ABIOMED INC
Form 10-K
June 08, 2009
Table of Contents

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, 2009

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 ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the registrant s common stock as of September 30, 2008, 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 $649,874,573.

As of May 29, 2009, 37,350,501 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 2009 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.

Table of Contents

Table of Contents

10-K - FORM 10-K

Table of Contents

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 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.

Table of Contents

PART I

ITEM 1. ***BUSINESS***

Overview

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

Industry Background

Heart Disease Overview

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

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

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

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

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

An IAB is an inflatable balloon inserted via a catheter 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

Table of Contents

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 VAD therapy only prolongs the end-stage disease, as the patient s heart condition is terminal and the patient s heart is not expected to recover. Furthermore, artificial replacement hearts, another destination therapy modality, may be suitable for end-stage heart failure patients requiring full support.

Our Solution

Our product portfolio is designed to provide a continuum of care in heart recovery to acute heart failure patients from the intensive care unit to the cath lab to the surgery suite to home discharge and to provide an array of choices for clinicians treating acute heart failure patients. Our products provide various levels of blood flow and are capable of supporting a patient from hours to months and longer to align with the clinical needs of the patient, whether in pre-shock or profound shock. Our cath lab products include an IAB and our catheter-based Impella ® pumps for support of acute pre-shock patients or for prophylactic support of patients undergoing high-risk percutaneous coronary intervention. Our surgery suite products include our Impella pumps (the Impella 2.5, Impella 5.0, and Impella LD), our IAB, 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.

Our Impella products are CE-marked in Europe. In June 2008, we received FDA 510(k) clearance for our Impella 2.5 device for partial circulatory support for up to six hours. In April 2009, we received FDA 510(k) clearance of our Impella 5.0 and Impella LD Circulatory Support Devices. These clearances allows us to sell the Impella pumps for commercial purposes. Our Impella 2.5 device is also the subject of two U.S. pivotal studies comparing the Impella 2.5 to the IABP. Our Impella 5.0 device is also currently in a U.S. study. Impella expands our product portfolio to include devices that address the majority of heart attack and high-risk angioplasty patients treated by interventional cardiologists in the cath lab. This population consists of patients whose hearts can potentially recover with assistance but without open heart surgery.

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

We developed our first heart recovery products for use in open heart centers and transplant centers. Our AB5000 and BVS 5000 are capable of assuming the pumping function of the heart. Unlike destination therapy and bridge-to-transplant devices, which are designed for

Table of Contents

heart patients with irreversible heart damage, our AB5000 and BVS 5000 systems are designed for heart recovery, requiring only a minimal incision in the left ventricle of the heart. We believe the AB5000 s high flow rates, ease of implant, and historically low incidence of adverse events facilitate heart recovery, avoiding unnecessary heart transplantation for patients with potential for heart recovery and thereby improving patient outcomes. The Centers for Medicare & Medicaid Services, or CMS, increased reimbursement in October 2007 for our AB5000 and BVS 5000 products for patients that recover using our devices to levels similar to those for patients who undergo heart transplants. These reimbursement levels for AB5000 and BVS 5000 are now the highest paying diagnosis-related group, or DRG code of all CMS codes. Since its introduction in 1992, the BVS 5000 has supported thousands of patients in hundreds of medical centers around the world. The AB5000, our next-generation heart recovery device introduced in 2004, provides up to six liters of pulsatile flow, and provides patient mobility. In January 2008, we received FDA labeling approval for one year bench reliability for our AB5000 VAD which is expected to complement the durability of our new Portable Circulatory Support Driver that is discussed below.

We recently announced that we have developed a new Portable Circulatory Support Driver, or Portable Driver, for both in-hospital and out-of-hospital patients. The Portable Driver is designed to support our AB5000 VAD. We received CE mark approval for our Portable Driver in March 2008 and in fiscal year 2009 began to sell the product commercially in Europe and other countries outside the U.S. that accept the CE mark designation. In January 2008, we submitted for an Investigational Device Exemption, or IDE, to conduct a patient discharge study in the U.S. In May 2008, we received conditional approval for the Portable Driver for this IDE to conduct a U.S. patient discharge study at 20 hospitals for 30 patients. In March, 2009, we received FDA approval of our Premarket Approval Application, or PMA, supplement for the AB Portable Driver. This clearance allows for immediate commercial shipment of the device to U.S. hospitals for use as a primary driver in hospitals and for transporting patients. Discharging inpatients is still limited to the trial in the U.S.

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

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

To support the IAB, we developed our iPulse™ combination console. The iPulse console is also designed to support our AB5000 and BVS 5000 systems, other manufacturers IABs and products we may offer in the future. We believe the ability of the iPulse console to support multiple devices will make it more attractive than consoles designed to operate a single device. The iPulse console supports procedures with associated Medicare reimbursement that extends across four DRGs. The iPulse console has CE mark approval in Europe and was approved by the FDA in late December 2007 for commercial sale in the U.S. The iPulse console is designed to support our IAB as well as other manufacturers IABs, which are used in the cath lab and surgery suite. Because our multi-functional console also supports our AB5000 and BVS 5000 blood pumps, we believe the iPulse will provide our customers additional flexibility in allocating console resources between the surgery suite and the cath lab. In addition, we believe adoption of our iPulse console and our Portable Circulatory Support Driver, as well as the introduction of the Impella 5.0 and Impella LD, will increase utilization of our AB5000 ventricle over time as we focus more attention on the surgery business.

In January 2008, we received Humanitarian Device Exemption, or HDE, supplement approval from the FDA for our engineering and product enhancements to our AbioCor® Implantable Replacement Heart or AbioCor, the first completely self-contained artificial heart. The AbioCor can be made available to a limited patient population, with no more than 4,000 patients receiving the technology under the limits of the HDE approval in the U.S. each year. Because the AbioCor is only available to a limited patient population, we do not expect that the 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. The AbioCor gives chronic patients with biventricular heart failure who are not eligible for a transplant and whose sole alternative is death, the opportunity to extend life. The AbioCor has no wires piercing the skin and allows the patient improved quality of life outside the hospital. The use of AbioCor is limited to normal to larger sized male patients and has a product life expectancy of 18-24 months. We are testing a newer version of the AbioCor, the AbioCor II, that will be smaller and may have a longer product life expectancy than 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 did not record any revenue from sales of the AbioCor in fiscal 2009. We do not expect that sales of the AbioCor will be a material portion of our total revenues for the foreseeable future.

Table of Contents

Our Strategy

Our strategic objective is to establish heart