ABIOMED INC

FORM 10-K
(Annual Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For fiscal year ended March 31, 2004

OR

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

Commission File Number: 0-20584

ABIOMED, Inc.
(Exact Name of Registrant as Specified in Its Charter)

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

(978) 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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Rule 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

The aggregate market value of the voting stock held by non-affiliates of the registrant as of September 30, 2003 was $136,393,834 based on the closing price of $8.61 on that date as reported on the Nasdaq National Market. As of May 26, 2004, 21,549,047 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 2004 Annual Meeting of Stockholders, which is scheduled to be filed within 120 days after the end of the registrant's fiscal year, are incorporated by reference in Part III (Items 10, 11, 12, 13 and 14) of this Report.

INTRODUCTORY NOTE

This report, including the documents incorporated by reference in this report, includes forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements in these documents include, but are not necessarily limited to, those relating to:

- *our plans regarding the timing and outcome of initial clinical trials for our AbioCor Implantable Replacement Heart;*
- *our ability to obtain and maintain regulatory approval of our products in the U.S. and internationally, including obtaining a Humanitarian Device Exemption (HDE) for initial commercial introduction of the AbioCor;*
- *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 to safely and effectively assist or replace the pumping function of the failing heart. ABIOMED's BVS 5000 console and blood pump comprise the most widely used advanced heart assist system for the treatment of all patients with failing but potentially recoverable hearts in the U.S. Our AB5000 Circulatory Support System is a new and improved heart assist product model. Introduced during fiscal 2004, the AB5000 incorporate 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 console is also designed to provide a unique adaptable common platform for a family of blood pumps which in the future, subject to FDA approval, we will be able to support a broader population of patients for longer periods of time. Our AbioCor Implantable Replacement Heart, the world's only battery-powered implantable replacement heart system, is the subject of an ongoing initial clinical trial that began in July 2001. The AbioCor, the development of which follows decades of fundamental and applied research and testing, is intended to extend life and provide an improved quality of life for end-stage acute and chronic heart failure patients. We are also engaged in research and development relating to other devices to assist or replace the pumping function of the heart. Another area of research and development for ABIOMED is the continued enhancement of our product line to serve more patients who require mechanical heart assistance. 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").

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 model. The new 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 a patient's diseased heart and takes over the heart's blood pumping function. It is designed for use in patients at risk of imminent death due to irreparable 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. ABIOMED is developing a smaller replacement heart that will provide the capability to serve more patients than the present AbioCor.

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 the pumping function of the 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., claiming approximately 700,000 lives in 2002. Illnesses and deaths from heart disease create an immense burden to many individuals and their families. Patients frequently experience extended suffering, and substantial economic cost. While a number of therapies exist for the treatment of patients in the 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 an acute myocardial infarction, resulting in permanent damage to the heart muscle. In severe heart attacks, death can occur suddenly or gradually over days and weeks.

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 heart 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 that in 2002, a total of 64.4 million people in the United States were alive with some form of cardiovascular disease, including 50 million with high blood pressure. Of those 13.2 million were diagnosed with coronary heart disease, 5 million with congestive heart failure, and 4.8 million had suffered from stroke. Thus, coronary heart disease patients outnumbered congestive heart failure patients by approximately 2.6:1. For patients newly diagnosed within 2002, however, the ratio of coronary heart disease to congestive heart failure patients was 2.4:1, indicating that congestive heart failure may be becoming relatively more prevalent as time goes on. We believe that 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 500,000 of these deaths were attributable to coronary (ischemic) heart disease, approximately 57,000 were attributable to congestive heart failure, and approximately 140,000 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 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 in the U.S. alone is therefore the 700,000 patients who die each year of heart disease. In the future, when devices have matured and become 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 700,000 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, a majority of coronary heart disease and congestive heart failure patients die 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 120,000 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 to be $145.9 million, and projected a compound annual growth rate of 43.1% from 2002 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 do not fully restart 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.

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 14,000 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.

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. 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.

Staging . 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 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.

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 120,000 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 classes of device 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. Each of these products are systems consisting of various component elements.

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 model approved for commercial distribution during fiscal 2004. It incorporates a number of features to facilitate 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 up-to-date 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 expanded indications for use for the AB5000 as soon as we have accumulated the appropriate data to support an application to the FDA.

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.

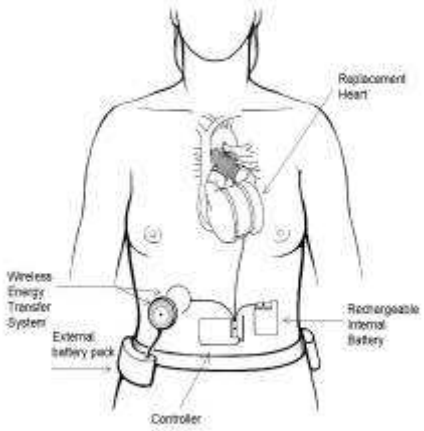
Any hospital performing open-chest heart surgery may use the BVS or the AB5000. There are approximately 900 of these hospitals in the U.S. and more than 1,000 such hospitals outside the U.S. As of March 31, 2004, nearly 600 medical centers in the U.S. had purchased the BVS, including 70% of the major 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 are initially focused on introducing the system in the largest cardiothoracic surgical centers through sales of consoles and sales of blood pumps.

The AbioCor Implantable Replacement Heart

The AbioCor is a battery-powered totally implantable replacement heart system. The AbioCor is referred to as totally implantable because it has been designed to operate on portable external battery power, without wires or any other material penetrating the patient's skin. The AbioCor is referred to as a replacement heart because it has been designed for implantation 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 virtually all adults who might benefit from a replacement heart.

- A rechargeable internal battery that is implanted beneath the skin in the abdomen of AbioCor recipients and allows the AbioCor to operate without any external power supply for limited periods of time.

- A microprocessor-based internal electronic device, or "controller", that is implanted beneath the skin in the abdomen of AbioCor recipients and controls and monitors the thoracic unit and provides radio communication with an external monitor affording patients 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.

- An external rechargeable battery pack and monitor designed to be worn by the patient. These components supply primary power to the system, allow patient mobility, provide system diagnostic 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 are 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, our initial trial consists of 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 is satisfactory to the FDA. Patients can be included in this initial clinical trial only if they have biventricular heart failure, are more than eighteen years old, are unresponsive to any other existing therapies, are ineligible for heart transplantation and are sufficiently large for the first generation AbioCor to fit and operate adequately. Patients are to be excluded from the clinical trial if their heart failure has a significant potential of being reversible, if they do not have a high likelihood of dying within the next 30 days, if they are pregnant, have serious psychiatric illness or an inadequate social support system. Patients may also be excluded if they are suffering from other serious non-cardiac medical ailments.

As of May 26, 2004, 14 patients have been enrolled in the initial AbioCor clinical trial. Twelve of those patients have been supported for some period of time, and 2 died just subsequent to surgery. Two patients implanted during the month of May 2004 are currently alive. The duration of support for the 10 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 4.4 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. We are not aware of any other clinically significant AbioCor malfunction. 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 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 all but one of these sickest of heart failure patients.

Five of 11 supported patients were ambulatory. Three patients had excursions outside of the hospital. Two patients were discharged to facilities near the hospitals an intermediate step toward final discharge to 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. One patient was discharged home.

Success of the initial clinical trial will be evaluated based upon periodic review of the survival of AbioCor patients and their quality of life as measured periodically by a variety of assessment criteria. It will also be evaluated according to the frequency and severity of adverse events, such as strokes. As we gain clinical experience with the most seriously ill patients and demonstrate clinical efficacy and safety, we expect to enhance the performance range, durability and reliability of AbioCor systems and plan to seek regulatory approval for current and subsequent generations of the AbioCor for use in imminently dying patients and in increasingly broad patient populations and with longer intended durations. Such regulatory approvals will likely require clinical data and trials beyond this initial trial. This regulatory plan is consistent with our experience with the BVS system.

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 18% 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 being gained in the initial AbioCor clinical trial is invaluable in guiding these ongoing development efforts.

Our development of the smaller second generation AbioCor II has entered 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 the NHLBI.

Other Products and Technologies

We are using the technology and know-how derived from the AbioCor, BVS and AB5000 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 April 30, 2004, our research and development staff consisted of 76 professional and technical personnel, including 16 individuals in design assurance and a total of 21 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 $27.1 million, $20.6 million and $14.3 million on research and development in fiscal 2002, 2003 and 2004, 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, 2004, 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.

The BVS and AB5000 are sold in the U.S. through direct sales and clinical support teams. As of April 30, 2004, our worldwide sales, clinical support, marketing and field service teams included 34 full-time employees. Our sales force primarily focuses on increasing sales from expanded usage of disposable blood pumps 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 that 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 BVS and AB5000 single-use blood pumps. We believe that the reputation and customer relationships of our sales and support teams will be key assets for the introduction of future products such as the AbioCor, additional heart assist product line extensions, and other products under development.

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 the AbioCor. In October 2001 we received approval from the Japanese Ministry of Health, Labor and Welfare to market and sell the BVS system in Japan. 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. It is our intention to expand our international market presence through distributorships in Canada and Latin America.

Manufacturing

We have over 10 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 ongoing initial clinical trial, 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.

As of April 30, 2004, a total of 60 employees were engaged in BVS and AB5000 manufacturing and AbioCor pilot manufacturing. Manufacturing and pilot manufacturing operations are further supported by an additional 14 people devoted to quality assurance and documentation and by 16 people in materials management and purchasing.

We believe our existing facility gives us the physical capacity to produce sufficient quantities of AbioCor systems throughout the period of our clinical trials as well as sufficient quantities of BVS and AB5000 disposable blood pumps and cannulae to meet market demand for the foreseeable future. Our BVS and AB5000 manufacturing area is ISO 13485 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 ISO 13485 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 May 15, 2004, we own 57 U.S. patents, including 17 related to the AbioCor, 10 related to the AbioCor II (Penn State Heart), and two related to the BVS. These patents have expiration dates ranging from June 21, 2005, to September 30, 2023. We also own a number of corresponding patents in a limited number of foreign countries. 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. Many of the companies developing or marketing cardiovascular products 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-reversable biventricular failure. As of May 26, 2004 the FDA had not yet acted on that recommendation. Unlike our AbioCor, the CardioWest heart is not fully implantable and is not conducive to discharge of patients from the hospital. For those reasons, we do not view it as a 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 Arrow International, Thoratec Corporation and World Heart Corporation 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 these research activities, 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 blood pumps, such as intra-aortic balloon pumps 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 that is conducting clinical trials in the U.S. with a device that may compete with our current heart assist products. 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. 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 Japan, reimbursement from government or third party payers must be applied for and approved. 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. Physicians bill separately for the procedures that they perform. Effective October 1, 2002, the U. S. Department of Health and Human Services created a new DRG (DRG 525) for hospital discharges involving implantation of external or implantable advanced mechanical cardiac assist devices. This action increased Medicare program reimbursement to hospitals for patient cases involving the BVS by approximately 40-60% over prior levels. Certain private health insurers and managed care providers provide incremental reimbursement to both the medical institutions and their physicians.

No reimbursement levels have been established for our products under development, including the AbioCor. Prior to approving coverage for new medical devices in the U.S., most third-party payers require evidence that the product has received FDA approval 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 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 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 . 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 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 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 an institution is subject to 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 IRB 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 the IDE and PMA processes and QSR requirements. 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 3, 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. Our clinical trial is being undertaken with patients who, despite all available therapies, have an extremely high probability of death within thirty days due to heart failure.

We anticipate 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, 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 counties 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 and the AB5000 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 April 30, 2004 we had 239 full-time employees, including:

- 76 in product development (including 21 engineers and 14 design assurance);
- 34 in sales, clinical support, marketing and field service; and
- 60 in manufacturing, including AbioCor manufacturing; and
- 14 in quality assurance and documentation.

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.

Executive Officers of the Registrant

Our executive officers consist of the following:

Name	Age	Position
Michael R. Minogue	37	Chief Executive Officer, President and Director
Anthony W. Bailey	48	Senior Vice President, Manufacturing
Edward E. Berger, Ph.D.	59	Vice President, Policy, Reimbursement and External Relations
William J. Bolt	52	Senior Vice President, Design Assurance and Quality Assurance
Charles B. Haaser	48	Principal Accounting Officer and Acting Chief Financial Officer
Robert T.V. Kung, Ph.D.	60	Senior Vice President, Chief Scientific Officer
Eugene D. Rabe	48	Senior Vice President, Global Sales and Services

Mr. Michael R. Minogue joined ABIOMED as Chief Executive Officer, President and a Director in April 2004 following a career at GE Medical Systems. Most recently, Mr. Minogue was Vice President and General Manager of Americas Sales and Marketing for GE Medical Systems Information Technology, where he was responsible for the commercial activity of over $1.2 billion in revenues and more than 700 direct employees and GE's Global PET/CT business. Prior to that assignment, he led GE Medical's Global Workstation & Software and Americas Cardiology businesses. Mr. Minogue received his Bachelor's degree in Engineering from the United States Military Academy at West Point and his MBA from the University of Chicago.

Mr. Anthony W. Bailey has served ABIOMED since 1997 and has been Senior Vice President, Manufacturing since 2004, prior to which he was Senior Vice President, Operations, Vice President, Business Development and Vice President, Engineering. From 1987 to 1997, he was Vice President and General Manager for Pace Medical, Inc. and from 1982 to 1987, was Manager of Design and Development at Shiley Infusaid, Inc. Prior to 1982, Mr. Bailey served in various engineering functions with manufacturers of implantable pacemakers, data acquisition and control systems and medical monitoring systems. Mr. Bailey received his Bachelor's degree in Electrical Engineering from the University of Lowell.

Dr. Edward E. Berger has served ABIOMED since 2001. He has been Vice President, Policy, Reimbursement and External Relations since 2003, having previously served as Vice President, Strategic Planning and Policy and Vice President, Government and External Relations. From 1998 to 2001 he served several healthcare companies as a consultant on public policy and reimbursement strategy. From 1983 to 1997, following a 14 year academic and consulting career, he held various positions for Fresenius Medical Care, including Vice President and Director of Government Relations. Dr. Berger received his Bachelor's degree in government from Harvard College and his Ph.D. degree in Political Science from Boston University.

Mr. William J. Bolt has served ABIOMED since 1982 and has been Senior Vice President for Design Assurance and Quality Assurance since January 2003. He is currently responsible for all Quality and Design Assurance activities in the Company. He was responsible for all product development and the AbioCor program from 2000-2002, and for BVS and AB5000 development from 1999-2002. From 1994 to 1998, he was President of ABIOMED's dental subsidiary, ABIODENT. From 1982 to 1994, he served in various roles, from Vice President of Engineering to Vice President of Operations, where he was the engineer in-charge of the development of the BVS and other systems. Mr. Bolt received his Bachelor's degree in Electrical Engineering and an MBA from Northeastern University.