ABIOMED INC
Form 424B5
March 22, 2007
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Filed pursuant to Rule 424(b)(5)

Registration No. 333-137746

PROSPECTUS SUPPLEMENT

(To Prospectus Dated October 17, 2006)

5,000,000 Shares

COMMON STOCK

ABIOMED, Inc. is offering 5,000,000 shares of its common stock.

Our common stock is quoted on the Nasdaq Global Market under the symbol ABMD. The last reported sale price of our common stock on the Nasdaq Global Market on March 21, 2007 was $14.05 per share.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page S-8.

PRICE $13.75 A SHARE

	Price to Public	*Underwriting Discounts and Commissions*	*Proceeds to Abiomed*
Per Share	*$13.75*	*$0.85938*	*$12.89062*
Total	*$68,750,000*	*$4,296,900*	*$64,453,100*

Essex Woodlands Health Ventures has placed an order for 2,600,000 of the shares we are offering at the public offering price. Please see Underwriting.

We have granted the underwriters the right to purchase up to an additional 750,000 shares of common stock to cover over-allotments.

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.

The underwriters expect to deliver the shares to purchasers on March 27, 2007.

MORGAN STANLEY *UBS Investment Bank*

March 21, 2007

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a shelf registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC. This prospectus supplement describes the specific details regarding this offering, including the price, the amount of common stock being offered and the risks of investing in our common stock. The accompanying prospectus provides more general information. To the extent information in this prospectus supplement is inconsistent with the accompanying prospectus or any of the documents incorporated by reference into the accompanying prospectus, you should rely on this prospectus supplement. You should read both this prospectus supplement and the accompanying prospectus together with the additional information about us described in the accompanying prospectus in the section entitled Where You Can Find More Information.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights only some of the information included or incorporated by reference in this prospectus supplement and the accompanying prospectus. You should read the entire prospectus carefully, including the section entitled Risk Factors beginning on page S-8 regarding our company and the common stock being sold in this offering. Unless otherwise indicated, the information in this prospectus supplement assumes that the underwriters will not exercise their over-allotment option.

Overview

We are a leading provider of medical devices that provide circulatory support to acute heart failure patients across the continuum of care in heart recovery. 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 currently the only company with commercially available cardiac assist devices approved for heart recovery by the Food and Drug Administration, or FDA, and our products have been used to treat thousands of patients to date. Our products can be used in a broad range of clinical settings, including by heart surgeons for patients in profound shock and by interventional cardiologists for patients who are pre-shock in the cardiac catheterization lab, or cath lab. We are focused on increasing awareness of heart recovery alternatives and establishing recovery as the standard of care for patients with failing but potentially recoverable hearts. We expect this standard of care to significantly increase the number of patients able to return home from the hospital with their own hearts. Since 2004, our new executive team has focused our efforts on expanding our product portfolio, and we currently have eight disposable products that have either been approved or cleared by the FDA or have received CE mark approval, as well as several additional products in development. In addition, we have significantly expanded our global distribution efforts over the past two years and increased revenue by approximately 70% to $43.7 million in the year ended March 31, 2006 from $25.7 million in the year ended March 31, 2004.

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. We began offering the BVS 5000 for post-cardiotomy cardiogenic shock in 1992, and we introduced the AB5000, our next-generation heart recovery system, in 2004. Unlike destination therapy and bridge-to-transplant devices, which are designed for heart patients with irreversible heart damage, our AB5000 and BVS 5000 systems are designed for heart recovery, requiring only a minimal incision in the left ventricle of the heart. We believe these two systems are currently the only commercially available cardiac assist devices approved by the FDA for heart recovery. 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, we believe these advantages, combined with the AB5000 s ease of implant and historically low incidence of adverse events, facilitate heart recovery, potentially avoiding the need for heart transplantation and improving patient outcomes.

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 procedures. Our devices designed primarily for pre-shock patients in the cath lab are our Impella 2.5 and Impella 5.0 catheters, which are percutaneous micro heart pumps, providing up to 2.5 and 5.0 liters of blood flow per minute, respectively. 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

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approval and have been used to treat more than 850 patients in Europe. These devices are not approved for commercial sale in the United States, but we plan to apply for premarket approval, or PMA, of the Impella 2.5 and 5.0 catheters. Since mid-2006, we have been conducting pilot clinical trials in the U.S. for both the Impella 2.5 and 5.0 to support these planned applications for premarket approval from the FDA. The Impella 2.5 trial is designed to study the use of the Impella 2.5 to support high-risk angioplasty. The Impella 5.0 trial will include post-cardiotomy patients who have been weaned from the heart-lung machine. In addition, we are also seeking 510(k) clearance from the FDA of our Impella 2.5 catheter for short duration use. We cannot assure you that we will receive PMA approval or 510(k) clearance for any intended use of the Impella 2.5 or PMA approval for any intended use of the Impella 5.0.

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 believe the iPulse s ability to support multiple devices, including IABs made by other manufacturers, will make it more attractive than consoles designed to operate a single device. In addition, we believe the iPulse will provide our customers additional flexibility in allocating resources between the surgery suite and the cath lab. The iPulse console has CE mark approval in Europe, and we have filed a PMA supplement to obtain FDA approval in the U.S.

Since March 31, 2004, we have increased the number of our direct sales and clinical personnel from 17 to 69 employees covering the U.S., France and Germany. In addition, we use distributors to sell our products in other international markets. We plan to continue to expand our global sales force and increase the number of our distributors over the next few years. We have historically focused our efforts on selling our AB5000 and BVS 5000 systems to cardiac surgeons in open heart centers and transplant centers, of which there are approximately 1,000 in the U.S. However, our recently FDA-cleared IAB product and, if approved by the FDA, our Impella products, will expand our potential target customer base to include interventional cardiologists in the approximately 1,750 U.S. hospitals with cath labs. We estimate that there are approximately 14,000 interventional cardiologists in the U.S.

Industry Background

According to the American Heart Association, or AHA, coronary heart disease is the leading cause of death in the U.S. The AHA estimates that in the United States in 2004 there were approximately two million hospital visits with coronary heart disease as the first-listed diagnosis and approximately 1.1 million hospital visits with congestive heart failure as the first-listed diagnosis. The number of hospital visits with acute myocardial infarction, or heart attack, as the first or second-listed diagnosis was approximately 896,000. Many heart failure patients are sent to the cath lab for treatments such as the implantation of defibrillators or pacemakers, angioplasty procedures and stenting procedures. In more severe cases, patients are sent directly to the surgery suite for coronary bypass or valve replacement surgery. The most severe heart failure patients are patients in profound shock, including those suffering from myocarditis or suffering from cardiogenic shock, or the impaired ability of the heart to pump blood, after a heart attack or heart surgery. For example, according to 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 strain on the heart. However, many less severe patients in the cath lab could also benefit from circulatory support devices, 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 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 by a catheter that is used as an initial line of therapy in the cath lab or the surgery suite for patients with diminished heart function. However, IABs typically provide only limited support

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and depend on the patient s own heart to generate the majority of the patient s blood flow. In addition, IABs are often used in conjunction with inotropes or other drugs that improve heart muscle ejection but significantly increase the risk of mortality. Moreover, IABs can also require significant time to put in place.

Ventricular assist devices are mechanical devices that help the failing heart pump blood. Historically, VADs have been highly invasive and require implantation in the surgery suite. The use of VADs generally falls into three sub-categories: destination therapy, bridge-to-transplant and recovery. Destination therapy generally involves the implantation of a mechanical support device as the last clinical alternative for a chronic patient with end-stage heart failure who is not eligible for transplantation. Destination therapy only prolongs the end-stage disease, as the patient s condition is terminal and the patient s heart is not expected to recover. In addition, a number of companies have been developing artificial replacement hearts, which are a form of destination therapy.

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

Recovery VADs are designed to enable the patient s heart to recover so that the patient can return home with his or her own heart. Because recovery is the goal, these devices are designed to minimize damage to heart tissue and be removed once the heart has recovered. If possible, recovery of one s own heart is generally preferred to transplantation or prolonged device implantation, both of which have significant side effects and increase the risk of mortality. Historically, however, recovery devices have not been widely available.

Our Solution

Our product portfolio is designed to provide heart recovery as an option across the continuum of care for acute heart failure patients. We believe our AB5000 and BVS 5000 products are currently the only commercially available cardiac assist devices approved by the FDA for heart recovery. In addition, if approved by the FDA, our Impella products and our iPulse console, together with our recently FDA-cleared IAB, will expand our heart recovery devices beyond the surgery suite by providing circulatory support for pre-shock heart failure patients in the cath lab. This expansion into the cath lab will significantly increase our target market opportunity and will enable us to offer products to interventional cardiologists in the approximately 1,750 U.S. hospitals with cath labs. We estimate that there are approximately 14,000 interventional cardiologists in the U.S. The new target patient population in the cath lab for our Impella and IAB devices includes approximately one million U.S. patients annually who enter the hospital for heart attacks and high-risk angioplasty procedures. This target patient base is in addition to our existing target population of approximately 75,000 patients suffering from cardiogenic shock after a heart attack or heart surgery, or suffering from myocarditis. Our existing target patients are those in the approximately 1,000 open heart centers and transplant centers in the U.S., which continue to represent a significant opportunity for growth as well.

We developed our first heart recovery products for use in open heart centers and transplant centers. Our AB5000 and BVS 5000 are capable of assuming the pumping function of the heart. Unlike destination therapy and bridge-to-transplant devices, which are designed for heart patients with irreversible heart damage, our AB5000 and BVS 5000 systems are designed for heart recovery, requiring only a minimal incision in the left ventricle of the heart. We believe the AB5000 s high flow rates, ease of implant, facilitation of patient mobility in the hospital and historically low incidence of adverse events facilitate heart recovery, potentially avoiding the need for heart transplantation and improving patient outcomes. In October 2005, the Centers for Medicare & Medicaid Services, or CMS, increased reimbursement for our AB5000 and BVS 5000 products for patients that

recover using our devices to levels similar to those for patients who undergo heart transplants. Since its introduction, the BVS 5000 has supported thousands of patients in hundreds of medical centers around the world. The AB5000, our next-generation heart recovery device introduced in 2004, has already supported more than 500 patients globally.

In 2005, we began to expand our product portfolio to include devices that address the larger population of heart attack and high-risk angioplasty patients treated by interventional cardiologists in the cath lab. This population includes patients whose hearts can potentially recover with assistance but without open heart surgery. Our Impella 2.5 and 5.0 catheters are micro heart pumps that can be quickly inserted percutaneously through the femoral artery over a guide wire to reach the left ventricle of the heart. This rapid procedure time facilitates early patient stabilization, giving an interventional cardiologist additional time to evaluate the most effective and clinically prudent treatment option for the patient. These devices allow the heart to rest, heal and potentially recover without the use of inotropes, drugs commonly used with IABs that increase the risk of mortality. In addition, the higher blood flow rate of our Impella 5.0 enables surgeons to use it to treat more severe heart conditions in the surgery suite. We believe our Impella products can provide solutions to patients with less severe heart disease, enhancing patient outcomes and increasing the number of patients who return home with their own hearts.

We expect that our iPulse console, if approved by the FDA, will further expand our product reach into the cath lab. The iPulse console is designed to support our IAB as well as other manufacturers IABs, which are used primarily in the cath lab. Because our multi-functional console also supports our AB5000 and BVS 5000 blood pumps, we believe the iPulse will provide our customers additional flexibility in allocating console resources between the surgery suite and the cath lab. In addition, because a significant portion of IABs are used in the surgery suite, we believe adoption of our iPulse console will increase utilization of our AB5000 ventricle.

In September 2006, we received Humanitarian Device Exemption, or HDE, approval from the FDA for our AbioCor Implantable Replacement Heart, the first completely self-contained artificial heart. The AbioCor gives chronic patients with biventricular heart failure who are not eligible for a transplant and whose sole alternative is death the opportunity to extend life. The AbioCor has no wires piercing the skin and allows the patient improved quality of life outside the hospital. We currently expect to begin a controlled roll-out of the AbioCor in the quarter ending September 30, 2007 at approximately five heart centers in the U.S. We are also developing our next-generation artificial heart, the AbioCor II, which is approximately 30% smaller than the existing AbioCor and is being designed with a goal of five-year reliability.

Our Strategy

Our strategic objective is to become the global leader in medical devices for heart recovery. To achieve this objective, we intend to:

- Expand our global distribution by hiring additional direct sales and clinical personnel and growing our network of international distributors
- Promote heart recovery as the standard of care through clinical data and published scientific studies
- Enhance our product portfolio to address patients along the entire continuum of care for heart recovery, from the cath lab, to the surgery suite, to the intensive care unit, to home discharge
- Evaluate strategic opportunities to add complementary products and technologies

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Risks Related to Our Business

Our business is subject to a number of risks that you should be aware of before making an investment decision. Some of these risks are:

- Our products are highly regulated medical devices and face substantial uncertainties relating to product development, clinical trials, regulatory approvals or clearances and commercial acceptance. Several of our products, including our Impella products and iPulse console, are not yet approved or cleared by the FDA, and we cannot assure you that they will ever be approved or cleared.

- Historically, we have not been profitable, and we cannot assure you that we will become profitable. Our operating results may continue to fluctuate unpredictably.

- The markets for most of our products are unproven, and we may be unable to successfully commercialize those products. We have limited experience selling our products to cath labs.

- Any failure on our part to manage growth successfully could adversely affect our business and operating results. We currently manufacture each of our products at only one location, and we may encounter difficulties in increasing our manufacturing capacity to meet anticipated demand.

- We may not be successful in expanding our sales activities, developing global distribution of our products, and recruiting and retaining key personnel.

- We may not be successful in defending our intellectual property, and we may face substantial claims for intellectual property infringement and product liability.

These and other risks related to our business and this offering are discussed more fully in the section of this prospectus supplement entitled Risk Factors, beginning on page S-8.

Our Corporate Information

We are a Delaware corporation and commenced operations in 1981. Our principal executive offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, and our telephone number is (978) 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 supplement, and you should not consider it part of this prospectus supplement.

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THE OFFERING

Common stock offered by ABIOMED, Inc.:	5,000,000 shares
Common stock to be outstanding after the offering:	32,231,012 shares
Use of Proceeds	We intend to use the net proceeds we receive from this offering to expand our global sales and distribution, to complete clinical studies and regulatory processes, and invest in research and development and for general corporate purposes, including working capital and potential acquisitions.
Nasdaq Global Market symbol:	ABMD

The number of shares of common stock to be outstanding after the offering is based on the number of shares outstanding as of March 21, 2007 and reflects our sale of 5,000,000 shares of common stock in this offering. This number excludes:

- options outstanding on March 21, 2007 to purchase 4,299,120 shares of common stock at a weighted average exercise price of $11.03 per share;
- options and other stock awards with respect to an additional 1,555,575 shares of common stock that may be granted under our stock incentive plans after March 21, 2007;
- 245,544 shares of common stock issuable under our employee stock purchase plan after March 21, 2007; and
- warrants to purchase up to 400,000 shares of common stock issued in connection with the purchase of intellectual property at an exercise price of $0.01 per share.

Unless otherwise noted, the information in this prospectus supplement assumes that the underwriters over-allotment option will not be exercised.

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SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with Management s discussion and analysis of financial condition and results of operations and our financials statements and the related notes included or incorporated by reference in this prospectus supplement and the accompanying prospectus. The consolidated statement of operations data include the results of operations attributable to our acquisition of all of the outstanding stock of Impella CardioSystems AG as of May 10, 2005. Our Impella acquisition was accounted for under the purchase method of accounting.

	Year ended March 31,			Nine months ended December 31,	
	2004	2005	2006	2005	2006
	(in thousands, except per share data)				
Statement of operations data:					
Total revenues	$ 25,739	$ 38,216	$ 43,670	$ 29,874	$ 36,798
Costs and expenses [1]:					
Cost of product revenues excluding amortization[1]	7,591	9,366	11,685	7,851	9,281
Research and development [1]	14,150	13,350	16,739	12,517	16,329
Selling, general and administrative [1]	14,037	18,566	30,923	21,558	31,355
Expensed in-process research and development			13,306	13,306	800
Amortization of intangibles	213	187	1,308	955	1,243
Total costs and expenses [1]	35,991	41,469	73,961	56,187	59,008
Loss from operations	(10,252)	(3,253)	(30,291)	(26,313)	(22,210)
Interest and other income, net	806	911	1,198	799	1,022
Net loss before provision for income taxes	(9,446)	(2,342)	(29,093)	(25,514)	(21,188)
Tax provision			356	253	344
Net loss	$ (9,446)	$ (2,342)	$ (29,449)	$ (25,767)	$ (21,532)
Basic and diluted net loss per share	$ (0.45)	$ (0.11)	$ (1.15)	$ (1.01)	$ (0.81)
Weighted average shares outstanding	21,153	21,845	25,649	25,447	26,602

	December 31, 2006	
	Actual	As adjusted [2]
Balance sheet data:		
Cash, cash equivalents, and short-term marketable securities	$ 17,241	$80,794
Working capital	23,995	87,548
Total assets	74,534	138,087
Long-term liabilities	6,456	6,456
Stockholders equity	57,079	120,632

(1) Costs and expenses for the nine months ended December 31, 2006 include stock-based compensation expense of $4.6 million, or approximately $0.17 per share, as a result of the adoption of SFAS No. 123(R), Share-Based Payment , in fiscal 2007. Approximately $3.1 million of this expense is included in selling, general and administrative expenses, approximately $1.3 million of this expense is included in research and development expenses and approximately $0.2 million of this expense is included in cost of product revenues excluding amortization.

(2) Reflects the sale of 5,000,000 shares of our common stock in this offering at the public offering price of $13.75 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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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 prospectus supplement, 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. 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 supplement.

Risks Related to Our Business

We have not operated at a profit and do not expect to be profitable in the foreseeable future.

We have had net losses in each of the past three fiscal years and in the nine months ended December 31, 2006. We plan to make large expenditures in fiscal 2007 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 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. 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 Impella products, our IAB, the AbioCor 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 United States 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 United States, 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 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.

For example, we plan to pursue premarket approval for each of our Impella 2.5 and Impella 5.0, and we are seeking 510(k) clearance of our Impella 2.5. In addition, we have submitted for premarket approval of our iPulse console.

We cannot assure you that we will receive any of these approvals or clearances. For example, in response to our 510(k) submission for the Impella 2.5 for short duration use, the FDA recently responded with a letter indicating that the FDA believes that the technological characteristics of the Impella 2.5 raise new questions of safety and effectiveness that are not addressed by the predicate devices we identified in our 510(k) submission.

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The FDA stated it is unaware of a predicate device raising the same questions and asked us to identify a predicate device that does so. We intend to respond to the FDA s letter by submitting additional data attempting to demonstrate that the device does not raise a new question of safety or effectiveness, and we believe we will be successful in answering the FDA s concerns. We may also amend our 510(k) submission to identify additional predicate devices. If we succeed in addressing these concerns, we expect to receive additional questions and requests for information from the FDA as we pursue 510(k) clearance of the Impella 2.5. If the FDA deems any of our responses unsatisfactory, we will not receive 510(k) clearance. We cannot assure you that we will successfully address the FDA s concerns or obtain 510(k) clearance for the Impella 2.5 on a timely basis, or at all. If we do not receive 510(k) clearance for our Impella 2.5 device, then based on our plan to continue with our PMA strategy, the commercial launch of the Impella 2.5 in the U.S. could take an additional 12 months or more. 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.

We intend to market our new products in international markets, including the European Union 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 currently conducting pilot clinical trials for each of our Impella 2.5 and Impella 5.0.

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 are not followed-up 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;

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.

The results of pre-clinical studies do not necessarily predict future clinical trial results, and predecessor 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

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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 would 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 and France. 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: