ABIOMED INC
Form 10-K
June 04, 2012
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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, 2012

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	***(I.R.S. Employer***
Incorporation or Organization)	***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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Rule 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K 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, 2011, 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 $425,320,352. As of May 21, 2012, 39,383,341 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 2012 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.

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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 and other customers 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;

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 and maintaining 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.

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PART I

ITEM 1. ***BUSINESS***

Overview

We are a world leader in mechanical circulatory support and we offer a continuum of care in heart recovery to heart failure patients. We develop, manufacture and market proprietary products that 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 in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophylactically or emergently before, during or after angioplasty or heart surgery procedures. We believe heart recovery is the optimal clinical outcome for patients experiencing heart failure because it restores their quality of life. In addition, we believe that for the care of such patients, heart recovery is the most cost-effective solution for the healthcare system.

Our strategic focus and the driver of the most recent revenue growth in our business is the market penetration of our Impella 2.5 product, which received 510(k) clearance in June 2008 for partial circulatory support for up to six hours. We received 510(k) clearance in April 2009 for our Impella 5.0 and Impella LD devices for circulatory support for up to 6 hours. These devices are larger and provide more blood flow to patients than the Impella 2.5.

In December 2011, we announced a new higher flow Impella device, named Impella cVAD. The Impella cVAD is implanted via the femoral artery and provides peak flow of approximately four liters of blood per minute. We received CE mark approval in April 2012. We will launch the Impella cVAD commercially in Europe in early fiscal 2013. This product is not currently approved by the FDA for sale in the U.S. We expect the Impella cVAD to receive 510(k) clearance and be commercially available in the U.S. in the second half of fiscal 2013.

In addition, we are currently conducting initial patient use trials outside of the U.S. of the Impella RP. The Impella RP is a percutaneous catheter-based axial flow pump that is designed to allow greater than four liters of flow and is intended to provide the flow and pressure needed to compensate for right heart failure. This product is not currently approved by the FDA for sale in the U.S.

In November 2011, we announced Symphony, a synchronized minimally invasive implantable cardiac assist device designed to treat chronic patients with moderate heart failure by improving patient hemodynamics and potentially improving their quality of life. The device is designed with the primary goal of stabilizing the progression of heart failure and recovering or remodeling the heart. We recently conducted the initial first in man implants of Symphony outside the U.S. This product is not currently approved by the FDA for sale in the U.S.

Revenues from our other products, largely focused on the heart surgery suite, have been lower recently as we have strategically shifted our sales and marketing efforts towards our Impella products and the cath lab. We expect revenues during fiscal 2013 from our non-Impella business, including BVS and AB5000, will continue to decrease as we continue to focus on our Impella products.

For the year ended March 31, 2012, we recognized net income of $1.5 million. With the exception of fiscal 2012, we have incurred net losses since our inception. Even though we were profitable in fiscal 2012, we may incur additional losses in the future as we continue to invest in research and development related to our products, conduct clinical studies and registries on our products, expand our commercial infrastructure and expand to new markets such as Japan.

Corporate Background

We are incorporated in Delaware and trade on the NASDAQ Global Select Market under the ticker symbol ABMD.

Our principal executive offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923. Our telephone number is (978) 646-1400. We make available, free of charge on our website located at www.abiomed.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission, or SEC. Our corporate governance guidelines, code of conduct, audit committee, governance and nominating committee and compensation committee charters are also posted on our website. The contents of our website are not incorporated by reference into this report.

Our Products

Impella 2.5

The Impella 2.5 catheter is a percutaneous micro heart pump with an integrated motor and sensors. 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.

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The Impella 2.5 catheter can be quickly inserted via the femoral artery to reach the left ventricle of the heart where it is directly deployed to draw blood out of the ventricle and deliver it to the circulatory system. This function is intended to reduce ventricular work 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. This pivotal study was to determine the safety and effectiveness of the Impella 2.5 as compared to medical management with an intra-aortic balloon, or IAB, during high-risk angioplasty procedures. In December 2010, we announced the termination of the Protect II study based on a futility determination at the planned interim analysis regarding the primary end-point, which we view as likely to have resulted from how rotational atherectomy was used in the study.

In November 2011, we announced additional analysis of the results from the Protect II study, including those patients enrolled following the initiation of the interim analysis, which showed a statistically significant 22% relative reduction in major adverse events compared to the IAB at 90 days per protocol (p=0.023), a 52% relative reduction in repeat revascularization (p=0.024) and a 56% relative reduction in material adverse events post hospital discharge (p=0.002). Furthermore, additional data analysis of the clinical data from the Protect II trial revealed that more aggressive revascularization is beneficial for patients with coronary artery disease and reduced left ventricular function. In addition, a November 2011 update to the American College of Cardiology Foundation /American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions Guidelines for Percutaneous Coronary Intervention, for the first time, included Impella in both the emergent and prophylactic hemodynamic support settings.

We are currently conducting USpella, the first U.S. multicenter observational registry collecting clinical data and outcomes for patients supported with Impella 2.5 and 5.0 during elective, urgent and emergent procedures. Currently, there are 41 hospitals in the U.S. and Canada contributing data to the USpella registry.

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 for up to ten days duration and are approved for use in over 40 countries.

The Impella 5.0 can be quickly implanted via a small incision in the femoral artery in the groin using a guide wire to reach the left ventricle of the heart where it can then be directly deployed to draw blood out of the ventricle, deliver it to the arterial system and perfuse the heart muscle. This function is intended to reduce ventricular work. The Impella LD is similar to the Impella 5.0 but is implanted directly through an incision in the subclavian vein or through an aortic graft. The Impella 5.0 and Impella LD can pump up to five liters of blood per minute, providing full circulatory support.

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. We believe the AB5000 and BVS 5000 systems are the only commercially available cardiac assist devices that are approved by the FDA for all indications where heart recovery is the desired outcome, including 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.

We have developed a Portable Circulatory Support 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. 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 commercial shipment of the device to U.S. hospitals for in hospital and transport use. Out-of-hospital use is being studied in the U.S. in a clinical trial, which, when successfully completed, would 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 patient infection. This technology provides patients with mobility and remote diagnostics. AbioCor devices have a life expectancy of 18 to 24 months and can only be implanted in normal to larger sized male patients.

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We received a humanitarian device exemption, or 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 due to end-stage biventricular heart failure and allows the AbioCor to be made available to a limited patient population. Because the AbioCor is only available to a limited patient population, we do not expect that there will be much demand for the product. We have no current plans to seek a broader regulatory approval of the AbioCor. We have not had any AbioCor sales since fiscal 2009, and we do not expect revenues from sales of the AbioCor for the foreseeable future as our primary strategic focus is centered on heart recovery for acute heart failure patients.

Our Markets

According to the American Heart Association, or AHA, Heart Disease and Stroke Statistics 2011 Update Report, coronary heart disease, or CHD, caused about 1 of every 6 deaths in the U.S. in 2007. 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. CHD mortality in 2007 was approximately 406,000. In 2009, an estimated 785,000 Americans had a first time coronary attack and about 470,000 had a recurrent attack. An estimated additional 195,000 silent first myocardial infarctions occur each year.

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 potentially have 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 their hearts 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 a patient s circulation and is inflated and deflated in the aorta. This is used as an initial line of therapy in the cath lab or the surgery suite for patients with diminished heart function. There are an estimated 124,000 IAB procedures performed annually in the U.S. 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. The use of these drugs, however, 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.

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 surgically placed 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 are removed once the patient s heart has recovered. If possible, recovery of a patient s 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 patients, 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. 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.

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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 for lengths of time ranging from several hours to months 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 partial or full circulatory support. Our primary surgery suite products include our Impella 5.0 pump and Impella LD pump, our BVS 5000 blood pump, and our AB5000 VAD. Our surgery suite products are designed to support acute heart failure patients in need of more blood flow. Our VADs are indicated for longer duration of support of up to 30 days for AMI, cardiogenic shock post-AMI, and myocarditis patients.

Research and Product Development

Since our founding in 1981, we have gained substantial expertise in circulatory support while developing the BVS and AB5000 systems, our Impella platform and our AbioCor. Our current strategy is to develop a complete portfolio of products for partial and full circulatory support to treat acute heart failure patients. 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, 2012, our research and development staff consisted of 84 employees. We expended $27.2 million, $26.7 million and $26.0 million on research and development in fiscal years 2012, 2011 and 2010, 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, 2012, our worldwide sales, clinical support, marketing and field service teams included 147 full-time employees, 130 of whom are in the U.S. and Canada and 17 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, France, and the U.K.

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 8%, 8% and 9% of total product revenue during the fiscal years ended March 31, 2012, 2011 and 2010, respectively.

Manufacturing

We manufacture our products in Danvers, Massachusetts and Aachen, Germany. Our U.S. operations manufacture the BVS AB5000, Portable Driver, and certain Impella subsystems, including our Automated Impella Console, or AIC, our new console for our Impella products. Our Aachen, Germany facility manufactures most of our Impella products. In addition, we rely on third-party suppliers to provide us with 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 current revenue forecast. We expect to increase Impella manufacturing capacity in our Aachen and Danvers facilities in fiscal 2013 to support the growing demand for our Impella products. Our U.S. and German manufacturing facilities are certified by the International Organization for Standardization, or ISO, 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 Impella products, AB5000, BVS 5000, and other products under development 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.

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We own or have rights to numerous U.S. and foreign patents. Our U.S. patents have expiration dates ranging from 2012 to 2029 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, 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. Among our medical device competitors are Getinge (Maquet Cardiovascular), Teleflex Inc., Thoratec Corporation, HeartWare International Inc., Jarvik Heart, CircuLite, Inc., Terumo Heart, Inc. and CardiacAssist Inc.

Our customers are hospitals that 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 and maintain reimbursement, and supply commercial quantities of our product to meet customer demand.

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. The Centers for Medicare & Medicaid Services, or 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 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

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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 our products 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 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, BVS 5000 or Impella 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, reducing benefit coverage, requiring second opinions prior to major surgery, negotiating reductions to charges on patient bills, promoting healthier lifestyle initiatives and exploring 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

In the U.S., the FDA strictly regulates medical devices under the authority of the Federal Food, Drug and Cosmetic Act, or FFDCA, and its regulations. The FDA classifies U.S. medical devices 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 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. Following the completion of a study, the data from the study must be collected, analyzed and presented 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. 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. The FDA s 510(k) clearance pathway usually takes between three to twelve 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

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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 can also require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Additionally, 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 pre-amendment 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 these devices. In addition, the Safe Medical Devices Act of 1990 requires the FDA either to down-classify pre-amendment Class III devices to Class I or Class II or to publish a classification regulation retaining the devices in Class III. Manufacturers of pre-amendment 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. The Impella 2.5, Impella 5.0, and Impella LD received clearance based on a pre-amendment Class III device. If the FDA calls for a PMA for a pre-amendment 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 pre-amendment 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 a 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 Quality System Regulation, or 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. 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.

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. Even if a device receives 510(k) clearance or PMA approval, the FDA may include significant limitations on the indicated uses for which a device 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.

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 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 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. In April 2012, our Impella cVAD received CE Mark regulatory approval that will allow us to market this product in 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

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devices. Among other FDA requirements, we must comply with the FDA s good manufacturing practice regulations. These 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 us to report to the FDA any incident in any of our products that may have caused or contributed to a death or serious injury, or required an unnecessary intervention for a patient, or in which any of our products malfunctioned and, if such malfunction were to recur, 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 U.S. 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. The 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 of products, 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 therefore subject to FDA export requirements.

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 to those provided by the federal Anti-Kickback Statute.

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.

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In recent years, several states 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 that we do business with are found to have not complied 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 knowingly 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.

Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act

In March 2010, Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or together, the Affordable Care Act. Under the Affordable Care Act, manufacturers are scheduled to begin paying an excise tax of 2.3% on certain U.S. sales of medical devices in January 2013. We expect that this excise tax will increase our expenses in the future.

The Affordable Care Act also includes provisions known as the Physician Payments Sunshine Act, or PPSA, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid starting in 2012 to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Similar reporting requirements have also been enacted in several states, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. Particularly, some states such as Massachusetts, Minnesota and Vermont, impose an outright ban on certain gifts to physicians. Failure to report appropriate data may result in civil or criminal fines and/or penalties.

Additionally, the compliance environment is changing, with more states, such as California and Massachusetts, mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states, such as Vermont, Maine, and Minnesota, requiring reporting to state governments of gifts, compensation and other remuneration to physicians. The PPSA also requires manufacturers of drug, device, biologics, and medical supplies covered under Medicare, Medicaid, or State Children s Health Insurance Program, or SCHIP, to report payments made to physicians on an annual basis to the U.S. Department of Health and Human Services, or HHS. HHS in turn will post this information on a public website. These laws all provide for penalties for non-compliance. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and reporting requirements, increases the possibility that a company may run afoul of one or more laws.

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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 our medical devices 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 ISO certifications in order to sell our products. Our BVS 5000, AB5000, Impella 2.5, Impella 5.0, Impella LD, Impella cVAD, IAB, iPulse console and Portable Driver are all CE marked and available for sale in the European Union. We are also subject to regulations and periodic review from various regulatory bodies in Canada, Japan 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.

Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Many of our customer relationships outside of the United States are, either directly or indirectly, with governmental entities and are therefore subject to various anti-bribery laws. Although our corporate policies mandate compliance with these anti-bribery laws, we operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our business, results of operations and financial condition.

Employees

As of March 31, 2012, we had 397 full-time employees, including:

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

147 in sales, clinical support, marketing, field service and related support;

127 in manufacturing; and

39 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.

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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 incurred losses in previous periods and may incur losses in future periods.

For the year ended March 31, 2012, we recognized net income of $1.5 million. For the years ended March 31, 2011 and 2010, we incurred net losses of approximately $11.8 million and $19.0 million, respectively. The profitability we achieved in the year ended March 31, 2012 may not be indicative of our ability to sustain profitability and we may incur losses from operations in future periods. We historically have incurred net losses from our operations. Any losses incurred in the future may result primarily from, among other things, the expansion of our global distribution network, investment in other foreign markets and ongoing product development. Additionally, due to the introduction of the U.S. medical device tax, we will incur a 2.3% excise tax on the sales of certain of our products regardless of whether we are profitable or not. These expenditures may 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 make significant expenditures to market and manufacture in commercial quantities our 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 between three to twelve months, but it can often last longer. The process of obtaining a PMA approval is much more costly and uncertain than the 510(k) clearance process. It generally takes between one to three years, or even longer, from the time the PMA application is submitted to the FDA. In January 2011, the FDA announced plans to make changes to its 510(k) clearance process. Although the effect of these changes is still unknown, these changes may further delay the time it takes us to prepare applications for 501(k) clearance or the length of time required to receive 510(k) clearance. 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 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.

If the FDA or another regulatory agency determines that we have promoted off-label use of our products, we may be subject to various penalties, including civil or criminal penalties.

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. If the FDA or another regulatory agency determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory

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agency could disagree and conclude that we have engaged in off-label promotion. In June 2011 we received a warning letter from the FDA stating that some of our promotional materials marketed the Impella 2.5 for uses that had not been approved by the FDA. We cooperated with the FDA and made changes to our promotional materials in response to the warning letter. However, in April 2012, we received a follow up letter from the FDA stating that some of our promotional materials continued to market the Impella 2.5 in ways that are not compliant with FDA regulations. We are cooperating with the FDA in addressing its concerns. While we hope to be able to resolve this matter without incurring penalties, we may not be able to resolve it, or any similar matters that may come up in the future without facing significant consequences. Such matters could result in reduced demand for our products and would have a material adverse effect on our operations and prospects.

Off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

The use of our products outside the indications cleared for use, or off-label use, may increase the risk of injury to patients. Clinicians may use our products for off-label uses, as the FDA does not restrict or regulate a clinician s choice of treatment within the practice of medicine. Off-label use of our products may increase the risk of product liability claims against us. Product liability claims are expensive to defend and could divert our management s attention and result in substantial damage awards against us.

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 PMA approval and in some cases, 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 the FDA. We have received IDE approval and are conducting clinical trials for our Impella 2.5 and Portable Driver medical devices. In December 2010, we announced the termination of our Protect II study based on a futility determination at the planned interim analysis regarding the primary end-point, which we view as likely to be due to unanticipated confounding variables related to the use of rotational atherectomy in the study.

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