ABIOMED INC
Form 10-K
June 08, 2010

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For fiscal year ended March 31, 2010

OR

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

Commission File Number: 0-20584

ABIOMED, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(978) 646-1400

(Registrant s Telephone Number, Including Area Code)

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

Title of Each Class	**Name of Each Exchange**

	on Which Registered
Common Stock, $.01 par value	**The Nasdaq Stock Market LLC**

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

None

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

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

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

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

The aggregate market value of the registrant s common stock as of September 30, 2009, held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of such date was $363,825,068.

As of May 28, 2010, 37,433,189 shares of the registrant s common stock, $.01 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for Abiomed, Inc. s 2010 Annual Meeting of Stockholders, which is scheduled to be filed within 120 days after the end of Abiomed, Inc. s fiscal year, are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the documents incorporated by reference in this report, includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, may and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements in these documents include, but are not necessarily limited to, those relating to:

our ability to obtain and maintain regulatory approval both in the U.S. and abroad for our existing products as well as for new products in development;

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

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

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

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

our business strategy;

our revenue growth expectations, our level of operating and capital expenses and our goal of achieving profitability; and

the sufficiency of our liquidity and capital resources.

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

PART I

ITEM 1. ***BUSINESS***
Overview

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

Our Products

Impella 2.5

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

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

In August 2007, we received approval from the FDA to begin a high-risk percutaneous coronary intervention, or PCI, pivotal clinical trial, known as the Protect II study, for the Impella 2.5. The pivotal study will determine the safety and effectiveness of the Impella 2.5 as compared to optimal medical management with an intra-aortic balloon, or IAB, during high-risk angioplasty procedures. The study inclusion criteria have been extended to include patients with triple vessel disease with low ejection fraction. The study is approved under category B2 status and the trial sites are eligible for full reimbursement from the Centers for Medicare and Medicaid Services, or CMS. The randomized pivotal study, in which 654 patients at up to 150 hospitals will undergo a high-risk PCI procedure, is comprised of two arms comparing nearly equal number of Impella 2.5 supported patients and IAB supported patients during the procedure. Patients receiving the Impella 2.5 can be supported for up to five days as a left ventricular assist device, or VAD. As of March 31, 2010, a total of 341 patients were enrolled in the Protect II study, or 52% of the 654 patients required. Based on current trial enrollment rates, we expect to complete the Protect II study in 2012.

In March 2008, we received approval from the FDA to begin a second pivotal study for our Impella 2.5 in the U.S. under an investigational device exemption, or IDE, for hemodynamically unstable patients undergoing a PCI procedure due to acute myocardial infarction, or AMI, commonly referred to as heart attack. The AMI study, known as Recover II, was to determine the safety and effectiveness of the Impella 2.5 as a left ventricular assist device for heart attack patients as compared to optimal medical management with an IAB. The study is approved under category B2 status and the trial sites are eligible for full CMS reimbursement. The randomized study, at up to 150 hospitals, is comprised of two arms; those patients that receive the Impella 2.5 for up to five days and patients that receive IAB therapy. The study will compare 192 Impella 2.5 patients to 192 IAB patients relative to a composite end point comparing safety and efficacy. In September 2009, we suspended further administrative progress towards new site activation on the Recover II study while exploring changes in the study design. Because Recover II is a pivotal trial conducted under IDE, any changes in the study design need to be approved by the FDA.

In addition to the FDA approved studies for Impella 2.5, we are also conducting USpella, the first U.S. multicenter observational registry collecting clinical data and outcomes for patients supported with Impella 2.5 during elective, urgent and emergent procedures. We invited 62 hospitals in the U.S. and Canada to participate in the USpella registry. Of these, 45 centers have accepted the invitation and have begun the activation process, and 24 of these sites have received Investigational Review Board, or IRB, approval. An independent Clinical Event Committee (CEC) has been established to adjudicate adverse event reporting. As of March 31, 2010, a total of 251 of the 301 patient data reports have completed the CEC adjudication process.

The clinical trial experience to date with our Impella 2.5 has been favorable, including our completed U.S. safety pilot clinical trial. Factors that affect the length of time to complete the pivotal studies in the U.S. study include the timing of each center receiving IRB approval, the timing of the training we provide each center, and the rate of patient enrollment.

Impella 5.0 and Impella LD

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

The Impella 5.0 is implanted via a small incision in the femoral artery in the groin and can be quickly inplanted via the femoral artery using a guide wire to reach the left ventricle of the heart where it is directly deployed to draw blood out of the ventricle, deliver it to the systemic system and perfuse the heart muscle. This function is intended to reduce ventricular work (resting the heart). The Impella LD is similar to the Impella 5.0 but is implanted directly through an incision in the subclavien or through an aortic graft. The Impella 5.0 and Impella LD can pump up to five liters of blood per minute and have been used to treat patients in need of cardiac support resulting from post-cardiotomy cardiogenic shock, myocarditis, low cardiac output after a heart attack, or post-coronary intervention procedures.

The Impella 5.0 is in a pilot clinical study that is enrolling up to 20 patients at 15 U.S. sites. The study will include postcardiotomy patients who have been weaned from heart-lung machines and whose hearts require added support to maintain good blood flow. The study is enrolling those patients that would typically need more flow and hemodynamic support than provided by an IAB.

AB5000 and BVS 5000

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

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

The AB5000 Circulatory Support System is designed to provide a longer duration of support than the BVS 5000 and facilitates patient mobility in the hospital. The AB5000 can provide up to 6.0 liters of pulsatile blood flow per minute to support patients in profound shock and was approved by the FDA in 2003. Our AB5000 is designed to provide enhanced patient mobility within and between medical centers and to provide enhanced features and ease of use for caregivers. We believe the AB5000 system s high flow rates, ease of implant and historically low incidence of adverse events facilitate heart recovery, for patients with potential for recovery, potentially avoiding the need for heart transplantation and thereby improving patient outcomes.

We have developed a Portable Circulatory Support Driver, or Portable Driver, for both in-hospital and out-of-hospital patients which is designed to support our AB5000 VAD. We received CE mark approval for our Portable Driver in March 2008. In May 2008, we received conditional approval for the Portable Driver under an investigational device exemption, or IDE, to conduct a U.S. patient discharge study at 20 hospitals for 30 patients. In March 2009, we received FDA approval of our PMA supplement for the AB Portable Driver. This clearance allows for immediate commercial shipment of the device to U.S. hospitals for in hospital and transport use. The out of hospital use is being studied in a clinical trial to allow patients to go home while waiting for recovery.

AbioCor

Our AbioCor Implantable Replacement Heart is the first completely self-contained artificial heart. Designed to sustain the body s circulation, the AbioCor is intended for end-stage biventricular heart failure patients whose other treatment options have been exhausted. Patients with advanced age, impaired organ function or cancer are generally ineligible for a heart transplant and are potential candidates to receive the AbioCor implantable heart. Once implanted, the AbioCor system does not penetrate the skin, reducing the chance of infection. This technology provides patients with mobility and remote diagnostics. The use of AbioCor is limited to normal to larger sized male patients and has a product life expectancy of 18-24 months.

We received HDE supplement approval from the FDA for product enhancement of the AbioCor in January 2008. HDE approval signifies that no comparable alternative therapy exists for patients facing imminent death without the technology. HDE approval allows the AbioCor to be made available to a limited patient population, with no more than 4,000 patients receiving the technology in the U.S. each year under HDE approval limits. Because the AbioCor is only available to a limited patient population, we do not expect that demand will meet the 4,000

patient limit under HDE approval. We have no current plans to seek a broader regulatory approval of the AbioCor. We began selling the AbioCor in the fourth quarter of fiscal 2008 in a controlled roll-out to a limited number of heart centers in the U.S. We are unable to determine how many patient procedures will be performed after the centers are trained; however, we do not expect it to be a material number. In May 2008, we received a positive National Coverage Determination, or NCD, from CMS to reimburse hospitals for the cost of the AbioCor replacement heart and the cost of implanting the device as part of Coverage with Evidence Development, or CED. In June 2009, the first AbioCor patient procedure under HDE approval was performed at Robert Wood Johnson University Hospital. This patient died on August 23, 2009, due to post-operative conditions unrelated to the AbioCor. We do not expect that revenues from sales of the AbioCor will be a material portion of our total revenues for the foreseeable future as our primary strategic focus is centered around heart recovery for acute heart failure patients.

Our Markets

According to the American Heart Association, or AHA, Heart Disease and Stroke Statistics 2009 Update Report, coronary heart disease, or CHD, caused about 1 of every 5 deaths in the U.S. in 2005. CHD mortality in 2005 was approximately 445,000. In 2009, an estimated 785,000 Americans will have a new coronary attack and about 470,000 will have a recurrent attack. An estimated additional 195,000 silent first myocardial infarctions occur each year. Coronary heart disease is a condition of the coronary arteries that causes reduced blood flow and insufficient oxygen delivery to the affected portion of the heart. Coronary heart disease leads to acute myocardial infarction, or AMI, commonly known as a heart attack, which may lead to heart failure, a condition in which the heart is unable to pump enough blood to the body s major organs.

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

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

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

An IAB is an inflatable balloon inserted via a catheter into the patient s circulation and is inflated and deflated in synchrony with the heart. This is used as an initial line of therapy in the cath lab or the surgery suite for patients with diminished heart function. However, IABs typically provide only limited enhancement and depend on the patient s own heart to generate the majority of the patient s blood flow. In addition, IABs are often required to be used in conjunction with inotropes or other drugs to stimulate heart muscle ejection. However, the use of these drugs increases the risk of mortality. Clinical publications have demonstrated that the need for two or more inotropes to improve blood flow results in mortality rates of approximately 80%. In addition, IABs have limited effectiveness in patients that are arrhythmic and /or in cardiogenic shock and published reports have indicated that IABs do not reduce mortality for patients in cardiogenic shock. However, there are an estimated 160,000 annual IAB procedures globally, with an estimated 110,000 IAB procedures annually in the U.S.

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

Recovery VADs are designed to enable the patient s heart to rest and potentially recover so that the patient can return home with his or her own heart. Because recovery is the goal, these devices are designed to minimize damage to heart tissue and be removed once the heart has recovered. If possible, recovery of one s own heart is generally preferred to transplantation or prolonged device implantation, both of which have significant side effects for the patient and increase the risk of mortality. We believe heart recovery is a preferred clinical outcome for the patient, since it also generally lowers the overall relative cost to the healthcare system versus alternative therapies and treatment paths that may require multiple surgeries, lengthy hospital stays, chronic therapeutic and immunosuppressant drugs and other related healthcare costs.

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

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

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

We developed our first heart recovery products for use in open heart centers and transplant centers.

Research and Product Development

Since our founding in 1981, we have gained substantial expertise in circulatory support while developing the BVS and the AB5000 systems and our AbioCor. Our current strategy is to develop a complete portfolio of products to treat acute heart failure patients with the goal of heart recovery. We have used this expertise to develop our IAB, iPulse and Portable Driver, and we intend to continue to use this experience to develop additional circulatory support products. Our research and development efforts are focused on developing a broader portfolio of products across the continuum of care in heart recovery, primarily focused in the area of circulatory care. In addition, we have a number of new products at various stages of development some of which integrate the Impella technology platform.

As of March 31, 2010, research and development staff consisted of 80 professional and technical personnel, including 28 engineers with advanced degrees, covering disciplines such as electrical engineering, mechanical engineering, computer science, reliability engineering, fluid mechanics, materials and physiology.

We expended $26.0 million, $25.3 million, and $24.9 million on research and development in fiscal years 2010, 2009, and 2008, respectively. Our research and development expenditures include costs related to clinical trials, including ongoing clinical studies for our Impella products.

Sales, Clinical Support, Marketing and Field Service

As of March 31, 2010, our worldwide sales, clinical support, marketing and field service teams included 128 full-time employees, 109 of whom are in the U.S. and 19 of whom are in Europe. Over the past five years, we have significantly increased the number of our direct sales and clinical support personnel covering the U.S., Canada, Germany, and France.

Our clinical support personnel consist primarily of registered nurses with experience in either the surgery suite or the cath lab, and they play a critical role in training current and prospective customers in the use of our products.

International sales (sales outside the U.S., primarily in Europe) accounted for 9%, 14%, and 17% of total product revenue during the fiscal years ended March 31, 2010, 2009, and 2008 respectively.

Manufacturing

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

We believe our existing manufacturing facilities give us the necessary physical capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months based on our revenue forecast. In fiscal 2008 and 2009, we invested in capacity expansion in our German facility to meet the growing demand of our Impella 2.5 product after the 510(k) clearance that we received in June 2008. In January 2010, we started performing some subassembly work on the Impella in Danvers to supplement main Impella manufacturing production in Aachen.

In July 2008, we entered into an agreement to lease additional manufacturing space in Athlone, Ireland in anticipation of supporting future demand of Impella 2.5. We deferred the start up activities at our Athlone, Ireland manufacturing facility and are in the process of moving the equipment from Athlone to Aachen and Danvers. We have started exploring opportunities to sub-lease the Athlone facility or terminate the lease early. We expect to record an expense of approximately $1.0 million as an estimate of the cost to terminate the Athlone lease when we fully vacate the facility, which is expected to occur in fiscal 2011. As of March 31, 2010, we have $1.2 million in fixed assets located in our Athlone facility.

We expect to start a second production line for Impella in Aachen during fiscal 2011 and are developing additional Impella manufacturing capacity in Danvers. Our U.S. and German manufacturing facilities are ISO certified and operate under the FDA s good manufacturing practice requirements set forth in the current quality system regulation, or QSR.

Intellectual Property

We have developed significant know-how and proprietary technology, upon which our business depends. To protect our know-how and proprietary technology, we rely on trade secret laws, patents, copyrights, trademarks, and confidentiality agreements and contracts. However, these methods afford only limited protection. Others may independently develop substantially equivalent proprietary information or technology, gain access to our trade secrets or disclose or use such secrets or technology without our approval.

A substantial portion of our intellectual property rights relating to the AB5000, the BVS 5000 and the AbioCor is in the form of trade secrets, rather than patents. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. We cannot assure you that our trade secrets will not become known to or be independently developed by our competitors.

We own or have rights to numerous U.S. and foreign patents. Our U.S. patents have expiration dates ranging from 2011 to 2026 and our foreign patents have expiration dates ranging from 2016 to 2023. We also own or have rights to certain pending U.S. and foreign patent applications. We believe patents will issue pursuant to such applications, but cannot guarantee it. Moreover, neither the timing of any issuance, the scope of protection, nor the actual issue date of these pending applications can be forecasted with precision. Where we have licensed patent rights from third parties, we are generally required to pay royalties.

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

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

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

Competition

Competition among providers of treatments for the failing heart is intense and subject to rapid technological change and evolving industry requirements and standards. We compete with companies that have substantially greater or broader financial, product development and sales and marketing resources and experience than we do. These competitors may develop superior products or products of similar quality at the same or lower prices. Moreover, improvements in current or new technologies may make them technically equivalent or superior to our products in addition to providing cost or other advantages. Other advances in medical technology, biotechnology and pharmaceuticals may reduce the size of the potential markets for our products or render those products obsolete.

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

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

Third-Party Reimbursement

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

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

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

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

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

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

Government Regulation

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

Premarket Regulation

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

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

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

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

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

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

Certain Class III devices that were on the market before May 28, 1976, known as preamendment Class III devices, and devices that are determined to be substantially equivalent to them, can be brought to market through the 510(k) process until the FDA, by regulation, calls for PMA applications for the devices. In addition, the Safe Medical Devices Act of 1990 requires the FDA either to down-classify preamendment

Class III devices to Class I or Class II or to publish a classification regulation retaining the devices in Class III. Manufacturers of preamendment Class III devices that the FDA retains in Class III must submit a PMA application within 90 days after the FDA publishes a final regulation requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Failure to meet the deadline can lead the FDA to prevent continued marketing of the device during the PMA application review period. Our IAB received 510(k) clearance based on a preamendment Class III device. The Impella 2.5, Impella 5.0, and Impella LD received clearance based on a preamendment Class III device. If the FDA calls for a PMA for a preamendment Class III device, a PMA must be submitted for the device even if the device has already received 510(k) clearance; however, if the FDA down-classifies a preamendment Class III device to Class I or Class II, a PMA application will not be required.

The PMA approval pathway requires proof of the safety and effectiveness of the device to the FDA s satisfaction. The PMA approval pathway is much more costly, lengthy and uncertain than the 510(k) path. In the PMA process, the FDA examines detailed data to assess the safety and effectiveness of the device. This information includes design, development, manufacture, labeling, advertising, preclinical testing and clinical study data. Prior to approving the PMA, the FDA may conduct an inspection of the manufacturing facilities and the clinical sites where the supporting study was conducted. The facility inspection evaluates the company s compliance with the QSR. An inspection of clinical sites evaluates compliance with the IDE requirements. Typically, the FDA will convene an advisory panel meeting to seek review of the data presented in the PMA. The panel s recommendation is given substantial weight, but is not binding on the agency. If the FDA s evaluation is favorable, the PMA is approved and the device may be marketed in the U.S. The FDA may approve the PMA with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

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

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

In addition, certain devices can be distributed under an HDE, rather than a PMA. In order for a device to be eligible for an HDE, a qualifying target patient population of less than 4,000 patients per year for which there is no other available therapy must be approved by the FDA. The FDA s approval of an HDE to treat that qualifying patient population then requires demonstration that the device is safe for its intended application, that it is potentially effective, and that the probable benefits outweigh the associated risks. Within the regulations for an HDE, if a device becomes available through the PMA process that addresses the same patient population as the HDE device, the HDE device may need to be withdrawn from the U.S. market. In January 2008 we received HDE supplement approval from the FDA for the AbioCor.

Our AB5000 and BVS 5000 systems are approved by the FDA for use in patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. The intent of therapy is to provide circulatory support, restore normal hemodynamics, reduce ventricular work, and allow the heart time to recover adequate mechanical function. In 1992, the FDA approved our PMA for the BVS 5000. In 1996 and 1997, the FDA approved the use of the BVS 5000 for additional indications, expanding its use to the treatment of all patients with potentially reversible heart failure. In April 2003, the AB5000 Circulatory Support System Console and in September 2003, the AB5000 VAD were approved under PMA supplements. We received FDA clearance for our new IAB in December 2006. Our iPulse console was approved by the FDA under a PMA supplement in December 2007. Our Impella 2.5 device received 510(k) clearance in June 2008 for partial circulatory support for up to six hours. We received FDA 510(k) clearance of our Impella 5.0 and Impella LD devices in April 2009 for circulatory support for up to six hours. Our AB Portable Driver received FDA approval under a PMA supplement in March 2009. All of these products have CE marks allowing distribution within the European Union.

Postmarket Regulation

The medical devices that we manufacture and distribute pursuant to FDA clearances or approvals are subject to continuing regulation by the FDA and other regulatory authorities. The FDA reviews design, manufacturing, and distribution practices, labeling and record keeping, and manufacturers required reports of adverse experience and other information to identify potential problems with marketed medical devices. Among other FDA requirements, we must comply with the FDA s good manufacturing practice regulations. These QSR regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. We must also comply with Medical Devices Reporting, or MDR, which requires that a firm report to the FDA any incident in which its product may have caused or contributed to a death or serious injury, required an unnecessary intervention for a

patient, or in which its product malfunctioned and, if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. Labeling, advertising, and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

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

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

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

International Regulation

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

Fraud and Abuse Laws

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

Anti-Kickback Statute

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

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

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

In recent years, several states, including California, Vermont, Maine, Minnesota, Massachusetts, New Mexico, Nevada, and West Virginia, in addition to the District of Columbia, have enacted legislation requiring biotechnology, pharmaceutical and medical device companies to establish marketing compliance programs and file periodic reports on sales, marketing, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and available guidance is limited. We could face enforcement action, fines and other penalties and could receive adverse publicity, all of which could harm our business, if it is alleged that we have failed to fully comply with such laws and regulations. Similarly, if the physicians or other providers or entities with whom we do business are found not to comply with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

Federal False Claims Act

The federal False Claims Act prohibits the knowing filing or causing the filing of a false claim or the knowing use of false statements to obtain payment from the federal government. When an entity is determined to have violated the False Claims Act, it must pay three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim. Private individuals can file suits under the False Claims Act on behalf of the government. These lawsuits are known as qui tam actions, and the individuals bringing such suits, sometimes known as relators or, more commonly, whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. In addition, certain states have enacted laws modeled after the federal False Claims Act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

HIPAA

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

HIPAA also protects the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses. HIPAA restricts the use and disclosure of patient health information, including patient records. Although we believe that HIPAA does not apply to us directly, most of our customers have significant obligations under HIPAA, and we intend to cooperate with our customers and others to ensure compliance with HIPAA with respect to patient information that comes into our possession. Failure to comply with HIPAA obligations can entail criminal penalties. Some states have also enacted rigorous laws or regulations protecting the security and privacy of patient information. If we fail to comply with these laws and regulations, we could face additional sanctions.

Employees

As of March 31, 2010, we had 365 full-time employees, including:

- 80 in product engineering, research and development, and regulatory;
- 128 in sales, clinical support, marketing and field service;
- 113 in manufacturing; and
- 44 in general and administration.

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

10

Our Corporate Information

We are a Delaware corporation and commenced operations in 1981. Our principal executive offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, and our telephone number is (978) 646-1400. Our web address is www.abiomed.com. We make available free of charge through the Investors section of our website, all reports filed with the Securities and Exchange Commission. We do not incorporate the information on our website into this report, and you should not consider it part of this report.

ITEM 1A. ***RISK FACTORS***

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider these risks as well as the other information we include or incorporate by reference in this report, including our consolidated financial statements and the related notes. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties of which we are unaware or that we deem immaterial may also adversely affect our business. If any of these risks materializes, the trading price of our common stock could fall and you might lose all or part of your investment.

This section includes or refers to forward-looking statements. You should read the explanation of the qualifications and limitations on such forward-looking statements discussed at the beginning of the report.

Risks Related to Our Business

We have not operated at a profit and do not expect to be profitable in our fiscal year 2011.

We have incurred net losses in each of the past three fiscal years and for most of our history. We plan to make significant expenditures in fiscal 2011 and subsequent fiscal years for, among other things, the expansion of our global distribution network and ongoing product development, which we expect will result in losses in our fiscal year 2011 and potentially in future periods. These expenditures include costs associated with hiring additional personnel, performing clinical trials, continuing our research and development relating to our products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing activities. The amount of these expenditures is difficult to forecast accurately and cost overruns may occur. We also expect that we will need to make significant expenditures to begin to market and manufacture in commercial quantities our recently approved circulatory care products, and any other new products for which we may receive regulatory approvals or clearances in the future.

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

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

If we do not receive FDA approval or clearance for one or more of our products, we will be unable to market and sell those products in the U.S. which would have a material adverse effect on our operations and prospects. Although we received 510(k) clearance of our Impella 2.5 device in June 2008 for partial circulatory support for up to six hours, we are also pursuing premarket approval for the Impella 2.5 for additional indications.

We intend to market our new products in international markets, including the European Union, Canada, and Japan. Approval processes differ among those jurisdictions and approval in the U.S. or any other single jurisdiction does not guarantee approval in any other jurisdiction. Obtaining foreign approvals could involve significant delays, difficulties and costs for us and could require additional clinical trials.

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

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

Conducting clinical trials is a long, expensive and uncertain process that is subject to delays and failure at any stage. Clinical trials can take months or years to complete. The commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including:

- the FDA may not approve a clinical trial protocol or a clinical trial, or may place a clinical trial on hold;
- subjects may not enroll in clinical trials at the rate we expect and/or subjects may not be followed-up on at the rate we expect;
- subjects may experience adverse side effects or events related or unrelated to our products;
- third-party clinical investigators may not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations may not perform data collection and analysis in a timely or accurate manner;
- the interim results of any of our clinical trials may be inconclusive or negative;
- regulatory inspections of our clinical trials or manufacturing facilities may require us to undertake corrective action or suspend or terminate our clinical trials if investigators find us not to be in compliance with regulatory requirements;
- 510(k) clearance of our devices may have the effect of slowing down the progress of related clinical trials since physicians can use our cleared devices commercially outside of the trials;
- our manufacturing process may not produce finished products that conform to design and performance specifications; or
- governmental regulations or administrative actions may change and impose new requirements, particularly on reimbursement.

The results of pre-clinical studies do not necessarily predict future clinical trial results and previous clinical trial results may not be repeated in subsequent clinical trials. A number of companies in the medical industry have suffered delays, cost overruns and project terminations despite achieving promising results in pre-clinical testing or early clinical testing. In addition, the data obtained from clinical trials may be inadequate to support approval or clearance of a submission. The FDA may disagree with our interpretation of the data from our clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate the safety and effectiveness of the product candidate. The FDA may also require us to conduct additional pre-clinical studies or clinical trials which could further delay approval of our products. If we are unable to receive FDA approval of an IDE to conduct clinical trials or the trials are halted by the FDA or others or if we are unsuccessful in receiving FDA approval of a product candidate, we would not be able to sell or promote the product candidate in the U.S., which could seriously harm our business. Moreover, we face similar risks in each other jurisdiction in which we sell or propose to sell our products.

If we make modifications to a product, whether in response to results of clinical testing or otherwise, we could be required to start our clinical trials over, which could cause serious delays that would adversely affect our results of operations. Even modest changes to certain components of our products could result in months or years of additional clinical trials.

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

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. Since 2004, we have experienced significant growth in the scope of our operations and the number of our employees. This growth has placed significant demands on our management as well as our financial and operations resources. In order to achieve our business objectives, we will need to continue to grow. However, continued growth presents numerous challenges, including:

- developing our global sales and marketing infrastructure and capabilities;

expanding manufacturing capacity, maintaining quality and increasing production;

expansion of foreign regulatory compliance capabilities;

implementing appropriate operational and financial systems and controls;

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

training, managing and supervising our personnel worldwide.

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

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

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

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

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

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

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