump product enhancements to address broadened patient populations for longer periods of support subject to regulatory approval.

The BVS and AB5000 are the only devices that the FDA has approved for the temporary treatment of all categories of patients with failing but potentially recoverable hearts. Both the BVS and AB5000 systems consist of the following components:

Single-use external blood pumps, which provide pumping of blood for the left, right or both sides of a patient s heart and are designed to emulate the function of the natural heart;

Cannulae, which are specially designed tubes used to connect the blood pumps to a patient s heart; and

A computer-controlled pneumatic drive and control console, which automatically adjusts the pumping rate to meet the basic needs of the patient. The BVS console can control only the BVS blood pump. The AB5000 console can be used to control the BVS and AB5000 blood pumps.

The integration of the cannulae, blood pumps and console creates an external heart system with the ability to reduce the load on the heart, provide pulsatile blood flow to vital organs and allow the heart muscles time to rest and recover. Both the BVS and the AB5000 are designed to be easy to use and do not require a specially trained technician to constantly monitor or adjust the pumping parameters.

These products are designed to facilitate the recovery of patients hearts as quickly as possible. Historically, patients who recover under BVS support typically stabilize in a period of less than one week. It generally takes three to five days for the damaged but recoverable heart muscle to restore its function in a post-cardiotomy patient. While the BVS has been used to support some patients for weeks or months, the BVS is not intended nor approved for long-term use. The BVS, although it is an external ventricular assist device, serves a different function than bridge-to-transplant devices, which are intended for long-term use by patients awaiting a heart transplant. In contrast, the AB5000, while its current regulatory approval is identical to that of the BVS, is designed to allow for longer periods of operation, and has already demonstrated its reliability for extended periods in the test laboratory. It is our intention to seek regulatory approval of expanded indications for use for the AB5000.

The BVS and AB5000 are most frequently used to support patients who have undergone open-heart surgery, when the heart cannot be successfully restarted and weaned off the heart-lung machine used in surgery. Each can assume the full pumping function of the heart for these patients while reducing certain risks associated with extended support on the heart-lung machine, including bleeding, strokes and blood cell damage. The traditional therapy for these patients has been the combined use of drugs and intra-aortic balloon pumps. Intra-aortic balloon pumps are capable of providing limited enhancement to the pumping function of a failing heart. Despite the availability of such therapy, many thousands of these patients die each year.

Other categories of patients who can be supported by the BVS or the AB5000 include those suffering from viral myocarditis, a viral infection of the heart. For these patients, the devices assume the full pumping function of the heart, allowing the patient s immune system to defend against the virus. Other uses include supporting patients following failed heart transplants, supporting heart attack patients while their status and therapeutic options are evaluated, and supporting the right ventricle of a patient s heart in conjunction with the implantation of a device to assist the left ventricle.

Any hospital performing open-chest heart surgery may use the BVS or the AB5000. There are approximately 900 of these hospitals in the U.S. and more than 1,000 such hospitals outside the U.S. Over 650 medical centers in the U.S. have purchased the BVS, including 70% of the major U.S. centers that perform more than 500 heart surgeries annually. In marketing the BVS, we are focusing on providing disposable blood pumps to existing customers. AB5000 marketing efforts were initially focused on introducing the system in the largest cardiothoracic surgical centers through sales of consoles and sales of blood pumps. Moving forward, we are focusing on upgrading the BVS installed base to the AB5000 console, enabling more centers to benefit from the flexibility and upgradeability of the AB5000 console platform.

The AbioCor Implantable Replacement Heart

The AbioCor is a battery-powered totally implantable replacement heart system, designed to operate without wires or any other material penetrating the patient s skin. Implantation is achieved in the space vacated by the removal of a patient s diseased ventricles, where it will take over the full pumping function of the heart. The AbioCor is intended for use as destination therapy by patients with irreparably damaged hearts who are at risk of imminent death but whose other vital organs remain viable.

In 1988, we began to receive directed funding for AbioCor development and testing from the National Heart, Lung and Blood Institutes, known as the NHLBI. We maintained this competitively-funded support through the research phase of our AbioCor development program by achieving various designated milestones. Cumulatively, the NHLBI has provided over $20 million toward of the development of the AbioCor.

Design of the AbioCor. The AbioCor system consists of the following principal components:

A thoracic unit, or replacement heart, which includes two artificial ventricles with their associated valves and a hydraulic pumping system. The unit weighs approximately two pounds and provides complete blood circulation to the lungs and the rest of the body. The ventricles and their associated valves have seamless surfaces made from our blood-contacting material, Angioflex, and special geometries with flow patterns designed to reduce the risk of blood cell damage and blood clots. Our current configuration of the thoracic unit is sized for patients with relatively large chest cavities. We are also developing future generation replacement hearts sized to fit the majority of adults who might benefit from a replacement heart.

An implantable rechargeable internal battery allows the AbioCor to operate without any external power supply for limited periods of time.

A microprocessor-based internal electronic device, or controller controls and monitors the thoracic unit and provides radio communication with an external monitor affording patients, clinicians and caregivers the opportunity for real-time information on its operating status.

An across-the-skin, or transcutaneous energy transmission system, which eliminates the need for wires penetrating the patient s skin and the inherent associated risks of infection. It transfers the power to operate the AbioCor system and to recharge the implantable battery without tethering the patient to an external drive console. This system includes an internal energy coil that is implanted beneath the skin and an external coil that is aligned in proximity to the internal coil but resides outside the skin. The external coil emits power that is received by the internal coil.

A patient-carried rechargeable battery pack and monitor is designed to be pulled by the patient like a small briefcase. These components supply primary power to the system, allow patient mobility, provide basic system alarm information, and recharge the implanted back-up battery as needed.

The AbioCor design is intended to preserve life and to restore the quality of a patient s life to an acceptable level. Restoration of the quality of a patient s life means that the patient should be able to return to a comfortable lifestyle, free from pain, with good mental acuity and an ability to carry out everyday activities. Among the quality-of-life features of the AbioCor design are quiet heart valves, no penetration of the skin, no tethering to a large external drive console and no need for immuno-suppression therapies. The AbioCor system is designed for both low maintenance and low patient involvement. However, during our ongoing initial clinical trial of the first generation AbioCor, patients have largely remained under sustained medical supervision in the hospital and have typically used a portable monitoring device in lieu of the less-burdensome patient-carried external battery pack and electronics until such time as their health has recovered and a greater degree of independence has been demonstrated.

We have also created tools and methods intended to make the AbioCor system easier to implant. These tools include quick-connectors for attachment of the AbioCor to the human anatomy and a virtual surgery software tool to allow for the simulated implant of the AbioCor into a three-dimensional anatomical computerized model of a particular patient prior to opening that patient s chest.

Initial Clinical Trial. In our initial clinical trial we were seeking to determine whether the first generation AbioCor can effectively and safely extend life with acceptable quality of life for patients who are otherwise likely to die within thirty days and who have no other life-saving option. The results of this initial fifteen patient trial will allow us to better assess our status with regard to obtaining regulatory approval to commercially market and sell the AbioCor for an initial subset of patients in the U.S.

In January 2001, we received FDA permission under an Investigational Device Exemption (IDE) to begin the initial human clinical trial. Under the terms of the IDE, we planned to implant up to a total of fifteen patients divided into three groups of five each, with expansion to each successive group of five patients if the 60-day experience of patients with the first generation AbioCor was satisfactory to the FDA. Patients could be included in this initial clinical trial only if they had biventricular heart failure, were more than eighteen years old, were unresponsive to any other existing therapies, were ineligible for heart transplantation and were sufficiently large for the first generation AbioCor to fit and operate adequately. Patients were excluded from the clinical trial if their heart failure had a significant potential of being reversible, if they did not have a high likelihood of dying within the next 30 days, if they were pregnant, had serious psychiatric illness or an inadequate social support system. Patients were also excluded if they were suffering from other severe irreversible non-cardiac medical ailments.

As of May 2005, a total of 14 patients have participated in the initial AbioCor clinical trial. Twelve of those patients were supported for some period of time, and 2 died just subsequent to surgery. The duration of support for the 12 patients supported by the AbioCor has ranged from 53 to 512 days, with an average support duration of approximately 5 months. In a cumulative total of approximately 5 patient-years of support, the mechanical operation of the first generation AbioCor system has been highly reliable, providing appropriate and predictable circulatory support. One device experienced wearout of one component after nearly 17 months of operation. This was within the predicted range of durability for the current first generation device, and the process was tracked by the clinical team and by ABIOMED s engineers, who were able to offer the patient an opportunity, which was declined, for a replacement AbioCor. There was also one device stoppage in one patient, the causes of which were determined and corrective actions implemented. None of the patients has experienced device-related infection or sepsis. Some patients have experienced strokes that led to withdrawal of support. Strokes are a continuing risk for any circulatory support system, and may be impacted by surgical technique, device characteristics and/or patient management. Potential causes of the strokes will continue to be monitored and addressed, primarily through efforts to identify and facilitate optimal blood flow at the point of surgical attachment of the AbioCor to the atria of the natural heart. Adequate anticoagulation management has been a challenge for most of these sickest of heart failure patients.

Five of 12 supported patients were ambulatory. Four patients had excursions outside of the hospital. Two patients were discharged to facilities near the hospitals as an intermediate step toward final discharge to

11

home. These patients were able to go to restaurants, attend shows, sporting events, and religious services, and visit with family and friends. Such activities have been conducted mostly with wearable external components allowing for freedom and mobility. Two patients were discharged from the hospital with one returning home.

Encouraged by the results of the initial clinical trials, we 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 May 31, 2005, an expert panel of cardiovascular surgeons and cardiologists are reviewing the HDE application and a recommendation is expected by June 23, 2005.

While the AbioCor is designed as a permanent replacement for the failing heart, the AbioCor as it exists today is a first-generation device that will likely require improvement over time to incorporate feedback from its clinical use. The patients who will be initially treated with the AbioCor will be relatively large framed adults who are near death and for whom the AbioCor represents the only potential viable alternative to death. We have tested the AbioCor extensively. The results of such testing were part of our IDE submission to the FDA from which we gained permission to commence initial clinical trials. We believe that for patients ill enough to qualify for the initial clinical trial, the first generation AbioCor presents the best alternative to potentially extend their lives and to provide them with an acceptable quality of life. However, we understand that this patient category represents only a fraction of the potential patients who might benefit annually from the AbioCor. Our clinical and regulatory strategy of continuing to improve the AbioCor based on clinical experience is intended to allow us to demonstrate that the AbioCor can provide patients with a reasonable quality of life for sustained periods of time. We believe that demonstration of this capability is needed for eventual use of the product in end-stage heart failure patients who are not as ill as is required to qualify for our initial clinical trial.

Cost Effectiveness. We are developing the AbioCor with the intent to eventually offer a cost-effective treatment for end-stage heart failure patients. In addition, the AbioCor has the potential to allow patients an opportunity to return to productive lives. This would allow the medical system to save money by discharging the patient from the hospital and allowing the person to become productive and lead a reasonably normal life.

If the safety, effectiveness and durability of the AbioCor are clinically demonstrated for multiple-year durations, it has the potential to be less expensive than heart transplantation over a five-year period. One reason for this reduced cost is that recipients of a mechanical replacement heart are not expected to need immuno-suppression drugs. The blood and tissue contacting portions of the AbioCor are constructed of inert materials, which are not expected to elicit a response from a patient s immune system. Other cost savings could result because the patients can receive a replacement heart sooner and would not require extensive tests and biopsies to assess donor heart compatibility. While recipients of the AbioCor will need to purchase new batteries periodically, we anticipate that the annual comparative cost of battery purchases will be significantly less than the cost of immuno-suppression drugs required by donor heart recipients. AbioCor patients do require common and relatively inexpensive anticoagulation drugs on an ongoing basis

While developing the AbioCor, we introduced the BVS, a temporary heart-assist device, which is currently being sold in the U.S. and international markets, and more recently the AB5000. Certain key elements of the technology developed for the AbioCor, especially the blood contacting material, Angioflex, have been clinically tested and are currently in commercial use in these heart assist products. The AbioCor blood pumping technology developed and refined over more than two decades has found a commercial application in the AB5000 Ventricle. In addition, our heart assist business has enabled us to develop significant experience in areas such as research and development, manufacturing, regulatory compliance, clinical support and sales and marketing. We believe our experience in these areas will provide us with a competitive advantage in commercializing the AbioCor.

Ongoing Development. The AbioCor is subject to ongoing development and refinements. The first generation AbioCor does not yet meet our longer-term goal of five years of operational reliability. In the United States its current size fits less than 50% of adult males and less than 20% of adult females. External

elements of the system are subject to ongoing refinement to improve ease of use for clinicians and quality of life for patients and their families. The experience gained in the initial AbioCor clinical trial is invaluable in guiding these ongoing development efforts.

Our development of the smaller, second-generation AbioCor II is in the animal testing phase. The AbioCor II incorporates features of both the first-generation AbioCor and the Penn State Heart. We acquired the technology rights to the Penn State Heart in 2000. Similar to the AbioCor, the development of the Penn State Heart was supported by significant funding from the NHLBI. The AbioCor and the Penn State Heart were the only two replacement heart programs that achieved the technological progress needed to qualify for the final pre-clinical rounds of funding from NHLBI. In addition to its size, approximately 30% smaller than AbioCor, AbioCor II has a reliability goal of five years of operation.

The Impella Recover 2.5/5.0 Micro Blood Pumps

In May 2005, we acquired Impella CardioSystems AG of Aachen, Germany. In so doing, we added to our heart assist product portfolio Impella s Recover System circulatory assist devices. The Recover 2.5 and 5.0 are the world s smallest, minimally invasive, high-performance micro blood pumps. These devices, designed for use by cardiologists in the cardiac catheterization lab, can be inserted percutaneously into patients to provide left ventricle support to patients with AMI, including those suffering cardiogenic shock. Currently, the Impella Recover devices have CE marks and are not yet approved by the FDA for sale in the U.S.

Other Products and Technologies

We are using the technology and know-how derived from the AbioCor, BVS, AB5000 and Impella products in the research and development of other potential cardiovascular products. We are also using our experience and commitment to this field to evaluate potential collaborative arrangements relating to third-party technologies and products.

Other new technologies are in various stages of research, development or evaluation, and include passive and active heart wraps as well as specialized implantable and external heart assist devices. Some are technologies developed earlier and placed on hold, such as an advanced intra-aortic balloon pump, the SupraCor. In addition, research and development activities under our product development programs incorporate certain technologies that have potential as separate spin-off products. Examples include implantable monitoring systems with remote transmission capability software for virtual surgery, non-invasive power transmission systems, and external monitoring systems.

Research and Product Development

As of May 31, 2005, our research and development staff, including those employees who joined us from Impella, consisted of 84 professional and technical personnel, including 9 individuals in design assurance and a total of 35 engineers, many with advanced degrees, covering disciplines such as electronics, mechanics, software, reliability engineering, fluid mechanics, physics, materials and physiology.

Our research and development efforts are focused on mechanical heart assist and heart replacement, and the continued enhancement of our product offerings. Interaction continues with the FDA and corresponding foreign regulatory agencies to obtain the necessary clearances and

approvals for our products. Sophisticated but established tools, such as three-dimensional computer-aided design systems are used to permit smooth transition of new designs from research to product development and into manufacturing. We have substantial expertise in electro-mechanical systems, cardiac physiology and experimental surgery, blood-material interactions, fluid mechanics and hemodynamics, internal and external electronic hardware, battery technology, software and plastics processing. Our expertise has been primarily focused on addressing challenges associated with the safe and effective pumping of blood.

We expended $20.6 million, $14.3 million and $13.5 million on research and development in fiscal 2003, 2004 and 2005, respectively. Since our inception, U.S. government agencies, particularly the NHLBI, have provided significant support to our product development efforts when such products are in their early stages of research and development. As of March 31, 2005, our total backlog of research and development contracts and grants was $0.3 million. All of these contracts and grants contain provisions making them terminable at the convenience of the government.

Sales, Clinical Support, Marketing and Field Service

We believe that the sales, clinical support, marketing and field service teams established for our heart assist product line and the relationships developed with existing customers will be instrumental not only in continuing to expand BVS and AB5000 usage and sales, but also in launching heart replacement products such as the AbioCor and the AbioCor II and the minimally invasive ventricular assist products gained through the recent acquisition of Impella CardioSystems, AG, once appropriate regulatory approvals are achieved.

The BVS and AB5000 are sold in the U.S. through direct sales and clinical support teams. As of May 31, 2005, our worldwide sales, clinical support, marketing and field service teams included 58 full-time employees. The acquisition of Impella in May 2005 added 5 clinical sales and service employees based in Aachen, Germany. Also in May 2005, two vice presidents of sales and two additional sales positions were added in the U.S. In the year ahead, we plan to increase our sales and clinical support personnel.

Currently, our sales force primarily focuses on increasing sales from expanded usage of disposable blood pumps and ventricles by our large installed base of customers as well as from initial and upgrade sales to new and existing customers. Our clinical support group focuses on training and educating new and existing customers in order to help improve clinical outcomes. We believe the efforts of our clinical support group contribute significantly to the number of lives saved by physicians using our products. This, in turn, promotes usage and reorders of single-use BVS blood pumps and AB5000 ventricles. We believe the reputation and customer relationships of our sales and support teams, strengthened by our best practices learned through experiences at leading heart centers, will be key assets for the introduction of future products such as the AbioCor, Impella products, and other products under development (once appropriate regulatory approvals are achieved).

Building on our experience in the U.S., in recent years we have expanded our international sales efforts for our heart assist products and in preparation for future availability of AbioCor and Impella products (once appropriate regulatory approvals are achieved). We conduct our international sales efforts through distributors and by selling directly in selected European markets through ABIOMED B.V., our wholly-owned subsidiary located in The Netherlands. As of May 31, 2005, we have signed international sales and distribution agreements with: Japan; China; Australia; Canada; and Latin America. We also utilize distributors in Spain; Italy; Greece; Turkey; and the Middle East.

Manufacturing

We have over 15 years of experience in the manufacture of mechanical circulatory support consoles, blood pumps, cannulae and related accessories. The manufacture of our BVS and AB5000 blood pumps and consoles, and the pilot manufacturing of our AbioCor system components, includes assembly, testing and quality control. All of the AbioCor systems manufactured are being used for our testing and other investigational purposes. None of the AbioCor systems manufactured are currently available or approved for commercial sale. Key blood-contacting components for the blood pumps, including valves and bladders, are manufactured from our proprietary Angioflex polymer. The production of the AbioCor is based on some processes that are similar to the processes used for the BVS. We produce the majority of the AbioCor blood contacting components in our facility and all such components are assembled in-house. A majority of the metallic mechanical parts and batteries used to produce the AbioCor are contract-manufactured or purchased. We contract with third parties to manufacture our

AB5000 and AbioCor consoles. Depending on the size and design of cannulae, they are either purchased or manufactured by us.

Impella CardioSystems has over ten years of experience manufacturing microminiature rotary blood pumps, control consoles and related accessories. Impella s subcomponents are procured from various suppliers. The rotary blood pumps are then assembled and tested at Impella in a clean room controlled environment using proprietary and patented processes. Control console components, including custom circuit board assemblies, power modules, molded enclosures and miscellaneous electronic components are purchased from outside suppliers. Finished control consoles are assembled and tested in-house at Impella.

As of May 31, 2005, a total of 98 employees were engaged in BVS and AB5000 manufacturing and AbioCor pilot manufacturing. Manufacturing and pilot manufacturing operations are further supported by an additional 18 people devoted to quality assurance and documentation and by 11 people in materials management and purchasing. We also have 13 employees located in Aachen, Germany supporting manufacturing documentation, materials management and purchasing for the Impella Recover blood pump and console products.

We believe our existing manufacturing facilities give us the physical capacity to produce sufficient quantities of BVS and AB5000 disposable blood pumps and cannulae and Impella Recover 2.5 and 5.0 micro blood pumps to meet market demand for the foreseeable future. Our BVS and AB5000 manufacturing area is ISO9001 certified and operates under the FDA s good manufacturing practice requirements set forth in the current quality system regulations, known as QSR. Our AbioCor manufacturing areas are ISO9001 certified, and we are taking steps towards ensuring that our AbioCor manufacturing area will be QSR compliant for purposes of eventual commercial distribution of AbioCor, subject to regulatory approvals. Raw material for processing of Angioflex, a material critical to our products, is purchased from a single source, and the company typically maintains inventory to last in excess of five years.

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 11, 2005, we own 47 U.S. patents, including 17 related to the AbioCor Implantable Replacement Heart and two related to the BVS 5000 Bi-Ventricular Support System. Additionally, we have an exclusive worldwide license to 10 U.S. patents related to the Penn State Heart. These 57 U.S. patents have expiration dates ranging from June 21, 2005, to January 25, 2025.

Through our acquisition of Impella CardioSystems AG, we own 12 U.S. patents and 37 foreign patents covering Impella s commercial products and products under development. 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.

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. For this reason, we do not view it as a direct competitor to the AbioCor. We believe that if and when other implantable replacement hearts are available, our AbioCor will compete with them based on quality-of-life advantages, cost effectiveness, device reliability, clinical support and customer relationships.

In addition to the developers of implantable replacement hearts, 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 ABIOMED s products. We believe that implantable replacement hearts, LVADs and other VADs, if developed and proven effective for destination therapy, will generally be used to address the needs of different patient populations, with an overlap for certain segments of the heart failure population. We believe that there is a need for both implantable LVADs and implantable replacement hearts as destination therapies, and that when both technologies demonstrate the required reliability, surgeons will make decisions based upon the specific needs and conditions of individual patients.

In addition to devices being developed for patients in need of heart replacement, several companies and institutions have been for many years investigating xenotransplantation, the transplantation of a heart from another species, as a potential therapy. Most notably, some developers are investigating the use of genetically engineered pig hearts as an alternative source of donor hearts. This technology remains in its formative stage and subject to a number of significant challenges, including controlling elevated immunologic reactions leading to heightened rejection problems between cross-species grafting and major concerns for cross-species disease transmission to the recipient and the public at large. We believe that this technology remains in the research phase. Research is also being conducted to develop gene and cell therapy as potential to reverse the disease process or to supplant diseased heart cells. We believe that the key research activities in this area, while promising, remain in the formative stage.

The BVS and AB5000 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 AB5000 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.

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.

Third-Party Reimbursement

We sell our current products and intend to sell most of our potential products under development to medical institutions. Medical institutions and their physicians typically seek reimbursement for the use of these products from third-party payers, including Medicare, Medicaid, and private health insurers and managed care organizations. As a result, market acceptance of our current and proposed products may depend in large part on the extent to which reimbursement is available to medical institutions and physicians for use of our products.

Coverage and the level of payment provided by U.S. and foreign third-party payers varies according to a number of factors, including the medical procedure, payer, location, outcome, and cost. In the U.S., many private health care insurance carriers follow the lead of the Centers for Medicare and Medicaid Services (CMS), which establishes guidelines for the coverage of procedures, services and medical equipment and the payment of health care providers treating Medicare patients. The amount that Medicare pays a medical institution for in-patient care of Medicare patients is based on the Diagnosis Related Group (DRG) to which a specific hospitalization is assigned for payment purposes, without regard to the actual costs of the specific hospitalization. AB5000 and BVS products are currently reimbursed under DRG 525 when implanted, one of the five highest paying DRGs available from CMS. Physicians bill separately for the procedures that they perform. Internationally, healthcare reimbursement systems vary significantly. In certain countries, medical center budgets are fixed regardless of levels of patient treatment. In other countries, such as Germany and Australia, a structure similar to that of the U.S. has been implemented. Impella products are not yet reimbursed in the U.S. prior to FDA approval, however are reimbursed in parts of Europe.

Reimbursement levels have not yet been established for our products under development, including the AbioCor. Prior to approving coverage for new medical devices, most third-party payers require evidence that the product has received FDA approval in the U.S. or clearance for marketing, is safe and effective and not experimental or investigational, and is medically necessary and appropriate for the specific patient for whom the product is being used. Increasing numbers of third-party payers require evidence that the procedures in which the products are used, as well as the products themselves, are cost-effective. Heart transplantation currently qualifies for reimbursement, as does bridge-to-transplant treatment with implantable and percutaneous VADs. Comparatively, we believe that when the AbioCor product reaches maturity, it should cost less over a five-year period than heart transplantation today. We believe that these factors should benefit the AbioCor when our customers begin to seek reimbursement for it from third-party payers. However, we cannot assure that the AbioCor or our other products under development will meet the criteria

17

for coverage and reimbursement or that third-party payers will reimburse physicians and medical institutions at levels sufficient to encourage the widespread use of the products.

Government Regulation

Clinical trials, manufacture and sale of our products and products under development, including the BVS, AB5000, AbioCor and AbioCor II are, or will be, subject to regulation by the FDA and corresponding state and foreign regulatory agencies. Noncompliance with applicable regulatory requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant marketing approval for devices, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed by ABIOMED.

U.S. Clinical Use Regulations. In the United States, our BVS and AB5000 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 medical devices are subject to the most rigorous regulation. 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. Class III devices are also subject to some of the requirements applicable to Class I and Class II devices, including general controls, such as labeling, pre-market notification, performance standards, post-market surveillance, patient registries and adherence to Quality System Regulations (QSR) requirements, which include testing, control and documentation requirements.

A PMA application is the most common route to obtain permission to market and sell a Class III device in the U.S. for a particular indication. A PMA application must be supported by valid scientific evidence, which typically includes extensive information including relevant bench tests, laboratory and animal studies and clinical trial data to demonstrate the safety and effectiveness of the device. The PMA application also must contain a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and the proposed labeling, advertising literature and training materials. By regulation, the FDA has 180 days to review the PMA application, and during that time an advisory committee may be called on to evaluate the application and provide recommendations to the FDA. Advisory committee reviews often occur over a significantly protracted period, and a number of devices for which FDA approval has been sought have never been cleared for marketing. In addition, modifications to a device that is the subject of an approved PMA, or to its labeling or manufacturing process, may require the submission of PMA supplements or new PMAs and approval by the FDA.

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. Adoption of an HDE device within a hospital is subject to the hospital s Institutional Review Board (IRB) approval. The regulatory hurdle for an HDE, while far from negligible, is therefore significantly less burdensome than that for a PMA. A device distributed under an HDE may be sold, but compensation may not exceed recovery of costs, including cumulative research and development costs as well as the costs of manufacturing and distribution.

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. If the FDA approves the IDE application, and the IRBs at the institutions at which the clinical trials will be performed approve the clinical protocol and related materials, clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. Sponsors of clinical trials are permitted to charge for investigational devices distributed in the course of the study provided that compensation does not exceed recovery of the costs of manufacture, research, development and handling. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness or the rights, safety or welfare of human subjects.

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. The initial clinical trial, which began on July 2, 2001, is subject to periodic review and to the readiness of each collaborating medical center, including training of its surgical and post-operative care teams and approval of the clinical trial protocol by the hospital s IRB. The trial was undertaken with patients who, despite all available therapies, had an extremely high probability of death within thirty days due to heart failure.

We are seeking initial FDA approval of the AbioCor for a limited category of indications and patients through an HDE, and subsequent approval via PMA for additional indications and patient populations. After the initial regulatory approval, we will need to complete additional clinical testing and request supplemental approvals for additional indications and broader marketing claims. If we obtain approval of the AbioCor in this manner, the FDA may initially impose restrictions on use of the AbioCor. Nevertheless, we believe that this phased approach will permit us to obtain initial marketing approval for the AbioCor more quickly than if we were to seek a broader approval from the outset.

U.S. Manufacturing and Sales Regulation. Any devices, including the BVS 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. We believe that foreign regulations relating to the manufacture and sale of medical devices are becoming more stringent. 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 Impella Recover temporary cardiac assist products comply with the Medical Devices Directive, are CE marked and available for sale in the European Union. We have obtained the requisite regulatory approvals for sale of the BVS in other foreign

countries, as well. In the European Union, implantable devices, such as the AbioCor, must comply with the Active Implantable Medical Devices Directive, known as AIMDD, which includes quality system requirements, in order to obtain CE certification. The scope of our quality system specifically includes the design, development, and manufacture of cardiac

replacement systems, but obtaining CE certification under the AIMDD for the AbioCor or other implantable products under development may be difficult, costly and time-consuming.

Employees

As of May 31, 2005 we had 305 full-time employees, including:

84 in product development, design assurance and regulatory;

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

111 in manufacturing, including pilot manufacturing quality control and materials management; and

12 in quality assurance.

Our remaining employees work in a variety of areas, including information technology, human resources, accounting, facilities, corporate development and management. We have entered into contractual agreements with all of our employees, which include confidentiality and non-competition commitments by each and every employee at all levels. None of our employees is represented by a union. We consider our employee relations to be good.

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 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.

ITEM 3. *LEGAL PROCEEDINGS*

As of March 31, 2005, 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, 2005.

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, 2004	**High**	**Low**
First Quarter	$ 7.56	$ 3.00
Second Quarter	9.83	4.77
Third Quarter	9.50	6.69
Fourth Quarter	8.60	6.69

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

Number of Stockholders

As of June 3, 2005, 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 more than 10,000 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 earnings to finance future growth.

Sales of Unregistered Securities

No sales of unregistered securities occurred during our fourth quarter ended March 31, 2005.

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)

	Fiscal Years Ended March 31,				
	2001	**2002**	**2003**	**2004**	**2005**
Statement of Operations Data:					
Revenues:					
Products	$ 19,724	$ 24,747	$ 23,127	$ 25,070	$ 37,945
Funded research and development	3,142	2,214	183	669	271
Total revenues	22,866	26,961	23,310	25,739	38,216
Costs and expenses:					
Cost of product revenues	7,222	7,925	7,501	7,591	9,366
Research and development (1)	28,667	27,108	20,552	14,299	13,497
Selling general and administrative	12,469	16,066	14,748	14,101	18,606
Total costs and expenses	48,358	51,099	42,801	35,991	41,469
Loss from operations	(25,492)	(24,138)	(19,491)	(10,252)	(3,253)
Interest and other income, net	6,160	2,945	1,320	806	911
Net loss	$ (19,332)	$ (21,193)	$ (18,171)	$ (9,446)	$ (2,342)
Basic and diluted net loss per share	$ (0.94)	$ (1.02)	$ (0.87)	$ (0.45)	$ (0.11)
Weighted average shares outstanding	20,583	20,869	20,994	21,153	21,845

	March 31,				
	2001	**2002**	**2003**	**2004**	**2005**
Balance Sheet Data:					
Cash, cash equivalents, marketable securities and long-term investments	$ 92,498	$ 71,321	$ 54,449	$ 45,541	$ 43,714
Working capital	94,651	74,127	56,987	32,154	50,439
Total assets	110,961	89,176	68,516	59,161	61,061
Long-term liabilities	368				
Stockholders equity	99,814	79,868	62,090	54,336	56,179

(1) Research and development expenses include certain contract costs.

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 below under Risk Factors as well as other risks and uncertainties referenced in this Report.

Overview

We are a leading developer, manufacturer and marketer of medical products designed to safely and effectively assist, recover or replace the pumping function of the failing heart. Our AbioCor Implantable Replacement Heart, the world s first battery-powered implantable replacement heart system, was submitted to the FDA for limited commercial approval under an HDE in September 2004. The FDA has subsequently announced that it will convene a special expert panel of cardiovascular surgeons and cardiologists on June 23, 2005 to review and potentially recommend approval for the groundbreaking technologies and clinical trial data behind the AbioCor. The AbioCor, the development of which follows decades of fundamental and applied research, development and testing, is intended to extend life and provide an improved quality of life for end-stage acute and chronic heart failure patients.

We currently manufacture and sell two models of our temporary heart assist product. The BVS 5000 Biventricular Support System was the first device approved by the FDA as a bridge-to-recovery device for temporary treatment of all patients with failing but potentially recoverable hearts. The BVS system has an installed base of approximately 900 consoles located in approximately 650 medical centers in the United States, including 70% of all medical centers that perform more than 500 heart surgeries annually. The BVS system has also been placed in more than 100 medical centers outside the United States, primarily in Europe. In marketing the BVS, we are focusing on providing disposable blood pumps to existing customers. Our newer AB5000 Circulatory Support System is a heart assist product model, designed to provide enhanced patient mobility within and between centers, to facilitate patient ambulation, and to provide enhanced features and ease of use for caregivers. In April 2003, we introduced the AB5000 console, a new console that will serve as a platform for ongoing and future blood pump product line enhancements to meet patient needs across a broader spectrum of temporary heart assist applications. In September 2003 we received FDA approval to market the AB5000 Ventricle, the first of these new blood pumps. AB5000 marketing efforts were initially focused on introducing the system in the largest cardiothoracic surgical centers through sales of consoles and sales of blood pumps. Moving forward, we are focusing on upgrading the BVS installed base to the AB5000 console, enabling more centers to benefit from the flexibility and upgradeability of the computer-based AB5000 console.

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 incorporates upgradeable software features to accommodate future product line enhancements, while the BVS console supports only the BVS blood pump. It is our intent 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.

On May 10, 2005, the Company acquired all of the outstanding capital stock of Impella CardioSystems AG (Impella), a privately held company located in Aachen, Germany. Accordingly, the operating results of Impella from May 10, 2005 will be included in the Company s results beginning with the

first quarter of fiscal 2006. Impella manufactures and sells small, minimally invasive, high performance micro blood pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. These pumps are designed to provide left ventricle support for patients suffering from reduced cardiac output and can potentially aid in recovering the hearts of patients suffering from acute myocardial infarction (AMI or Heart Attack), including those who have gone into cardiac shock. Impella has CE marks for each 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 in order to address wider market opportunities for cardiac assist and recovery. ABIOMED acquired Impella in exchange for approximately $1.6 million in cash and 4,029,004 shares of ABIOMED common stock, of which 210,000 shares are to be held in escrow for potential claims for indemnification by the Company pursuant to the terms of the purchase agreement. The 4,029,004 shares of ABIOMED common stock have a fair value of $42.2 million. Accordingly, the purchase price (before contingent payments) will be $45.3 million, inclusive of approximately $1.5 million of acquisition costs. In addition, the agreement provides that ABIOMED may make additional contingent payments to Impella s former shareholders based on the Company s 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 $29 million and will be made in a combination of cash or stock, if at all. The Company has not yet determined the preliminary purchase price allocation due to the recent nature of the acquisition. However, management believes that more than half of the purchase price will be recorded to goodwill, and a write-off of in-process research and development will be recorded in the first quarter of fiscal 2006. Also, significant amortization of intangible assets will impact fiscal 2006 and future results.

Research and development is a significant portion of our operations. Our research and development efforts are focused on the development of new products related to heart assist, heart recovery and heart replacement, and the continued enhancement of current technologies. One such effort is the AbioCor II, a smaller replacement heart incorporating a pumping mechanism different from that of the AbioCor that is currently undergoing animal testing. Our operating results reflect the dual activities of commercial operations and investments in the research and development of new technologies.

Critical Accounting Estimates

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 estimates 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. We believe that our revenue recognition policies are in compliance with SAB 104.

We derive our revenues from two principal sources: (1) product sales, including maintenance service agreements, and (2) funded research and development contracts and grants from government and other third party sources. The great majority of our product revenues are derived from our shipment of BVS and AB5000 products 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.

During the three years ending March 31, 2005 a declining percentage of our BVS product revenue was derived from extended-term contracts with certain of our customers. These contracts, the last of which ended in due course this past fiscal year, provided customers with units of our BVS product under contract terms of one to three years. The Company received a fixed, non-refundable amount of money for providing these customers with BVS blood pumps during the term of the contract to replace those used to support patients. In addition to SAB 104, we followed the guidance of EITF 00-21*, Revenue Arrangements with Multiple Deliverables*, in our calculation and recognition of the relative sales value for each element of these extended-term contracts. In so doing, we recognized revenue and recorded cost of product revenues ratably over the term of the contract using an estimated per unit selling price based upon actual shipments of pumps to customers compared to the maximum number of additional pumps allowable under the contract. When a maximum number of pumps was not specified in the sales contract, we compared actual shipments to our estimate of additional pumps that might be required by the customer. In the majority of contracts that contained contractual limits on the number of pumps, customers did not use the maximum number of allowable pumps and, as a result, we recognized the remaining deferred revenue at the end of the contract term with no associated incremental cost.

Cash received in advance of revenue in connection with the sale of blood pumps under extended-term contracts is recorded as deferred revenue and is classified as a current or long-term liability depending on the expected shipment dates of the blood pumps.

Maintenance service 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.

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, 2004 and March 31, 2005, are net of accumulated impairment write-downs of $1,119,000 and $887,000, 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, 2005, the Company had federal and state tax net operating loss carryforwards of approximately $74.8 million and $34.6 million, respectively, that begin to expire in 2006. The Company also has federal and state research and development credit carryforwards of approximately $5.1 million and $3.3 million, respectively, that begin to expire in 2006. We have recorded a valuation allowance of $52.2 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.

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,		
	2003	**2004**	**2005**
Revenues:			
Products	99.2%	97.4%	99.3%
Funded research and development	0.8	2.6	0.7
Total revenues	100.0	100.0	100.0
Costs and expenses:			
Cost of product revenues	32.2	29.5	24.5
Research and development	88.2	55.5	35.3
Selling, general and administrative	63.2	54.8	48.7
Total costs and expenses	183.6	139.8	108.5
Loss from operations	(83.6)	(39.8)	(8.5)
Other income, net	5.7	3.1	2.4
Net loss	(77.9)%	(36.7)%	(6.1)%

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

Product Revenues. Product revenues increased by $12.9 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 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.

Going forward, we expect our core legacy products to generate revenue growth of 26 36% during our fiscal year ending March 31, 2006, in addition to sales of Impella product sales of approximately $4 million in Europe. We also expect that the BVS will remain an important part of our heart assist product portfolio, as we anticipate continuing demand for BVS blood pumps.

Funded Research and Development Revenues. During recent years our efforts to obtain government research and development contracts and grants have been limited, as a result of directing our technical personnel and other resources towards development and commercialization of existing technology. As a result, externally funded research and development revenue decreased by $0.4 million, or 59%, from $0.7 million during the fiscal year ended March 31, 2004 to $0.3 million during the fiscal year ended March 31, 2005.

As of March 31, 2005, our total backlog of research and development contracts and grants was $0.3 million. All of these contracts and grants contain provisions that make them terminable at the convenience of the government.

Cost of Product Revenues. Our cost of product revenues as a percentage of product revenue improved for the fiscal year 2005 as compared to fiscal 2004. Cost of product revenues as a percentage of product revenues was 25% for fiscal 2005 compared to 30% in fiscal 2004. Approximately 80% of the improvement in margin is the result of higher average unit selling prices for our AB5000 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 $14.3 million in fiscal 2004 to $13.5 million in fiscal 2005. Research and development expenses were 35% of total revenues for fiscal 2005 and 56% 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. We expect research and development expenses to increase year over year as we invest in the development of new products in circulatory care to be introduced in the market in the next 12 to 18 months.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $4.5 million, or 32%, from $14.1 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.

Fiscal Years Ended March 31, 2004 and March 31, 2003 (fiscal 2004 and fiscal 2003)

Product Revenues. Product revenues increased by $2.0 million, or 8%, from $23.1 million in fiscal 2003 to $25.1 million in fiscal 2004. The increase is attributable to sales of AB5000 consoles and ventricles during the controlled clinical rollout that began in the first fiscal quarter for the console and in the second fiscal quarter for the ventricle. Product revenue reflects fulfillment of all of the sales backlog reported at the end of our third fiscal quarter. Going forward, we expect total revenue growth in excess of 10% annually driven by sales of AB5000 consoles and ventricles subsequent to the full product rollout in April 2004. Revenue growth may be concentrated in the second half of fiscal 2005. We also expect that the BVS will remain an important part of our heart assist product portfolio, as we anticipate continuing demand for BVS blood pumps.

Domestic sales accounted for 92% of total product revenue during fiscal 2004 and 94% of product revenue for fiscal 2003.

Funded Research and Development Revenues. Contract revenues increased by $0.5 million to $0.7 million in fiscal 2004 from $0.2 million in fiscal 2003. As of March 31, 2004, our total backlog of research and development contracts and grants was $0.3 million. All of these contracts and grants contain provisions that make them terminable at the convenience of the government.

Cost of Product Revenues. Cost of product revenues as a percentage of product revenues improved to 30% for fiscal 2004 from 32% in fiscal 2003. The improvement in margin is primarily the result of lower manufacturing costs, increased sales as a result of the introduction of the new AB5000 system, and a write-down of inventory of an older model of the BVS console to its net realizable value in the prior year. We expect that the growth of AB5000 product revenues will support continued margin improvement in future reporting periods.

Research and Development Expenses. Research and development expenses decreased by $6.3 million, or 30%, from $20.6 million in fiscal 2003 to $14.3 million in fiscal 2004. Research and development expenses were 88% of total revenues for fiscal 2003 and 56% of total revenues in fiscal 2004. The largest portion of this decrease is attributable to research and development expenses incurred for the AbioCor, which decreased by $5.3 million from $15.0 million for fiscal 2003 to $9.7 million during fiscal 2004. These AbioCor reductions are primarily due to labor and material purchases related to manufacture of AbioCor units as well as development and testing activities. Research and development expense for fiscal 2004 also included costs associated with ongoing development of the AB5000, including costs associated with efforts to obtain regulatory approval for our new AB5000 ventricle as well as those associated with future heart assist blood pumps and cannulae that are expected to operate with the new AB5000 platform. Also included in research and development expense during fiscal 2004 are lesser costs associated with continued development and testing of the AbioCor II. We anticipate that the majority of our near-term research and development focus will be on further extending the AB5000 product line, completing the initial AbioCor clinical trial and securing approval of a humanitarian device exemption for initial commercial introduction of the AbioCor, and developing the AbioCor II.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased by $0.6 million, or 4%, from $14.7 million in the prior year to $14.1 million in fiscal year ended March 31, 2004. This reduction is attributable to lower accounting and legal costs as well as reductions in selling and clinical support costs. As we plan to increase both sales and clinical support staffing in order to support the ongoing rollout of the AB5000 product, selling and clinical support costs are likely to increase going forward.

Throughout fiscal 2004 we incurred certain expenses associated with business development activities, primarily related to the review of business opportunities related to rotary blood pump technologies. These activities may continue in the coming year and beyond, and may be expanded to encompass a wider array of different business opportunities clustered around our existing mechanical circulatory support business. If these activities were to result in a major new business initiative, it is possible that we would decide to seek new financing in order to support that initiative.

In April 2004 David M. Lederman, Ph.D., ABIOMED s founder, stepped down as President and Chief Executive Officer and was succeeded in those positions by Michael R. Minogue. Subsequent to our fiscal year ending March 31, 2004, ABIOMED s management team has been strengthened by a number of new appointments to fill existing vacancies and/or newly defined senior management functions. We have incurred one-time costs associated with recruitment and/or relocation of Mr. Minogue and these new senior personnel, much of which were recorded in the Company s fiscal year ending March 31, 2005.

Other Income. Other income consists primarily of interest earned on our investment balances, net of expenses and foreign exchange gain or loss. Interest and other income was $0.8 million in fiscal 2004, a decrease of $0.5 million from $1.3 million in fiscal 2003. This decrease was primarily due to reduced yields on investments resulting from lower average interest rates and lower average fund balances available for investment. As a result of our improving financial performance and the continuing reduction in research and development expenditures as the AbioCor approaches initial commercial introduction, we were able during fiscal 2004 to move some of our cash and short term assets into longer term instruments in order to improve future yields. Foreign translation costs were nearly constant year-to-year.

Net Loss. Net loss for the fiscal year ended March 31, 2004 was approximately $9.4 million, or $0.45 per share. This is a 48% reduction from the net loss of approximately $18.2 million, or $0.87 per share, in the prior fiscal year. The losses for both years are primarily attributable to development and clinical testing costs associated with the AbioCor, the AbioCor II, the AB5000 circulatory assist system and costs of developing other technologies and products. Continued reduction of our net loss is an important goal of management, and we anticipate moving into profitability before the end of fiscal 2005.

Liquidity and Capital Resources

We have supported our operations with net revenues from sales of our BVS and AB5000 circulatory assist product line, government contracts and proceeds from our equity offerings. As of March 31, 2005, our cash, cash equivalents, short-term marketable securities and long-term investments totaled $43.6 million.

During the year our financial performance from business operations, driven by higher product revenues, resulted in a substantial reduction in our use of cash. During the fiscal year ended March 31, 2005, cash used by operating activities was $ 5.2 million, or 49%, less than the $10.0 million consumed by operations in the comparable period of the prior year. There was also an increase in accounts receivable and inventory of $2.6 million and $1.2 million, respectively as a result of the Company's planned higher level of product sales. Net cash consumption from all activities, as determined by the net change in cash, short-term marketable securities and long-term investments, decreased to $1.9 million for the fiscal year ended March 31, 2005, compared to $9.0 million consumed in the prior fiscal year. The difference of $7.1 million represents an 79% decline in cash consumption. During this fiscal year the Company benefited from $4.1 million in cash proceeds from the employee stock option exercises and employee participation in the company s stock purchase plan.

Income taxes incurred during the fiscal year 2005 were not material, and we continue to have significant net tax operating loss and tax credit carryforwards.

We believe that our revenue from product sales together with existing resources will be sufficient to fund our planned operations for the next twelve months, including funding operating capital of approximately $12.0 million to $15.0 million for Impella operations and the planned expenditures for our AbioCor and AbioCor II implantable replacement hearts, and continued development and commercialization efforts of our BVS 5000 and AB5000 circulatory assist products. We may, however, need additional funds for possible strategic acquisitions of businesses, products or technologies complementary to our business and their subsequent integration and operating capital. If additional funds are required, 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, 2005 and the effects such obligations are expected to have on its liquidity and cash flows in future periods.

		Payments Due By Fiscal Year					
Contractual Obligations	**TOTAL**	**2006**	**2007**	**2008**	**2009**	**2010 and after**
Operating Lease Obligations	$ 3,797	$ 776	$ 769	$ 772	$ 772	$ 708

The Company has no long-term debt or material commitments at March 31, 2005. We have elected not to exercise a buyout option available under the Company s primary lease that would have allowed for early termination of the lease in 2005.

On May 10, 2005, the Company acquired all of the outstanding capital stock of Impella CardioSystems AG (Impella), a privately held company located in Aachen, Germany. Accordingly, the operating results of Impella from May 10, 2005 will be included in the Company s results beginning with the first quarter of fiscal 2006. Impella manufactures and sells small, minimally invasive, high performance micro blood pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. ABIOMED acquired Impella in exchange for approximately $1.6 million in cash and 4,029,004 shares of ABIOMED common stock, of which 210,000 shares are to be held in escrow for potential claims for indemnification by the Company pursuant to the terms of the purchase agreement. The 4,029,004 shares of ABIOMED common stock have a fair value of $42.2 million. Accordingly, the purchase price (before contingent payments) will be $45.3 million, inclusive of approximately $1.5 million of acquisition costs. The agreement provides that ABIOMED may make additional contingent payments to Impella s former shareholders based on the Company s 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 $29 million and will be made in a combination of cash or stock, if at all. The Company has not yet determined the preliminary purchase price allocation due to the recent nature of the acquisition. However, management believes that more than half of the purchase price will be recorded to goodwill, and a write-off of in-process research and development will be recorded in the first quarter of fiscal 2006. Also, significant amortization of intangible assets will impact fiscal 2006 and future results.

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 The Company routinely accrues for estimated future warranty costs on its product sales at the time of sale. The AB5000 and BVS products are subject to rigorous regulation and quality standards. While the Company engages in extensive product quality programs and processes, including monitoring and evaluating the quality of component suppliers, its warranty obligation is 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 the Company s products. The indemnifications contained within sales contracts usually do not include limits on the claims. The Company has never incurred any material costs to defend lawsuits or settle patent infringement claims related to sales transactions. Under the provisions of FIN No. 45, intellectual property indemnifications require disclosure only.

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 for our new products, including those acquired in connection with our recent acquisition of Impella CardioSystems, AG, under development in fiscal 2006 and subsequent fiscal years, 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 limited 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.

The BVS and AB5000 circulatory assist products, our principal product and current primary source of revenues, 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 BVS and AB5000 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 BVS and AB5000 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 BVS and AB5000 products could potentially result. Further, the BVS and AB5000 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 BVS and AB5000 product line, our overall business and financial condition could be adversely affected.

Our product revenues increased in fiscal 2005 by 51% in comparison to fiscal 2004 and in fiscal 2004 our product revenues increased by 8% in comparison to fiscal 2003. 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 BVS and AB5000 product line in 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.

We are seeking to expand our international sales of the AB5000, BVS and Impella Recover circulatory assist systems by recruiting direct sales and support teams for selected countries in Europe. To date we have limited experience in selling our products internationally. In fiscal 2005 and fiscal 2004, approximately 8% of our product revenues were derived from international sales. Our international operations will be subject to a number of risks, which may vary from the risks we experience in the U.S., including:

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

longer sales cycles;

dependence on local distributors;

limited protection of intellectual property rights;

difficulty in collecting accounts receivable;

fluctuations in the values of foreign currencies; and

political and economic instability.

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

We 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 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 or third party insurers, 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 BVS and AB5000. 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. The AbioCor and our 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 and Impella Recover 2.5/5.0 micro blood pump 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 the AB5000, BVS, Impella Recover 2.5/5.0 micro blood pumps, AbioCor, AbioCor II, and our 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, Impella Recover 2.5/5.0 micro blood pumps, 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, Impella Recover 2.5/5.0, 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, Impella Recover 2.5/5.0, 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 recent Impella acquisition to achieve its potential benefits could harm our business and operating results.

We recently acquired all of the outstanding capital stock of Impella CardioSystems AG. The acquisition may not achieve its anticipated benefits for a variety of reasons, including:

problems in successfully integrating our operations;

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

problems with compatibility of business cultures;

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 $29,350,000, 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 business.

In addition to our recent acquisition of Impella, in the future, we may pursue additional 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 s 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, for which we expect to obtain FDA approval and to market in the next twelve to eighteen months. The development of assist and replacement heart devices such as the AbioCor and AbioCor II, 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 would 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 Recover 2.5 and Recover 5.0 micro blood pumps 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 Recover 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 from foreign regulatory authorities, we cannot market and sell the AbioCor or other products in the U.S. and in 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. Our initial clinical testing of the AbioCor has been completed and the results were submitted to the FDA to support our request for market approval under an HDE in September 2004. The FDA has subsequently announced that it will convene a special expert panel of cardiovascular surgeons and cardiologists on June 23, 2005 to review and potentially approve the groundbreaking technologies and clinical trial

data behind the AbioCor. 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 the AbioCor based on a phased approach that begins with an HDE, 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 the AbioCor and our other 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 AbioCor, 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 and other planned new products acquired in connection with our acquisition of Impella CardioSystems, AG, is substantial for a company of our size and might exert a strain on our available resources.

While our total research and development expenditures have decreased, spending on our AbioCor, AbioCor II and other products under development or acquired in connection with our acquisition of Impella CardioSystems, AG 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.

39

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

While we do not invest for speculative purposes, we are exposed to market risk related to changes in interest rates. Our guidelines allow for an investment portfolio consisting mainly of U.S. Treasury notes, federal agency obligations, state and municipal bonds, and corporate bonds with maturities of two years or less and ratings of at least AA by Moody s or Standard & Poor s. These held-to-maturity 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, 2005, 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.

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 Acting Chief Financial Officer (the principal accounting officer), and all members of the senior management team held a Disclosure Committee meeting on May 18, 2005 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, 2005, 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, 2005. Our management s assessment of the effectiveness of our internal control over financial reporting as of March 31, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Important Considerations

The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, and the risk of fraud. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions and the risk that the degree of compliance with policies or procedures may deteriorate over time. Because of these limitations, there can be no assurance that any system of disclosure controls and procedures or internal control over financial reporting will be successful in preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management.

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:

FINANCIAL STATEMENT SCHEDULES

(1) Unaudited Quarterly Results of Operations, as previously reported for each of the fiscal quarters in the fiscal years ending March 31, 2005 and 2004. Except for the schedule of unaudited Quarterly Results of Operations, other schedules are not provided because the required information is given in the financial statements or notes thereto.

(2) The financial statements from our Annual Report for our fiscal year ending March 31, 2005 are attached hereto.

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets as of March 31, 2004 and 2005
Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2003, 2004 and 2005
Consolidated Statements of Stockholders Equity for the Fiscal Years Ended March 31, 2003, 2004 and 2005
Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2003, 2004 and 2005
Notes to Consolidated Financial Statements

(3) *Exhibits*

(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.

(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 (the September 1997 10-Q).* **

(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 Agreem