ABIOMED INC
Form S-3
June 10, 2009
Table of Contents

As filed with the Securities and Exchange Commission on June 10, 2009

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

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 Number)**

22 CHERRY HILL DRIVE

DANVERS, MASSACHUSETTS 01923

(978) 777-5410

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Michael R. Minogue

Chief Executive Officer and President

ABIOMED, Inc.

22 Cherry Hill Drive

Danvers, Massachusetts 01923

(978) 777-5410

(Name, address, including zip code, and telephone number, including area code, of agent for service)

With a copy to:

Peter M. Rosenblum, Esq.

Foley Hoag LLP

155 Seaport Boulevard

Boston, Massachusetts 02210

(617) 832-1000

Approximate date of commencement of proposed sale to the public: From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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.

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
common stock, $.01 par value	663,535	$6.67(1)	$4,425,779	$247

(1) Calculated pursuant to Rule 457(c) under the Securities Act of 1933 based on the average of the high and low prices of the common stock as reported by the NASDAQ Global Market on June 4, 2009.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting an offer to buy these securities, in any state where the offer or sale is not permitted.

Subject to completion, dated June 10, 2009

PROSPECTUS

ABIOMED, Inc.

663,535 Shares of

Common Stock

The shares of our common stock covered by this prospectus are being offered for sale by the selling stockholders identified in this prospectus on a delayed or continuous basis.

We will not receive any proceeds from the offering. We will bear the costs related to the registration of the shares covered by this prospectus, other than selling commissions.

The selling stockholders, or other pledgees, donees, transferees or other successors-in-interest of the selling stockholders, may offer and sell the shares from time to time in one or more transactions. Sales may be made on one or more exchanges, including the NASDAQ Global Market, in the over-the-counter market or in privately negotiated transactions at prevailing market prices or at negotiated prices. The selling stockholders may sell the shares through broker-dealers or agents, who may receive compensation in the form of commissions, discounts or concessions.

Our common stock trades on the NASDAQ Global Market under the symbol ABMD. The last reported sale price of our common stock on the NASDAQ Global Market on June 9, 2009 was $7.61 per share.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 3.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Unless the context otherwise requires, all references to ABIOMED, we, our, us or our company in this prospectus refer to ABIOMED, Inc., Delaware corporation and its subsidiaries .

The date of this prospectus is June , 2009.

Table of Contents

TABLE OF CONTENTS

You should rely on the information contained in this prospectus, in any applicable prospectus supplement and in the documents incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where their offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only at the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the securities. Our business, financial condition, results of operations and prospects may have changed since the date indicated on the front cover of this prospectus.

This prospectus contains summaries of certain provisions contained in some of the documents described herein, and reference is made to the actual documents filed with the United States Securities and Exchange Commission, or SEC, for complete information. Copies of some of the documents referred to herein have been filed, or will be filed or incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under Where You Can Find More Information.

Table of Contents

SUMMARY

This summary is a brief discussion of material information contained in, or incorporated by reference into, this prospectus as further described below under Where You Can Find More Information and Information Incorporated by Reference. This summary does not contain all of the information that you should consider before investing in our common stock being offered by this prospectus. We urge you to read carefully this entire prospectus, the documents incorporated by reference into this prospectus and all applicable prospectus supplements relating to our common stock before making an investment decision.

About this Prospectus

This prospectus is part of a shelf registration statement that we filed with the SEC. Under this shelf registration statement, the selling stockholders may from time to time offer up to 663,535 shares of our common stock owned by them, at prices and on terms to be determined at or prior to the time of sale. We will not receive any proceeds from the sale of these shares of common stock by the selling stockholders.

Upon receipt of notice from the selling stockholders, we will file any amendment or prospectus supplement that may be required in connection with any sale by a selling stockholder. You should carefully read this prospectus and each applicable prospectus supplement, if any, together with the additional information described under the headings Where You Can Find More Information and Information Incorporated by Reference beginning on page 5. If there is any inconsistency between the information in this prospectus and a prospectus supplement, you should rely on the information in that prospectus supplement.

About ABIOMED, Inc.

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.

We currently manufacture and sell the AB5000 Circulatory Support System and the BVS 5000 Biventricular Support System for circulatory support of acute heart failure patients in profound shock, including patients suffering from cardiogenic shock after a heart attack or heart surgery, and patients with myocarditis, or a virus in the heart. These devices, which are used in the surgery suite, can assume the pumping function of the heart, allowing the patient s heart to rest, heal and potentially recover. The AB5000 has several clinical advantages over the BVS 5000, including a higher pulsatile blood flow of up to six liters per minute, the ability to provide a longer duration of support and the facilitation of patient mobility within the hospital. These advantages enable us to offer our heart recovery solution to a broader range of patients, including patients who have had an acute myocardial infarction or are suffering from myocarditis.

In addition to our products for the surgery suite, we offer other circulatory assist devices that can be used in cath labs, where interventional cardiologists treat a larger percentage of heart attack patients and also perform angioplasty and high-risk angioplasty

Table of Contents

procedures. Our devices designed primarily for pre-shock patients in the cath lab are our Impella 2.5, Impella 5.0 and Impella LD catheters, which are percutaneous micro heart pumps. The Impella 2.5 provides up to 2.5 liters of blood flow per minute while the Impella 5.0 and Impella LD each provide up to 5.0 liters of blood flow per minute. These catheters can be quickly inserted through the femoral artery over a guide wire to reach the left ventricle of the heart. Our Impella devices have CE mark approval and have been used to treat more than 1500 patients in Europe and other countries outside of the U.S. In June 2008, we received 510(k) clearance for our Impella 2.5 device for partial circulatory support for periods up to six hours. In April 2009 we received FDA 510(k) clearance to market our Impella 5.0 and Impella LD Circulatory Support Systems for circulatory support for periods up to six hours. The clearance allows for immediate commercial shipment of the devices to U.S. hospitals that purchase them.

Our other product for the cath lab is our recently introduced percutaneous intra-aortic balloon, or IAB. An IAB is typically used as an initial line of therapy for patients with diminished heart function. To support our IAB, we developed our iPulse combination console, which is also designed to support our AB5000 and BVS 5000 systems, as well as other products we may offer in the future.

We are a Delaware corporation and commenced operations in 1981. Our principal executive offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, and our telephone number is (978) 777-5410. Our web address is www.abiomed.com. We make available free of charge through the Investors section of our website all reports that we file with the Securities and Exchange Commission. We do not incorporate the information on our website into this prospectus, and you should not consider it part of this prospectus.

Table of Contents

RISK FACTORS

An investment in our common stock involves a high degree of risk. In addition to the risks detailed below, please see the risk factors described under the heading Risk Factors in our most recent annual report on Form 10-K, as updated by any subsequent quarterly reports on Form 10-Q, each of which are incorporated by reference in this prospectus.

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 prospectus, 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 currently deem immaterial may also adversely affect our business or operations. 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 elsewhere in this prospectus.

Risks Related to Our Business

We have not operated at a profit and do not expect to be profitable in our fiscal year 2010.

We have incurred net losses in each of the past three fiscal years and for most of our history. We plan to make significant expenditures in fiscal 2010 and subsequent fiscal years for, among other things, the expansion of our global distribution network and ongoing product development, which we expect will result in losses in our fiscal year 2010 and potentially in future periods. These expenditures include costs associated with hiring additional personnel, performing clinical trials, continuing our research and development relating to our products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing activities. The amount of these expenditures is difficult to forecast accurately and cost overruns may occur. We also expect that we will need to make significant expenditures to begin to market and manufacture in commercial quantities our recently approved circulatory care products, and any other new products for which we may receive regulatory approvals or clearances in the future.

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

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

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

Historically, certain Class III devices that were on the market before May 28, 1976, known as preamendment Class III devices, and devices that are determined to be substantially equivalent to them, could be brought to market through the 510(k) process. In April 2009, the FDA published new regulations requiring manufacturers of certain Class III preamendment devices to submit to the

Table of Contents

FDA a summary of, and citation to, any known, or otherwise available, safety or efficacy information by August 7, 2009. Based on the safety information a manufacturer submits to the FDA concerning its medical device product, the agency can make a determination concerning whether the product must seek PMA approval, or whether the class III device can be reclassified as a class I or class II device, and therefore remain available for sale under the 510(k) clearance. We are required to submit a response to an FDA request for evaluating Class III device classes currently cleared for marketing under 510(k) regulations. We plan to comply with the FDA request by submitting the appropriate responses for our Class III 510(k) cleared devices, which include the Impella 2.5 and Impella 5.0 catheters, and the iPulse Balloon Catheter and Console. If the FDA does not reclassify these devices to a Class I or Class II device, we may be required to pursue PMA approval of these devices. Our understanding of the timeframe for the FDA s decision to reclassify all of the product classes is that it will be a multiple year process, including a 30 month window after the FDA final decision on classification, during which we can continue to market each of the devices, so long as we are in the process of obtaining a PMA. There is no guarantee as to whether we will receive PMA approval for these devices and how long a PMA approval will take to obtain. If we are unable to market and sell those products in the U.S. it would have a material adverse effect on our revenues, operations and prospects.

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

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

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

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

- the FDA may not approve a clinical trial protocol or a clinical trial, or may place a clinical trial on hold;
- subjects may not enroll in clinical trials at the rate we expect and/or subjects may not be followed-up on at the rate we expect;
- subjects may experience adverse side effects or events related or unrelated to our products;
- third-party clinical investigators may not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices, or other third-party organizations may not perform data collection and analysis in a timely or accurate manner;
- the interim results of any of our clinical trials may be inconclusive or negative;
- regulatory inspections of our clinical trials or manufacturing facilities may require us to undertake corrective action or suspend or terminate our clinical trials if investigators find us not to be in compliance with regulatory requirements;

Table of Contents

510(k) clearance of our devices may have the effect of slowing down the progress of related clinical trials since physicians can use our cleared devices commercially outside of the trials;

our manufacturing process may not produce finished products that conform to design and performance specifications; or

governmental regulations or administrative actions may change and impose new requirements, particularly on reimbursement.

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

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

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

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

developing our global sales and marketing infrastructure and capabilities;

expanding manufacturing capacity, maintaining quality and increasing production;

expansion of foreign regulatory compliance capabilities;

implementing appropriate operational and financial systems and controls;

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

training, managing and supervising our personnel worldwide.

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

Table of Contents

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

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

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

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

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

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

Clinicians must be trained to use our products proficiently. It is critical to the success of our sales efforts that we ensure that there are a sufficient number of clinicians familiar with, trained on and proficient in the use of our products. Convincing clinicians to dedicate the time and energy necessary to obtain adequate training in the use of our products is challenging and we may not be successful in these efforts. If clinicians are not properly trained, they may misuse or ineffectively use our products. Any improper use of our products may result in unsatisfactory outcomes, patient injury, negative publicity or lawsuits against us, any of which could harm our reputation and product sales. Furthermore, our inability to educate and train clinicians to use our products may lead to inadequate demand for our products.

Our products are subject to extensive regulatory requirements, including continuing regulatory review, which could affect the manufacturing and marketing of our products.

The FDA and other regulatory agencies continue to review products even after they have received initial approval. If and when

Table of Contents

the FDA or another regulatory agency clears or approves our products under development, the manufacture and marketing of these products will be subject to continuing regulation, including compliance with the FDA s adverse event reporting requirements, prohibitions on promoting a product for unapproved uses, and Quality System Regulation, or QSR, requirements, which obligate manufacturers, including third-party and contract manufacturers, to adhere to stringent design, testing, control, documentation and other quality assurance procedures during the design and manufacture of a device.

Any modification to an FDA-cleared device 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 PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA may review any such decision. Modifications of this type are common with new products. We anticipate that the first generation of each of our products will undergo a number of changes, refinements and improvements over time. For example, the current configuration of the AbioCor s thoracic unit, or replacement heart, is sized for patients with relatively large chest cavities and we anticipate that we will need to obtain regulatory approval of thoracic units of other sizes, such as the AbioCor II. If the FDA requires us to seek clearance or approval for modification of a previously cleared product for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval and we may be subject to significant regulatory fines or penalties, which could have a material adverse effect on our financial results and competitive position. We also cannot assure you that we will be successful in obtaining clearances or approvals for our modifications, if required. We and our third-party suppliers of product components are also subject to inspection and market surveillance by the FDA and other regulatory agencies for QSR and other requirements, the interpretation of which can change. Compliance with QSR and similar legal requirements can be difficult and expensive. Enforcement actions resulting from failure to comply with government requirements could result in fines, suspensions of approvals or clearances, recalls or seizure of products, operating restrictions or shutdown, and criminal prosecutions that could adversely affect the manufacture and marketing of our products. The FDA or another regulatory agency could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements, the occurrence of unanticipated problems with products following approval, or other reasons, which could adversely affect our operating results.

Even after receiving regulatory clearance or approval, our products may be subject to product recalls which may harm our reputation and divert our managerial and financial resources.

The FDA and similar governmental authorities in other countries have the authority to order mandatory recall of our products or order their removal from the market if the governmental entity finds that our products might cause adverse health consequences or death. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including labeling defects. We have in the past initiated voluntary recalls of some of our products and we could do so in the future. Any recall of our products may harm our reputation with customers and divert managerial and financial resources.

Our AB5000 and BVS 5000 are vulnerable to competitive pressures.

Until recently, we have derived most of our product revenues from sales of the AB5000 and BVS 5000. Revenues from these products, especially the BVS 5000, have been declining in recent quarters. If another company were to introduce new treatments, products or technologies that compete with our products, add new features to its existing products or reduce its prices to make its products more financially attractive to customers, revenue from our AB5000 and BVS 5000 could decline further. For example, in the event of the expansion of technologies that allow heart surgical procedures to be performed without stopping the heart, a reduction in the market for these products could result. In addition, variations in the quantity and timing of sales of our consoles have a disproportionate effect on our revenues, because the price of a console is substantially greater than the price of our disposable blood pumps. The higher price of our consoles may limit sales of our consoles in the future by third-party payers. If we cannot maintain and increase our disposable revenues from our AB5000 and BVS 5000, our overall business and financial condition could be adversely affected.

Table of Contents

If we are unable to develop additional, high-quality manufacturing capacity, our growth may be limited and our business could be seriously harmed.

To be successful, we believe we will need to increase our manufacturing capacity. In July 2008, we executed a lease for a facility in Athlone, Ireland, in which we are establishing a high-throughput manufacturing facility for the production of our Impella products. We do not have experience in manufacturing our Impella products in the commercial quantities that might be required to meet potential demand, nor do we have experience manufacturing our other products in large quantities. We may encounter difficulties in scaling up manufacturing of our products, including problems related to product yields, quality control and assurance, component and service availability, adequacy of control policies and procedures and lack of skilled personnel. If we cannot hire, train and retain enough experienced and capable scientific and technical workers, we may not be able to manufacture sufficient quantities of our current or future products at an acceptable cost and on time, which could limit market acceptance of our products or otherwise damage our business. We expect our Ireland facility to be operational by the end of fiscal year 2010. If we are unable to get our Ireland facility operational by the time we expect, it could inhibit our revenue growth.

Each of our products is currently manufactured in a single location, and any significant disruption in production could impair our ability to deliver our products.

We currently manufacture our Impella heart pumps at our facility in Aachen, Germany and we manufacture our other products at our facility in Danvers, Massachusetts. In addition, we expect our Ireland facility, in which we are establishing a high-throughput manufacturing facility for the production of our Impella products, to be operational by the end of fiscal year 2010. Events such as fire, flood, power loss or other disasters could prevent us from manufacturing our products in compliance with applicable FDA and other regulatory requirements, which could result in significant delays before we restore production or commence production at another site. These delays may result in lost sales. Our insurance may not be adequate to cover our losses resulting from disasters or other business interruptions. Any significant disruption in the manufacturing of our products could seriously harm our business and results of operations. In addition, if we are unable to get our Ireland facility operational on a timely basis as a result of disasters or other business interruptions, it could inhibit our revenue growth.

Any failure to achieve and maintain the high manufacturing standards that our products require may seriously harm our business.

Our products require precise, high-quality manufacturing. Achieving precision and quality control requires skill and diligence by our personnel. Our failure to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, design defects or component failures, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business. We have from time to time voluntarily recalled certain products. Despite our very high manufacturing standards, we cannot completely eliminate the risk of errors, defects or failures. If we are unable to manufacture the AB5000, BVS 5000, Impella products, Portable Driver and iPulse console in accordance with necessary quality standards, or if we are unable to procure additional high-quality manufacturing facilities, our business and results of operations may be negatively affected.

Our AbioCor products involve even greater manufacturing complexities than our other current commercial products, such as our BVS 5000, AB5000, and Impella products. Our AbioCor products must be significantly more durable and meet different standards, which may be more difficult to achieve, than those that apply to our current products. If we are unable to manufacture our AbioCor products or other future products on a timely basis at acceptable quality and cost, or if we experience unanticipated technological problems or delays in production, our business will suffer.

We depend on third-party reimbursement to our customers for market acceptance of our products. If third-party payers fail to provide appropriate levels of reimbursement for purchase and use of our products, our sales and profitability would be adversely affected.

Sales of medical devices largely depend on the reimbursement of patients medical expenses by government health care programs and private health insurers. Without the financial support of government reimbursement or third-party insurers payments for patient care, the market for our products will be limited. Medical products and devices incorporating new technologies are closely examined by governments and private insurers to determine whether the products and devices will be covered by reimbursement, and if so, the level of reimbursement which may apply.

Table of Contents

We cannot be sure that additional third-party payers will cover and/or adequately reimburse sales of our products or other products under development, to enable us to sell them at profitable prices.

In addition, third-party payers are increasingly requiring evidence that medical devices are cost-effective. If we are unable to meet the standards of a third-party payer, that payer may not reimburse the use of our products, which could reduce sales of our products to healthcare providers who depend upon reimbursement for payment. We also cannot be sure that third-party payers will continue the current level of reimbursement to physicians and medical centers for use of our AB5000, BVS 5000, Impella products, Portable Driver and iPulse console. Any reduction in the amount of this reimbursement could harm our business.

Changes in health care reimbursement systems in the U.S. and abroad could reduce our revenues and profitability.

The Federal government is considering ways to change, and has changed, the manner in which healthcare services are provided and paid for in the U.S. Occasionally, the U.S. Congress passes laws that impact reimbursement for health care services, including reimbursement to hospitals and physicians. States may also enact legislation that impacts Medicaid payments to hospitals and physicians. In addition, the Centers for Medicare & Medicaid Services, the Federal agency responsible for administering the Medicare program, establishes payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities.

In particular, the new administration has set in motion a number of proposed initiatives to reform healthcare and contain costs, and we cannot predict how pending and future legislative and regulatory proposals would influence the manner in which medical devices, including ours, are purchased or covered and reimbursed. For example, the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, includes $1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This funding will be used, among other things, to conduct, support or synthesize research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of medical products. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact coverage, reimbursement or other third-party payor policies. To the extent these or other reform measures impact the coverage and reimbursement of our current or future products, our revenues and results of operations could be adversely impacted.

Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we succeed in bringing our new products to market, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at profitable prices.

We must comply with healthcare fraud and abuse laws, and we could face substantial penalties for non-compliance and be excluded from government healthcare programs, which would adversely affect our business, financial condition and results of operations.

Our business is regulated by laws pertaining to healthcare fraud and abuse, including:

- the Federal Anti-Kickback Statute, which 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 healthcare program such as Medicare and Medicaid; and

- state law equivalents to the Anti-Kickback Statute, which may not be limited to government-reimbursed items.

Table of Contents

We have various arrangements with customers that may implicate these laws. For example, some physicians who use our products also provide medical advisory and other consulting and personal services. Some of these physician arrangements may not meet Anti-Kickback Statute safe harbor requirements, which may result in increased scrutiny by government authorities having responsibility for enforcing these laws. Additionally, we do not maintain a formal compliance plan concerning interactions with healthcare professionals nor have we formally adopted the recommendations issued by the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG. The OIG may interpret the absence of such formal plan negatively in the case of an enforcement action, which could result in a material adverse effect on our financial condition and results of operations. Further, the absence of a formal compliance plan causes us to be out of compliance with certain state laws such as in Nevada and California that require drug and device companies to have formal compliance plans. We are in the process of adopting a formal compliance plan under recently enacted laws in Massachusetts, the adoption of which should put us in compliance with the Nevada and California laws as well.

If our operations are found to be in violation of any of these or similar laws or regulations, we or our officers may face significant civil and criminal penalties, damages, fines, imprisonment and exclusion from the Medicare and Medicaid programs. Any violations may lead to curtailment or restructuring of our operations, which could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention from the operation of our business and damage our reputation. If enforcement action were to occur, our reputation and our business and financial condition may be harmed, even if we were to prevail or settle the action. Similarly, if the physicians or other providers or entities with whom we do business are found not to comply with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

If we cannot attract and retain key management, scientific, sales and other personnel we need, we will not be successful.

We depend heavily on the contributions of the principal members of our business, financial, technical, sales and support, regulatory and clinical, operating and administrative management and staff, many of whom would be difficult to replace. Our key personnel include our senior officers, many of whom have very specialized scientific, medical or operational knowledge. The loss of the service of any of the key members of our senior management team may significantly delay or prevent our achievement of our business objectives. Our ability to attract and retain qualified personnel, consultants and advisors is critical to our success. For example, many of the members of our clinical staff are registered nurses with experience in the surgery suite or cath lab, only a limited number of whom seek employment with a company like ours. Competition for skilled and experienced management, scientific, clinical and sales personnel in the medical devices industry is intense. We face intense competition for skilled and experienced management, scientific, clinical and sales personnel from numerous medical device and life sciences companies, universities, governmental entities and other research institutions. If we lose the services of any of the principal members of our management and staff, or if we are unable to attract and retain qualified personnel in the future, especially scientific and sales personnel, our business could be adversely affected.

If our suppliers cannot provide the components we require, our ability to manufacture our products could be harmed.

We rely on third-party suppliers to provide us with some components used in our existing products and products under development. For example, we outsource the manufacturing of all of our consoles other than final assembly and testing. Relying on third-party suppliers makes us vulnerable to component part failures and to interruptions in supply, either of which could impair our ability to conduct clinical tests or to ship our products to our customers on a timely basis. Using third-party vendors makes it difficult and sometimes impossible for us to test fully certain components, such as components on circuit boards, maintain quality control, manage inventory and production schedules and control production costs. Manufacturers of our product components may be required to comply with the FDA or other regulatory manufacturing regulations and to satisfy regulatory inspections in connection with the manufacture of the components. Any failure by a supplier to comply with applicable requirements could lead to a disruption in supply. Vendor lead times to supply us with ordered components vary significantly and often can exceed six months or more. Both now and as we expand our manufacturing capacity, we cannot be sure that our suppliers will furnish us required components when we need them. These factors could make it more difficult for us to manufacture our products effectively and efficiently and could adversely impact our results of operations.

Table of Contents

Some of our suppliers may be the only source for a particular component, which makes us vulnerable to significant cost increases. Sole source vendors may decide to limit or eliminate sales of certain components to the medical industry due to product liability or other concerns and we might not be able to find a suitable replacement for those products. Our inventory may run out before we find alternative suppliers and we might be forced to purchase substantial inventory, if available, to last until we qualify an alternate supplier. If we cannot obtain a necessary component, we may need to find, test and obtain regulatory approval or clearance for a replacement component, produce the component ourselves or redesign the related product, which would cause significant delay and could increase our manufacturing costs. Any of these events could adversely impact our results of operations.

We may not be successful in expanding our direct sales activities into international markets.

We are seeking to expand our international sales of the AB5000, Portable Driver, iPulse console and Impella circulatory assist systems, by recruiting direct sales and support teams outside the U.S. Our international operations in Germany, France, Ireland, and the United Kingdom will be subject to a number of risks, which may vary from the risks we experience in the U.S., including:

- the need to obtain regulatory approvals in foreign countries before our products may be sold or used;
- the need to procure reimbursement for our products in each foreign market;
- the generally lower level of reimbursement available in foreign markets relative to the U.S.;
- longer sales cycles;
- limited protection of intellectual property rights;
- difficulty in collecting accounts receivable;
- fluctuations in the values of foreign currencies; and
- political and economic instability.

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

We intend to expand our reliance on distributors in some international markets and poor performance by a distributor could reduce our sales and harm our business.

We rely on distributors to market and sell our products in parts of Europe, Asia, South America and Australia. Many of these distributors have the exclusive right to distribute our products in their territory. We may hire distributors to market our products in additional international markets. Our success in these markets will depend almost entirely upon the efforts of our distributors, over whom we have little or no control. If a distributor does not market and sell our products aggressively, we could lose sales and impair our ability to compete in that market. We are also subject to credit risk associated with shipments to our distributors and this could negatively impact our financial condition and liquidity in the future.

Our operating results may fluctuate unpredictably.

Historically, our annual and quarterly operating results have fluctuated widely and we expect these fluctuations to continue. Among the factors that may cause our operating results to fluctuate are:

- the timing of customer orders and deliveries, particularly for our consoles, which are substantially more expensive than our disposable products;

Table of Contents

competitive changes, such as price changes or new product introductions that we or our competitors may make;

the timing of regulatory actions, such as product approvals or recalls;

costs we incur developing and testing our Impella heart pumps, IAB, Portable Driver, iPulse console, AbioCor, AbioCor II and any other product products;

costs we incur in anticipation of future sales, such as inventory purchases, expansion of manufacturing facilities, or establishment of international sales offices;

the effect of fluctuations in currency exchange rates on our results of operations;

economic conditions in the healthcare industry; and

efforts by governments, insurance companies and others to contain health care costs, including changes to reimbursement policies.

We believe that period-to-period comparisons of our historical results are not necessarily meaningful, and investors should not rely on them as an indication of our future performance. To the extent we experience the factors described above, our future operating results may not meet the expectations of securities analysts or investors from time to time, which may cause the market price of our common stock to decline.

We may be unable to obtain any benefit from our net operating loss carryforwards and research and development credit carryforwards.

At March 31, 2009, we had federal and state net operating loss (NOL) carryforwards of approximately $145.1 million and $97.1 million, respectively, which begin to expire in fiscal 2010. Additionally, at March 31, 2009, we had federal and state research and development credit carryforwards of approximately $8.1 million and $4.2 million, respectively, which also begin to expire in fiscal 2010.

Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset our net deferred tax assets and liabilities. Additionally, the future utilization of our NOL and research and development credit carry forwards to offset future taxable income may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code due to ownership changes that have occurred previously or that could occur in the future. Ownership changes, as defined in Section 382 of the Internal Revenue Code, can limit the amount of NOL s and research and development credit carry forwards that a company can use each year to offset future taxable income and taxes payable. We believe that all of our federal and state NOL s are available for carryforward to future tax periods, subject to the statutory maximum carryforward limitation of any annual NOL. Any future potential limitation to all or a portion of the NOL or research and development credit carry forwards, before they can be utilized, would reduce our gross deferred tax assets. We will monitor subsequent ownership changes, which could impose limitations in the future.

Our future success depends in part on the development of new circulatory assist products, and our development efforts may not be successful.

We are devoting our major research and development and regulatory efforts, and significant financial resources, to the development of our Impella heart pumps, iPulse console, Portable Driver, AbioCor and product extensions of existing commercial products and new products. The development of new products and product extensions presents enormous challenges in a variety of areas, many or all of which we may have difficulty in overcoming, including blood compatible surfaces, blood compatible flow, manufacturing techniques, pumping mechanisms, physiological control, energy transfer, anatomical fit and surgical techniques. We may be unable to overcome all of these challenges, which could adversely affect our results of operations and prospects.

Table of Contents

We may not have sufficient funds to develop and commercialize our new products.

The development, manufacture and sale of any medical device in the U.S. and abroad is very expensive. We cannot be sure that we will have the necessary funds to develop and commercialize our new products, or that additional funds will be available on commercially acceptable terms, if at all. If we are unable to obtain the necessary funding to develop and commercialize our products, our business may be adversely affected. We believe we have sufficient liquidity to finance our operations for the next fiscal year. We also may evaluate from time to time other financing alternatives as necessary to fund operations.

Our marketable securities are subject to market risks and decreased liquidity.

Marketable securities at March 31, 2009 consist of $7.0 million in the Columbia Fund and $52.1 million in four funds that invest in U.S. backed government securities. In December 2007, the Columbia Fund ceased accepting redemption requests from investors and changed its method of valuing the securities in the Columbia Fund to market value rather than amortized cost. We deemed that the unrealized loss on the Columbia Fund was not temporary as the market value of the Columbia Fund was approximately 83% of its carrying value as of March 31, 2009, and we do not expect to recover the loss of value in liquidation. This determination of the fair value of our holdings in the Columbia Fund requires significant judgment or estimation. As discussed in Note 4 to our financial statements, certain of these securities were valued primarily using broker pricing models that incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity. The Columbia Fund has been partially liquidated during fiscal 2008 and 2009 and is expected to continue making redemptions through the next twelve months. Since December 6, 2007 and through May 27, 2009, we have received disbursements of approximately $40 million from the Columbia Fund with the most recent disbursement occurring on May 27, 2009 at approximately 86% of its original value. We have recorded $3.7 million of the Columbia Fund as long-term marketable securities at March 31, 2009 because Bank of America, the sponsor of the Columbia Fund, has indicated that it cannot predict with certainty whether or not the Columbia Fund will redeem this amount within the next year. We expect conditions in the credit markets to remain uncertain for the foreseeable future. While it is our intent to liquidate securities in the Columbia Fund in future periods to reduce our exposure to future deterioration of these securities, we believe that operating results or cash flows could be affected significantly by fair value adjustments to the Columbia Fund. There can be no assurance that we will not have to take additional losses on the Columbia Fund.

We own patents, trademarks, trade secrets, copyrights and other intellectual property and know-how that we believe gives us a competitive advantage. If we cannot protect our intellectual property and develop or otherwise acquire additional intellectual property, competition could force us to lower our prices, which could hurt our profitability.

Our intellectual property rights are and will continue to be a critical component of our success. A substantial portion of our intellectual property rights relating to the AB5000, BVS 5000, Impella products, AbioCor, AbioCor II and other products under development is in the form of trade secrets, rather than patents. Unlike patents, trade secrets are only recognized under applicable law if they are kept secret by restricting their disclosure to third parties. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. However, certain consultants and third parties with whom we have business relationships, and to whom in some cases we have disclosed trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities and research organizations that are developing competing products. In addition, some of our former employees who were exposed to certain of our trade secrets and other proprietary knowledge in the course of their employment may seek employment with, and become employed by, our competitors. We cannot assure you that consultants, employees, and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge, that we will have adequate remedies for any such breach, or that our trade secrets will not become known to or be independently developed by our competitors. The loss of trade secret protection for technologies or know-how relating to our product portfolio and products under development could adversely affect our business and our prospects.

Table of Contents

Our business position also depends in part on our ability to maintain and defend our existing patents and obtain, maintain, and defend additional patents and other intellectual property rights. We intend to seek additional patents, but our pending and future patent applications may not be approved, may not give us a competitive advantage, could be challenged by others, or if issued, could be deemed invalid or unenforceable. Patent prosecution, related proceedings, and litigation in the U.S. and in other countries may be expensive, time consuming and ultimately unsuccessful. In addition, patents issued by foreign countries may afford less protection than is available under U.S. patent law and may not adequately protect our proprietary information. Our competitors may independently develop proprietary technologies and processes that are the same as or substantially equivalent to ours or design around our patents. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect our business and our prospects.

Companies in the medical device industry typically obtain patents and frequently engage in substantial intellectual property litigation. Our products and technologies could infringe on the rights of others. If a third party successfully asserts a claim for infringement against us, we may be liable for substantial damages, be unable to sell products using that technology, or have to seek a license or redesign the related product. These alternatives may be uneconomical or impossible.

Intellectual property litigation could be costly, result in product development delays and divert the efforts and attention of management from our business.

Product liability claims could damage our reputation and adversely affect our financial results.

The clinical use of medical products, even after regulatory approval, poses an inherent risk of product liability claims. We maintain limited product liability insurance coverage, subject to deductibles and exclusions. We cannot be sure that product liability insurance will be available in the future or will be available on acceptable terms or at reasonable costs, or that such insurance will provide us with adequate coverage against potential liabilities. Claims against us, regardless of their merit or potential outcome, may also hurt our ability to obtain physician endorsement of our products or expand our business. As we continue to introduce more products, we face an increased risk that a product liability claim will be brought against us.

Many of our products are designed for patients who suffer from late-stage or end-stage heart failure, and many of these patients do not survive, even when supported by our products. There are many factors beyond our control that could result in patient death, including the condition of the patient prior to use of the product, the skill and reliability of physicians and hospital personnel using and monitoring the product, and product maintenance by customers. However, the failure of the products we distribute for clinical testing or sale could give rise to product liability claims and negative publicity.

The risk of product liability claims will increase as we sell more products that are intended to support a patient until the end of life. The finite life of our products, as well as complications associated with their use, could give rise to product liability claims whether or not the products have extended or improved the quality of a patient s life. For example, the AbioCor will have a finite life and could cause unintended complications to other organs and may not be able to support all patients successfully. Its malfunction could give rise to product liability claims whether or not it has extended or improved the quality of the patient s life. If we have to pay product liability claims in excess of our insurance coverage, our financial condition will be adversely affected.

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. Product liability claims are expensive to defend and could divert our management s attention and result in substantial damage awards against us.

Table of Contents

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 agency could disagree and conclude that we have engaged in off-label promotion.

Quality problems can result in substantial costs and write-downs.

Government regulations require us to track materials used in the manufacture of our products, so that any problem identified in one product can be traced to other products that may have the same problem. An identified quality problem may require reworking or scrapping related inventory and recalling previous shipments. Because a malfunction in our products can be life-threatening, we may be required to recall and replace, free of charge, products already in the marketplace. Any quality problem could cause us to incur significant expenses, lead to significant write-offs, injure our reputation and harm our business and financial results.

If we fail to compete successfully against our existing or potential competitors, our product sales or operating results may be harmed.

Competition from other companies offering circulatory care products 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.

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

Our AB5000 and BVS 5000 systems compete with a temporary cardiac assist device from Thoratec Corporation, which is approved as a recovery device for post-cardiotomy support. In addition, the AB5000 and BVS 5000, in addition to our Impella products, compete with other blood pumps that are used in medical centers for a variety of applications, such as intra-aortic balloon pumps, including those offered by Datascope and Arrow International, and centrifugal pumps. Levitronix is conducting clinical trials in the U.S. for a device that may compete with our current heart assist products in some applications. Levitronix has licensed this product to Thoratec for distribution in the U.S. The FDA recently approved a product designed by CardiacAssist, Inc. that may compete with our Impella products. Approval by the FDA of products that compete directly with our products would increase competitive pricing and other pressures.

Advances in medical technology, biotechnology and pharmaceuticals may reduce the size of the potential markets for our products or render those products obsolete. We are aware of other heart replacement device research efforts in the U.S., Canada, Europe and Japan. In October 2004, the FDA approved Syncardia Systems CardioWest Total Artificial Heart for use as a bridge to transplantation in cardiac transplant-eligible candidates at risk of imminent death from non-reversible biventri