

A photograph of a smiling man wearing a light-colored hat, glasses, and a grey polo shirt, holding a golf club. He is standing on a lush green golf course with a sand trap and palm trees in the background.

The Pathway to  
**Heart Recovery**

**Annual Report**  
for fiscal year ended  
March 31, 2007

# ABIOMED IS A GLOBAL LEADER IN HEART ESTABLISHING HEART RECOVERY AS THE

## Recent Milestones

### April 2005

#### Impella

- Acquisition of Impella, a German-based company

### October 2005

#### Recovery Ventricular Assist Devices (VADs)

- CMS increased reimbursement 70% to an average of \$140,000 per patient for recovery

### May 2006

#### Impella 2.5

- U.S. FDA approval to start pilot clinical trial for Impella 2.5 with reimbursement

### June 2006

#### Impella 5.0

- U.S. FDA approval to start pilot clinical trial for Impella 5.0 with reimbursement

### July 2006

#### Impella 2.5

- Enrolled first U.S. patient BVS / AB5000
- PMA supplement approval for new integrated cannula system

### September 2006

#### AbioCor

- U.S. FDA approval under a Humanitarian Device Exemption (HDE)

### December 2006

#### IAB / iPulse

- U.S. FDA 510(k) clearance for new IAB
- Submitted PMA supplement for iPulse combination console

### January 2007

#### IAB / iPulse

- Announced CE mark approval for IAB and iPulse console
- First IAB patient treated

### February 2007

#### Impella

- Announced 510(k) submission to U.S. FDA for Impella 2.5
- Impella Pediatric pump announced

### March/April 2007

- Completed common stock offering at \$13.75 per share resulting in \$65M net proceeds; \$75M total cash and investments at March 31, 2007

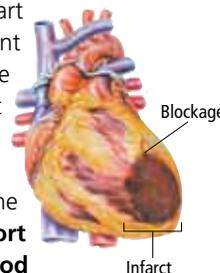
### April 2007

#### Impella 2.5

- Announced completed enrollment for 20-patient pilot clinical trial

## What is Heart Recovery?

For patients in acute heart failure, such as patients experiencing a heart attack, a blockage in the heart can limit the blood flow and the amount of oxygen delivered to the heart. When this occurs, the heart muscle (myocardium) may go into a state of "hibernation" where it cannot pump an adequate amount of blood to support the patient. If this continues for too long, the muscle can die, becoming a permanent scar or "infarct" and if the heart does not pump enough blood, the patient will die. **The goal of heart recovery with circulatory support technologies is to temporarily rest the heart and supply vital blood flow.** This provides an opportunity for the heart to heal and recover.



## The Abiomed Solution

Abiomed's portfolio of products 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 for all recoverable indications. In addition, if approved by the FDA, our Impella® products and iPulse™ console, together with our recently FDA-cleared intra-aortic balloon, will expand our heart recovery devices beyond the surgery suite by providing circulatory support for high-risk angioplasty and potential cardiogenic shock patients in the catheterization (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 and 2,200 heart surgeons in the U.S. alone. We are focused on establishing heart recovery as the goal for all acute cardiac attacks globally.

## A Global Opportunity to Recover Hearts and Save Lives

	Cath Lab (interventional cardiologists)		Surgery Suite (heart surgeons)	
	High-Risk Angioplasty (10%)	Reduction of Infarct after Heart Attack	Cardiogenic Shock from Heart Attack	Post Cardiotomy Shock/Myocarditis
U.S. Annual Patients*	~100K	~900K	~75K	~10K
Annual Patients Outside of U.S.	>150K	~2.5M	>125K	~15K

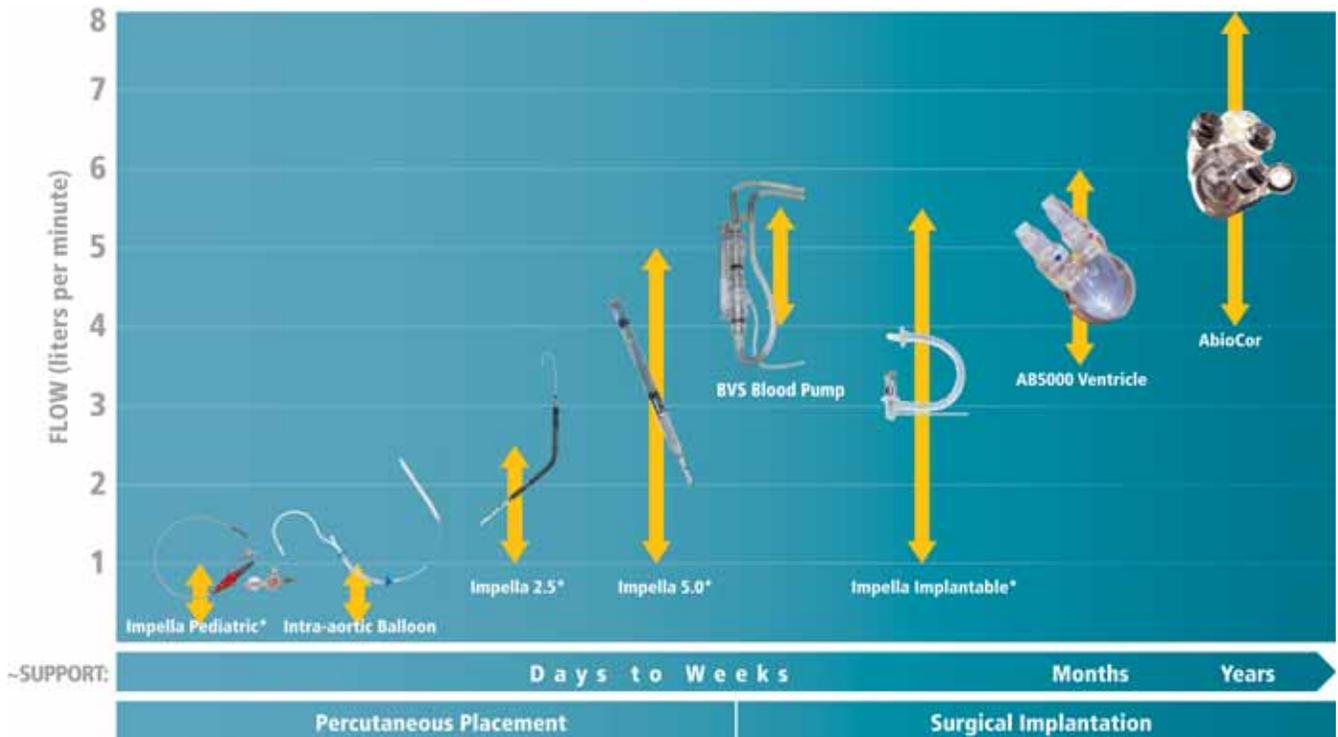
\*American Heart Association (AHA) 2006 Heart Disease and Stroke Statistics; Hochman, JAMA 285:190, 2001

## Strategic Goals for Fiscal Year 2008

- ▶ Establishing heart recovery as the goal for all acute cardiac attacks
- ▶ Expanding our product portfolio and working through the regulatory process
  - Impella 2.5 pivotal trial and potential 510(k) clearance
  - Impella 5.0 pilot study completion and initiation of pivotal trial
  - iPulse Console supplement approval
  - AbioCor® supplement approval and launch
- ▶ Growing revenue greater than 20%

# ASSIST TECHNOLOGIES, FOCUSED ON GOAL FOR ALL ACUTE CARDIAC ATTACKS.

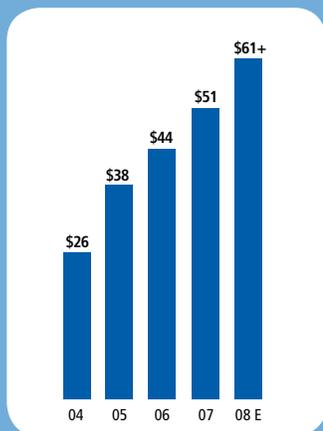
## The Abiomed **Spectrum of Care**



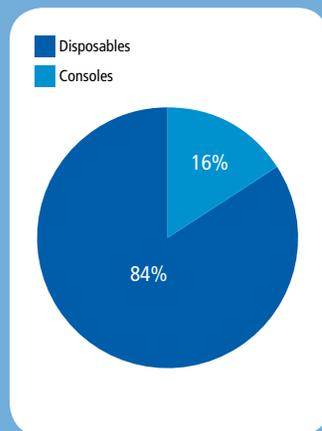
\*Not FDA approved.

*A healthy human heart pumps approximately 5 to 8 liters of blood per minute; Abiomed's recovery products increase blood flow for patients with heart failure, to rest and recover their native hearts.*

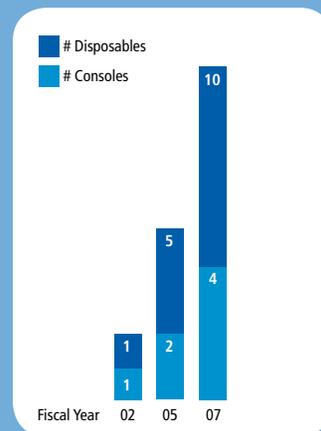
## Financial and Product Highlights



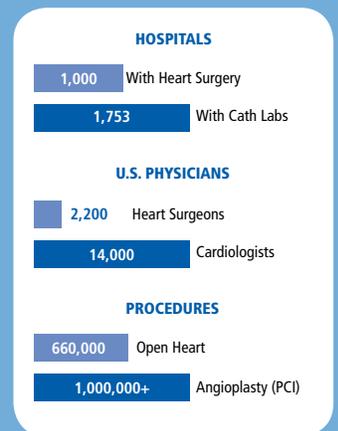
Revenue  
Fiscal Years Ended (\$M)



Fiscal Year 2007  
Disposables Mix



Expanded Portfolio\*\*  
(Not all products are FDA approved)



U.S. Market Opportunity<sup>†</sup>

\*\*FY '07 disposables include AbioCor and AbioCor II

<sup>†</sup>Source: AHA 2005, Adv. Board 2006

## Fellow Stakeholders:

*“Abiomed has transitioned to become the leader in circulatory care for heart recovery. We are now well positioned with a continuum of products from the cath lab, to the intensive care unit (ICU), to the surgery suite.”*

Looking back on Abiomed’s fiscal year 2007, our company achieved and progressed on our strategic goals of:

1. Establishing recovery as the standard of care for acute heart events
2. Expanding our product portfolio through regulatory progress
3. Increasing our global distribution
4. Growing revenue by double digits

**Heart recovery is the goal; however, it is not yet the standard of care.** Patients who experience a sudden, serious heart failure, such as a heart attack, should be given every opportunity to recover their own hearts. While heart transplantation is a life-changing gift to patients fighting chronic heart failure, at Abiomed, our mission is to allow sudden heart failure patients to keep their own hearts. The best option for these patients is to go home with their native hearts, untethered by wires, batteries or anticoagulation therapy.

Our progress during fiscal 2007 can be confirmed at every major heart failure meeting with HEART RECOVERY fast becoming the physicians’ goal. No other company has the technological breadth to recover as many patients across such a wide spectrum of disease indications. Whether it is support during high-risk angioplasty or salvaging the myocardium post AMI (acute myocardial infarction or heart attack), heart recovery is the goal and Abiomed has the highest published recovery rates. Our focus is to eliminate the leading cause of in-hospital mortality, which is death from AMI.

We have improved recovery outcomes through our focus on evidence-based medicine and the breadth of Abiomed’s advanced circulatory support technologies, providing heart failure patients the circulatory support they need – whether they need the incremental flow enhancement of an intra-aortic balloon; significant flow improvement in the catheterization (cath) lab with our

Impella 2.5 or 5.0; or full support of both sides of the heart with our BVS 5000 or AB5000.

**We achieved our goal of expanding our product portfolio by working through the regulatory process.** We announced four new products – the iPulse combination console, our intra-aortic balloon, the Impella Pediatric pump and the Integrated Cannula System – and received FDA approvals on pilot clinical trials for the Impella 2.5 and the Impella 5.0. We received FDA clearance on our intra-aortic balloon and approvals on our Integrated Cannula System, and the AbioCor, the world’s only fully implantable artificial heart. We submitted for product supplement approvals on our iPulse combination console, and applied for 510(k) clearance on the Impella 2.5 while simultaneously pursuing a PMA (premarket approval) path. Our company has a growing portfolio across a continuum of care.

**We increased our sales and clinical field teams by 40% over last fiscal year, and we now have over 60 direct sales and clinical representatives.** We are selling direct in the U.S., Germany and France and are now selling our recovery technologies in 40 countries through our direct and global distributor network. We believe every cath lab and surgery suite is a potential customer for our Impella and iPulse platforms. Through our increased portfolio, we have significantly grown our customer base and the addressable market opportunities by adding 14,000 interventional cardiologists performing over one million angioplasty procedures in the U.S. alone. Our global field teams will allow Abiomed to help patients earlier in the process and directly in the cath lab, as well as facilitate transitions to the surgery suite for profound cardiogenic shock.

**We achieved our fourth goal to grow revenue by double digits with a 16% growth rate for the year.** Our robust mix of disposables drove a strong gross margin of 76% for the year.



Moving forward, our strategic goals for fiscal year 2008 are as follows:

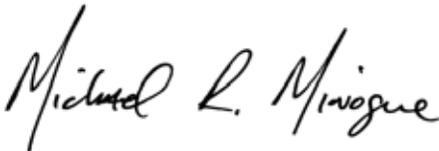
1. Establishing heart recovery as the desired goal for all acute cardiac events
2. Expanding our product portfolio and making regulatory progress
3. Growing revenue greater than 20%

We have a great opportunity for this coming year – Abiomed can provide the worldwide market with breakthrough technologies, data on the optimal use of these technologies and the ability to recover more patients.

In summary, this has been a rewarding three years for the company and for me personally. Through vision, strategy, execution and hard work, Abiomed has transitioned to become the leader in circulatory care for heart recovery. We are now well positioned with a continuum of products from the cath lab, to the intensive care unit (ICU) to the surgery suite. We believe our products are either best in class, have exclusive patents or maintain exclusive regulatory approvals, and our gross margins validate our perceived value. We have doubled revenue in the last three years based primarily on the AB5000 platform, quadrupled the number of products and increased our gross margins. The excitement is evident for the U.S. launch of Impella, iPulse and AbioCor. I believe the best is yet to come.

I would like to thank all of our investors for your support and our employees for their passion and dedication each day to saving lives.

All the best,



Michael R. Minogue  
Chairman, Chief Executive Officer and  
President

## FISCAL YEAR 2007 HIGHLIGHTS

- **FDA approval to start pilot clinical studies for the Impella 2.5 (enrollment completed in April 2007) and Impella 5.0, both with reimbursement**
- **Submission of 510(k) clearance for Impella 2.5**
- **Humanitarian Device Exemption (HDE) approval of AbioCor**
- **510(k) clearance on IAB and FDA approval of Integrated Cannula System**
- **Announced development of Impella Pediatric pump**
- **A multi-center study presented at the Transcatheter Cardiovascular Therapeutics (TCT) Conference by Dr. Mark Anderson, Chief of Cardiac Surgery at Robert Wood Johnson University Hospital, on 100 AMI cardiogenic shock patients showed recovery as the most likely outcome for AB5000 survivors**
- **A study from Dr. J.P.S. Henriques, Cardiologist at the Academic Medical Center in Amsterdam, at the American College of Cardiology (ACC) showed that pre-shock AMI patients supported early by the Impella 2.5 had improved cardiac function at three days and at four months post-procedure, as compared to conventional therapies**
- **A multi-center retrospective study presented at ACC of 109 patients undergoing elective, urgent or emergent percutaneous coronary interventions (PCIs) demonstrated ease-of-use, safety and feasibility of the Impella 2.5**
- **Revenue growth of 16% with gross margin of 76%**

# Leading in **Technology** and **Innovation**

Our engineering and scientific expertise have enabled the expansion of our product portfolio from one disposable in 2002 to ten disposables today, including AbioCor and AbioCor II, with six products under regulatory review. Today, we have three platforms for circulatory care: Impella, iPulse and AbioCor. We are excited about our growth opportunities as we bring these and other new products to the global markets to help clinicians (cardiologists and heart surgeons) provide advanced circulatory care for patients.

## iPulse

Abiomed recently announced an exciting new combination console platform called the iPulse. This culminates more than two years of internal research and development and reflects Abiomed's leading expertise and core competency in advanced circulatory care technologies. **The iPulse combination console supports Abiomed's new intra-aortic balloon (IAB), our BVS 5000 and AB5000 Circulatory Support Systems**, and serves as a platform for new product introductions in the future. The iPulse was designed and rigorously tested to be compatible with other manufacturers' balloons as well.

The iPulse platform extends Abiomed's clinical and market reach further upstream in patient care for acute heart failure. The IAB complements Abiomed's heart recovery products in the cardiac cath lab and surgical suite, including direct usage in the intensive care unit (ICU), allowing access to more acute heart failure patients. The iPulse is available in Europe and is awaiting PMA supplement approval in the U.S.

## Impella

**Our Impella platform provides both interventional cardiologists and heart surgeons with less-invasive treatment options for heart patients suffering from diminished blood flow.** Abiomed has a broad portfolio of Impella pumps that range in amount of blood flow and duration of patient support. For example, our Impella 2.5 is a ventricular assist catheter, which is inserted percutaneously in the cath lab via the femoral artery into the left ventricle. Up to 2.5 liters of blood per minute are delivered by the pump from the left ventricle into the ascending aorta, providing the heart with active support in critical situations. Abiomed also offers an Impella Implantable pump and recently announced our Impella Pediatric pump. These technologies are driven by the Impella Mobile Console, which facilitates patient transport in-house and to other hospitals for additional care. Abiomed is focused on improving the standard of circulatory care through the use of our Impella technologies. The Impella products, excluding the Impella Pediatric pump, have CE Mark approval and we are pursuing FDA approval.

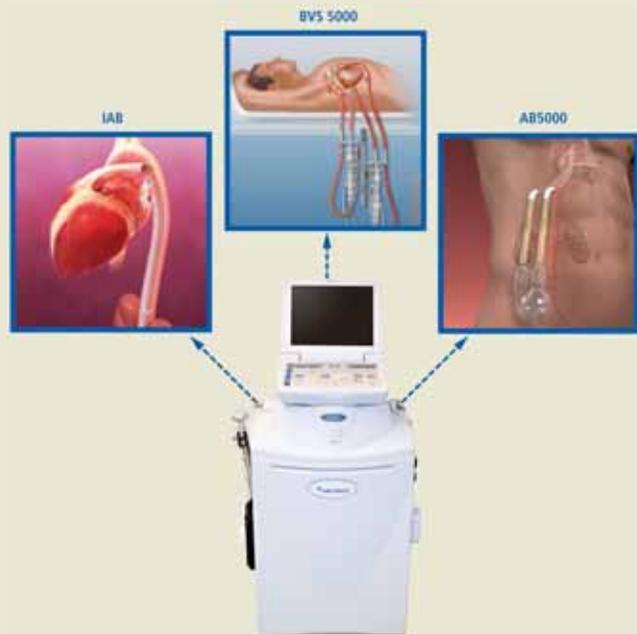
## AbioCor

In September 2006, Abiomed received Humanitarian Device Exemption (HDE) approval of the world's only fully implantable artificial heart, the AbioCor. **This technology represents the culmination of more than 25 years of engineering and scientific efforts.** The AbioCor is intended to replace the severely damaged native heart for patients who would otherwise die of heart failure. This HDE approval signifies that the AbioCor meets the standards of safety and probable benefit to patients. We plan to launch AbioCor in a controlled roll-out at five to ten U.S. hospitals later this year.



## The iPulse Platform

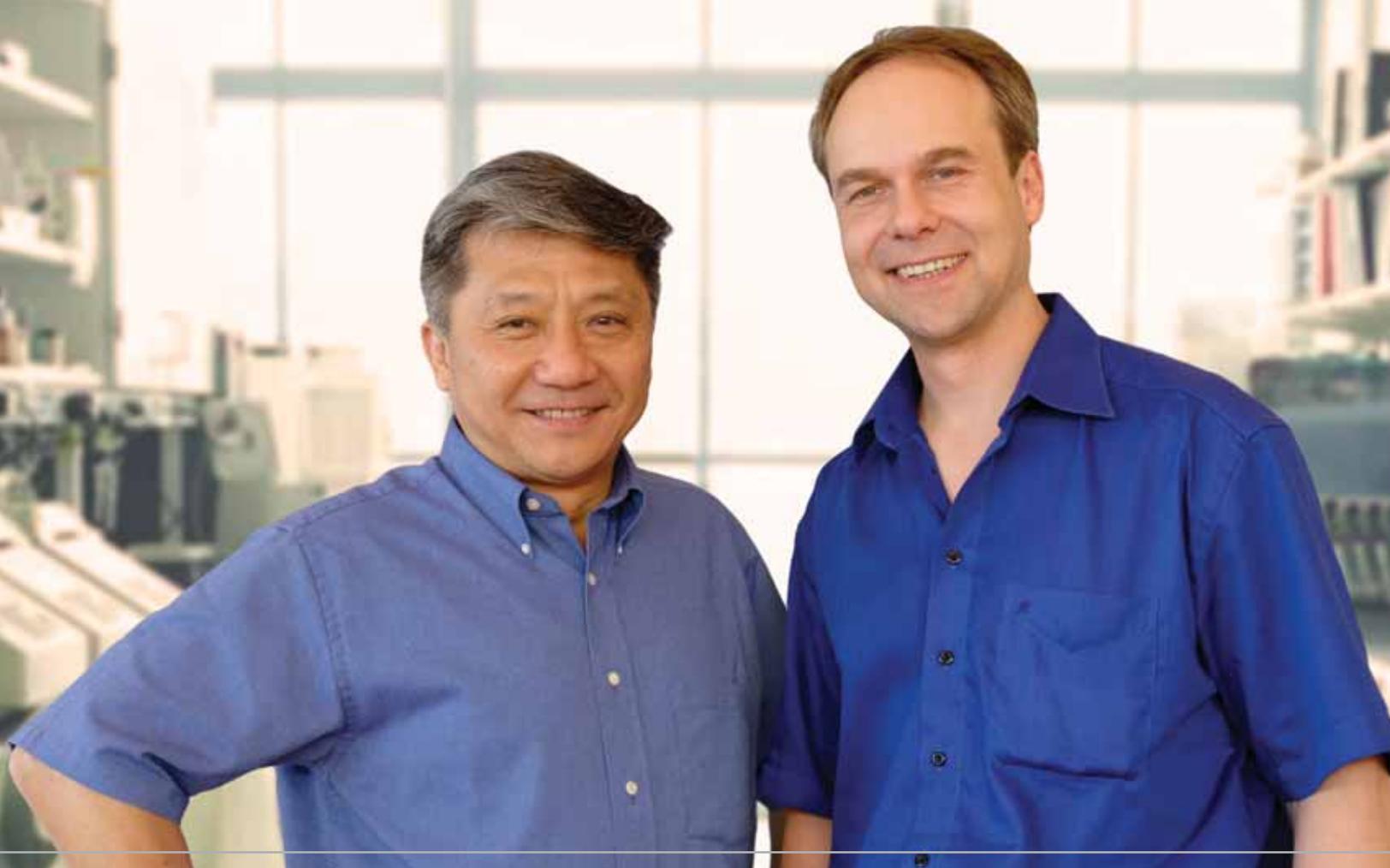
The iPulse is the only product that combines a state-of-the-art IAB and ventricular assist device (VAD).



## The Impella Platform

The Impella® Mobile Console drives the Impella family of circulatory support devices.





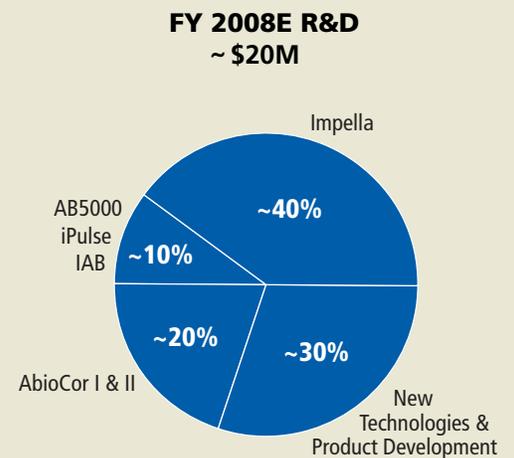
**Robert Kung, Ph.D.,** Senior Vice President and Chief Scientific Officer  
**Thorsten Siess, Ph.D.,** Chief Technology Officer, Impella R&D

Abiomed's global research and development efforts are led by two world-renowned scientists and technology innovators, Dr. Bob Kung and Dr. Thorsten Siess. Their passion and unrelenting focus are aimed towards the development and advancement of circulatory care technologies that recover hearts, save lives and improve quality of life.

**Dr. Robert T.V. Kung** has been with Abiomed for more than 25 years, leading the pursuit of the world's only fully-implantable artificial heart, the AbioCor, and helping to advance Abiomed's heart recovery technologies including the world's first FDA approved ventricular assist device, the BVS 5000, and the AB5000 circulatory support system, which we believe have the highest published recovery rates for acute heart failure. Dr. Kung has authored or co-authored more than 60 publications, has more than 50 patents, patents pending and patent applications, and has been Principal Investigator for many highly competitive National Institute of Health (NIH) grants and programs. Dr. Kung received his Ph.D. in Physical Chemistry from Cornell University and devoted his Post Doctoral research to Applied Physics at Yale University. He is a board member of the American Society for Artificial Internal Organs (ASAIO) and is widely recognized as a global thought leader, pioneer and innovator in heart technologies.

**Dr. Thorsten Siess** joined the Abiomed team in 2005 with the acquisition of Impella, a company he co-founded and a technology he developed during his time at the world renowned Helmholtz-Institute for Biomedical Engineering at the Technical University of Aachen in Germany. His scientific breakthroughs include the Impella 2.5 and 5.0, the Impella Implantable and the recently-announced Impella Pediatric pump. Dr. Siess was recognized as one of the "World's 40 Leading Technology Pioneers" by the Davos World Economic Forum in February 2003. Dr. Siess leads a team focused on developing the world's smallest ventricular assist devices that also provide safe and effective support to patients. He has authored or co-authored 14 peer-reviewed publications, holds 95 patents with more than 70 patents pending, and he continues to explore new technologies in circulatory care. He is now instrumental in the regulatory approval efforts at Abiomed to make the Impella products available in the U.S.

*Abiomed holds more than **110 patents** or patents pending derived from over **\$150 million in R&D***



# Impella: A Global Breakthrough



Actual size

Our Impella products have been used to treat over 1,000 patients outside the U.S. We are focused on obtaining FDA approvals to bring these technologies to the U.S. market. Abiomed is committed to helping patients by providing simple and effective cardiac support in the cath lab. Clinical highlights include:

#### **American Journal of Cardiology** (April 2006, Volume 97, Issue 7)

This study by Dr. J.P.S. Henriques, Cardiologist at the Academic Medical Center in Amsterdam, included 19 patients undergoing high-risk percutaneous coronary interventions (PCI) and who were poor candidates for surgery. Entitled "Safety and Feasibility of Elective High-Percutaneous Coronary Intervention Procedures with Left Ventricular Support of the Impella 2.5," the study found:

- The device successfully supported 100% of patients undergoing elective or emergent high-risk PCI procedures
- There were no significant device-related adverse events
- No aortic valve regurgitation or valve dysfunction during or after device operation
- There were no strokes
- There was no limb pain or ischemia

#### **Multiple Studies at the 2007 American College of Cardiology (ACC)**

A multi-center retrospective study of 109 patients undergoing elective, urgent or emergent percutaneous coronary interventions (PCIs) demonstrated ease-of-use, safety and feasibility of the Impella 2.5.

Dr. Henriques presented a 20-patient study which found that the Impella 2.5 improved post-procedure cardiac function for patients with pre-shock acute myocardial infarction (AMI or heart attack) as compared to conventional care including intra-aortic balloon pump (IABP) therapy.

#### **U.S. Regulatory Approval Paths**

The pilot study of the Impella 2.5 enrolled 20 patients undergoing high-risk angioplasty procedures at leading U.S. hospitals. The pivotal study is expected to commence later this year. Abiomed has also submitted data for a potential 510(k) clearance for the Impella 2.5 while pursuing premarket approval (PMA) for the technology. The Impella 5.0 is currently in a pilot study for patients with low cardiac output after cardiac surgery.

#### **Transcatheter Cardiovascular Therapeutics (TCT) Conference Studies**

Two Impella studies at TCT 2006 included a look at the safety and clinical utility of the technology and a presentation on the Impella 2.5 pilot study design for high-risk angioplasty patients.

*"I consider the Impella 2.5 a very innovative technology and think it will definitely change the standard of care for patients undergoing procedures in the cardiac cath lab. The device will become an integral part of management for many patients undergoing cardiac catheterization procedures."*

— Dr. Simon R. Dixon  
Director, Cardiac  
Catheterization Laboratory  
William Beaumont Hospital

*"Our experience with the Impella 2.5 has been quite positive. The device has proven to be safe and I am pleased with its ease-of-use and ability to provide both hemodynamic support and improved, sustained coronary circulation in the cath lab."*

— Dr. J.P.S. Henriques, Cardiologist at the Academic Medical Center in Amsterdam

*"Compared to anything that I've ever been involved with in terms of hemodynamic support, the Impella 2.5 is by far the most exciting, impressive and effective hemodynamic support system I've ever seen. I think it's going to have a huge role in the cath lab."*

— Dr. William O'Neill  
Executive Dean for Clinical Affairs at the University of Miami  
and the National Principal Investigator of the pilot study for the Impella 2.5

## The Pathway to Heart Recovery

### **Jon Hawes, 65 First U.S. Impella 2.5 patient**

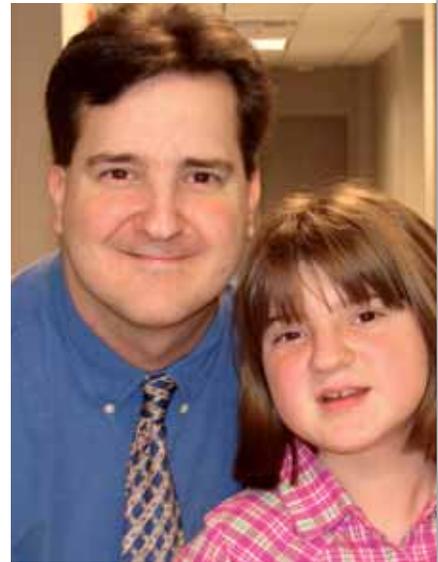
Jon Hawes had his first heart attack at age 31 and has since experienced diminishing heart function. He deteriorated to the point that last spring he would become exhausted just walking to his mailbox. His only option besides a heart transplant was to undergo a high-risk angioplasty procedure which would stop blood flow to his heart while a balloon was inserted to clear the blocked vessel. With the help of the Impella 2.5, his interventional cardiologists at William Beaumont Hospital in Detroit were able to supply necessary blood flow and support his heart while they took the time necessary to perform the angioplasty and insert several stents to restore blood flow to his heart.



# Recovering **Hearts.** Saving **Lives.**

There are approximately one million AMIs each year in the U.S., with roughly 75,000 patients experiencing the deadly condition known as AMI cardiogenic shock. For acute heart failure survivors, recovery is the most likely outcome with Abiomed technologies.

Dr. Mark Anderson, Chief of Cardiac Surgery at Robert Wood Johnson University Hospital in New Brunswick, NJ, presented a 100-patient, multi-center study at TCT 2006, with the AB5000 used to treat patients with acute myocardial infarction (AMI) cardiogenic shock. This study remains the most in-depth analysis of AMI cardiogenic shock. These patients represented the sickest population ever treated with a ventricular assist device (VAD) and were sicker than the patients who died in the groundbreaking SHOCK\* Trial from 1999. The majority of AB5000 patients in the TCT 2006 study who survived recovered their hearts. The AB5000 provides high pulsatile flows, the ability to ambulate the patient and the flexibility for bi-ventricular support, contributing to improved clinical outcomes for patients.



**Andy Sarricchio, 37**  
(with daughter Allyson)  
Recovered after nine days of  
BVS 5000 support following post  
cardiotomy cardiogenic shock  
(PCCS) from a valve repair.

***“Patients in acute heart failure have a window of opportunity where their hearts can fully recover, and they can avoid organ failure. This can only be accomplished with adequate circulatory support with VADs designed specifically for that purpose.”***

***— Dr. Michael M. Madani  
Associate Professor in Surgery  
University of California San Diego  
Chief, Division of Cardiothoracic Surgery  
San Diego VA Medical Center***

\* Hochman et al, NEJM 1999; 341:625-624



**Melissa Moser, 22**

Melissa had a near fatal encounter with a pulmonary embolism – a large blood clot that worked its way into her lungs. Her doctors performed surgeries to remove the embolism and implanted the AB5000 Ventricular Assist Device (VAD) to take over the pumping of the right side of her heart. After four days of support, her heart had recovered and the device was explanted. She graduated from college only a few weeks later and got married the following month. Melissa and her husband are looking forward to starting a family as her doctors have declared her to be in excellent health.

# Proven Results

## IMPELLA CLINICAL EXPERIENCE

- CE marked with more than 1,000 patients treated in Europe.
- Over 20 peer-reviewed publications, including the study\* by Dr. J.P.S. Henriques in the *American Journal of Cardiology* of 19 patients having high-risk percutaneous coronary interventions (PCI) with the Impella 2.5.
- A second study from Dr. Henriques at ACC showed that pre-shock AMI patients supported early by the Impella 2.5 demonstrated better cardiac function at three days and at four months post-procedure, as compared to the control group treated with conventional therapies.
- A multi-center retrospective study presented at ACC of 109 patients undergoing elective, urgent or emergent percutaneous coronary interventions (PCIs) demonstrated ease-of-use, safety and feasibility of the Impella 2.5.

## AB5000: IMPRESSIVE RECOVERY RESULTS

- Abiomed's data registry of greater than 650 patients supported on the AB5000 shows the majority of survivors recover their native heart.
- A multi-center study presented at TCT 2006 on the AB5000 for AMI patients found that 63% of survivors recovered their own hearts.
- Abiomed conducted a meta analysis of more than 45 peer-reviewed and hospital acute heart failure cases from 1993 to 2007 and found that AB5000 and BVS 5000 have the highest recovery rates.

## REGULATORY STATUS

Product	FDA	CE
AB5000 / BVS	✓	✓
Impella 2.5	Completed enrollment for 20-patient pilot study; 510(k) submitted	✓
Impella 5.0	In pilot study	✓
Intra-Aortic Balloon (IAB)	✓	✓
iPulse Console	PMA supplement under review	✓
AbioCor	✓ HDE; Additional supplements submitted	—
Impella Implantable	Not yet submitted	✓
Impella Pediatric	Not yet submitted	—
AbioCor II	Not yet submitted	—

\*Henriques JP, Rimmelink M, Baan J, Jr., van der Schaaf RJ, Vis MM, Koch KT, Scholten EW, de Mol BA, Tijssen JG, Piek JJ, et al. Safety and Feasibility of Elective High-Risk Percutaneous Coronary Intervention Procedures With Left Ventricular Support of the Impella Recover LP 2.5. *Am J Cardiol*. 2006 Apr 1;97(7):990-2.



**Brad Derrenger, 63,** recovered his new transplanted heart on the AB5000.



**Ralph Stein, 62,** recovered from Acute Myocardial Infarction (heart attack) cardiogenic shock with 15 days of AB5000 support.



**Janie Adkins, 49,** recovered from post cardiectomy cardiogenic shock (PCCS) following 10 days of BVS 5000 support.

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549  
FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For fiscal year ended March 31, 2007

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-20584

**ABIOMED, Inc.**

*(Exact Name of Registrant as Specified in Its Charter)*

**Delaware**

*(State or Other Jurisdiction of  
Incorporation or Organization)*

**04-2743260**

*(I.R.S. Employer  
Identification No.)*

**22 Cherry Hill Drive**

**Danvers, Massachusetts**

*(Address of Principal Executive Offices)*

**01923**

*(Zip Code)*

**(978) 646-1400**

*(Registrant's Telephone Number, Including Area Code)*

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

Title of Each Class

Name of Each Exchange  
on Which Registered

Common Stock, \$.01 par value  
Preferred Stock Purchase Rights

The Nasdaq Stock Market LLC

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

None

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

The aggregate market value of the registrant's common stock as of September 30, 2006, held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of such date was \$354,996,105.

As of June 8, 2007, 32,439,174 shares of the registrant's common stock, \$.01 par value, were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive Proxy Statement for Abiomed, Inc.'s 2007 Annual Meeting of Stockholders, which is scheduled to be filed within 120 days after the end of Abiomed, Inc.'s fiscal year, are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The Securities and Exchange Commission, or SEC, encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This report, including the documents incorporated by reference in this report, includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements in these documents include, but are not necessarily limited to, those relating to:

- *our ability to obtain and maintain regulatory approval both in the U.S. and abroad for our existing products, including U.S. approval for our Impella products as well as for new products in development;*
- *the ability of patients using our products to obtain reimbursement of their medical expenses by government healthcare programs and private insurers including potential changes to current government and private insurers' reimbursements;*
- *the other competing therapies that may in the future be available to heart failure patients;*
- *our plans to develop and market new products and improve existing products;*
- *the potential markets that exist or could develop for our products and products under development;*
- *our business strategy;*
- *our revenue growth expectations and our goal of achieving profitability; and*
- *the sufficiency of our liquidity and capital resources.*

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

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a leading provider of medical devices in circulatory support and offer a continuum of care in heart recovery to acute 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 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 in pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab. We are focused on increasing awareness of heart recovery and establishing it as the goal for patients with failing but potentially recoverable hearts. We expect that recovery awareness and utilization of our products will 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 have eight disposable products that have either been approved or cleared by the FDA in the U.S. or have received CE mark approval in Europe as well as several additional products in development.

#### Industry Background

##### *Heart Disease—Overview*

According to the American Heart Association, or AHA, coronary heart disease is the leading cause of death in the U.S. Coronary heart disease is a condition of the coronary arteries that causes reduced blood flow and insufficient oxygen delivery to the affected portion of the heart. Coronary heart disease leads to acute myocardial infarction, or AMI, commonly known as a heart attack, and with multiple heart attacks over time, this leads to congestive heart failure, a condition in which the heart is unable to pump enough blood to the body's other organs. 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.

A broad spectrum of therapies exists for the treatment of patients in early stages of coronary heart disease. Patients who have rhythm management problems can be treated with anti-arrhythmic drugs, pacemakers or implantable defibrillators. Additionally, angioplasty procedures and stents are commonly used in the cath lab for early-stage circulatory complications to increase blood flow to and from the heart. These treatments are often successful in slowing the progression of heart disease, extending life, and/or improving the quality of life for some period of time. Acute patients have potentially recoverable hearts. Treatment for acute patients in pre-shock in the cath lab is primarily focused on hemodynamic stabilization and clinical procedures aimed at improving reduced cardiac output. Acute patients in profound shock typically require treatment in the surgery suite including patients suffering from cardiogenic shock after a heart attack, post-cardiotomy cardiogenic shock or myocarditis. Chronic patients have hearts that are not recoverable due to left and right side heart failure or after chronic conditions that cause a heart to fail over time. Limited therapies exist today for patients with severe, end-stage, or chronic heart failure.

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

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

There are two primary types of devices used in the cath lab and surgery suite 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 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 enhance heart muscle ejection but increase the risk of mortality. IABs have limited effectiveness in patients that are arrhythmic and /or in cardiogenic shock.

Ventricular assist devices are mechanical devices that help the failing heart pump blood or take over the pumping function of the failing heart. Historically, VADs have been highly invasive and require implantation in the surgery suite. The use of VADs generally falls into three sub-categories: 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 VAD therapy only prolongs the end-stage disease, as the patient's heart condition is terminal and the patient's heart is not expected to recover. Furthermore, artificial replacement hearts, another destination therapy modality, may be suitable for end-stage heart failure patients requiring full support.

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, about one third of the patients eligible for transplant must rely on bridge-to-transplant devices for an extended period while waiting for a heart transplant. During this time, these patients frequently experience significant medical complications, such as infection. Moreover, 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 the only commercially available cardiac assist devices approved by the FDA. 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 U.S. patient 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 treated in the approximately 1,000 open heart centers and transplant centers in the U.S., which continue to represent a significant opportunity for growth as well.

We 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, and historically low incidence of adverse events facilitate heart recovery, potentially avoiding the need for heart transplantation and improving patient outcomes. Also, the AB5000 console's relatively small size, light weight and affixed wheels enable patient mobility in the hospital which can also contribute to improved patient care and clinical 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 approximately fifteen years ago, the BVS 5000 has supported thousands of patients in hundreds of medical centers around the world. The AB5000, our next-generation heart recovery device introduced in 2004, provides up to six liters of pulsatile flow, can provide support for days to months, provides patient mobility, and has already supported more than 500 patients globally.

In May 2005, we completed the acquisition of Impella CardioSystems AG, located in Aachen, Germany. Impella expands 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 utilized in the cath lab by cardiologists and 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 clinical use by surgeons as well to treat more severe heart conditions in the surgery suite. We believe our Impella products can provide solutions to patients with less severe heart disease, 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. We have submitted a PMA supplement to the FDA for our iPulse console and expect approval in the summer of calendar 2007; however, we cannot guarantee approval. The iPulse console is designed to support our IAB as well as other manufacturers' IABs, which are used in the cath lab and surgery suite. Because our multi-functional console also supports our AB5000 and BVS 5000 blood pumps, we believe the iPulse will provide our customers additional flexibility in allocating console resources between the surgery suite and the cath lab. In addition, 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 expect to begin a controlled roll-out of the AbioCor in late calendar 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 establish heart recovery as the goal for all acute cardiac attacks. 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.* With the growth in our product portfolio and recent regulatory approvals for certain products, we now have greater opportunities to market and sell our products to both heart surgeons and interventional cardiologists in the United States and abroad. To address this larger market, we plan to continue to expand our global sales and clinical headcount. In particular, we intend to hire sales representatives with extensive clinical experience, particularly in the cath lab, to enhance our ability to market and sell our products to interventional cardiologists. To address international markets, we intend to augment our direct sales force in Germany and France and expand our network of international distributors to include additional territories.
- *Establish recovery awareness through clinical data and published scientific studies.* Many heart surgeons and cardiologists are unfamiliar with the clinical results that have been achieved with our heart recovery devices and accordingly do not consider heart recovery as a viable medical alternative. We are using evidence-based medicine to promote heart recovery as the goal for patients with failing but potentially recoverable hearts. We also plan to demonstrate that our Impella products are an alternative to the use of IABs and inotropes as the initial treatment for less severe heart failure patients. We intend to continue to support the publication of papers that illustrate the benefits of heart recovery, provide webcasts and seminars on the cost savings associated with recovery, promote heart recovery at industry trade shows, and hold training sessions for clinicians to begin using our heart recovery products. We will also continue to educate hospitals on the reimbursement options available for our products.
- *Continue to 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.* Our earliest circulatory assist product, the BVS 5000 system, and our next-generation AB5000 system address heart failure patients requiring surgical intervention to improve their heart function and are sold primarily to open heart centers and transplant centers. We now have Impella 2.5 and 5.0 catheters and recently launched our IAB and iPulse console. These products target the larger population of acute heart failure patients in the cath lab, whose hearts might recover with assistance but without open heart surgery. Our Impella 2.5 and 5.0 products and iPulse platform are CE marked and we are in the process of pursuing FDA approval in the U.S. for our Impella 2.5 and 5.0 catheters, as well as our iPulse console. We intend to continue to develop and introduce additional new products to cover a broader population of potential heart recovery patients, and we also plan to seek regulatory approval for the use of our products for a broader range of patient indications. We have a number of new products at various stages of development. For example, in January 2007 we announced that we are conducting pre-clinical studies for our Impella Pediatric product that is a catheter-based heart pump to provide left-ventricular support to pediatric patients.
- *Evaluate strategic opportunities to add complementary products and technologies.* We constantly evaluate strategic opportunities to add complementary products and technologies, and we may pursue selective additions that would provide products or intellectual property that enhance our product portfolio to address patients across the continuum of care in heart recovery. For example, as a result of our acquisition of Impella CardioSystems AG in May 2005, we added the Impella line of products, which expanded our target market for heart recovery devices beyond the surgery suite and into the cath lab.

## Our Products

We are building a portfolio of cardiac assist solutions for cardiologists and surgeons. Our cardiac assist products provide circulatory support to acute heart failure patients across the continuum of care in heart recovery.

Product Name	Description of Use	Regulatory Status US	CE Mark
<b><i>Disposable Products for the Surgery Suite</i></b>			
BVS 5000 Blood Pump	Provides temporary LVAD, RVAD or BiVAD support until recovery for cardiogenic shock from heart attack; post-cardiotomy cardiogenic shock; myocarditis, failed transplant and certain other clinical instances where the physician believes heart recovery is possible	✓	✓
AB5000 Ventricle	Provides temporary LVAD, RVAD or BiVAD support until recovery for cardiogenic shock from heart attack: post-cardiotomy cardiogenic shock; myocarditis, failed transplant and certain other clinical instances where the physician believes heart recovery is possible; allows for full patient mobility	✓	✓
Integrated Cannula System	Connects the BVS 5000 and AB5000 ventricle to the body and provides an option for the removal of the devices without re-opening the chest	✓	Not yet submitted
Impella RD (implantable)	Provides temporary RVAD support until recovery for any temporary right heart failure due to implantation of an LVAD, post-cardiotomy and heart attack patients after coronary bypass surgery, angioplasty, or after transplantation	Not yet submitted	✓
Impella LD	Provides temporary LVAD support until recovery from cardiogenic shock due to heart attack: post-cardiotomy cardiogenic shock, myocarditis, failed transplant and certain other clinical instances where the physician believes heart recovery is possible	IDE approved and pilot clinical trial in progress	✓
<b><i>Disposable Products for the Cardiac Catheterization Lab and the Surgery Suite</i></b>			
Impella 2.5	Miniature percutaneous heart pump providing up to 2.5 liters of blood flow per minute intended to support the heart while undergoing high-risk angioplasty procedures or for assisting the heart while in pre-shock for hemodynamic stabilization	IDE approved and pilot clinical trial in progress; patient enrollment completed; and seeking 510(k) clearance	✓
Impella 5.0	Percutaneous heart pump providing up to 5.0 liters of blood flow per minute for low cardiac output post-surgery patients intended to assist the heart while in pre-shock or profound shock for recovery	IDE approved and pilot clinical trial in progress	✓
IAB	Percutaneous intra-aortic balloon used to support a wide variety of prophylactic, pre-shock and profound shock conditions	✓	✓
<b><i>Consoles</i></b>			
AB5000 Console	Driver console for both BVS 5000 Blood Pump and AB5000 Ventricle	✓	✓
Mobile Pump Console	Driver console for Impella products	IDE approved and pilot clinical trial in progress; patient enrollment completed; and seeking 510(k) clearance	✓
iPulse Console	Multi-purpose driver console for IAB, AB5000, BVS 5000 and other manufacturers' balloons	PMA supplement under review	✓
<b><i>Disposable Implants</i></b>			
AbioCor	Fully implantable replacement heart for severe biventricular heart failure when chronic patients are ineligible for a heart transplant	Approved under HDE	Not yet submitted

### ***AB5000 and BVS 5000***

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

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

The AB5000 Circulatory Support System, our next-generation product for heart recovery, is designed to provide a longer duration of support than the BVS 5000 and facilitates patient mobility in the hospital. The AB5000 can provide up to 6.0 liters of pulsatile blood flow per minute to support patients in profound shock. The AB5000 was approved by the FDA in 2003 and has supported more than 600 patients globally. Our AB5000 is designed to provide enhanced patient mobility within and between medical centers and to provide enhanced features and ease of use for caregivers. We believe the AB5000's high flow rates, ease of implant and historically low incidence of adverse events facilitate heart recovery, potentially avoiding the need for heart transplantation and improving patient outcomes. We expect to rely increasingly on sales of the AB5000 system, as sales of the BVS 5000 decline.

Each of the AB5000 and BVS 5000 systems consists of a blood pump, or ventricle, one atrial or ventricular cannula, one arterial cannula and a driver console to operate the pump. Other than the console, each component is a disposable item. The AB5000 console supports biventricular BVS 5000 blood pumps, AB5000 ventricles or a combination of the two. Both the AB5000 and BVS 5000 systems use the same cannulae and console, allowing for seamless transition of devices without requiring an additional surgical procedure.

### ***Impella 2.5, Impella 5.0, Impella RD and Impella LD***

Our Impella 2.5 and 5.0 catheters are percutaneous micro heart pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. These devices are designed for use by interventional cardiologists to support pre-shock patients in the cath lab who may not require as much support as patients in the surgery suite. Our Impella catheters are also designed to provide ventricular support for patients requiring hemodynamic stabilization or suffering from reduced cardiac output, and can aid in recovering the hearts of patients following a heart attack. These products increase flow to the heart and organs without the need for drugs such as inotropes while reducing the workload of the heart. Our Impella devices have already been used to treat more than 1,000 patients in Europe and other countries outside the U.S. and have been the subject of over 20 peer-reviewed publications and other clinical presentations and publications.

These catheters can be quickly inserted through the femoral artery over a guide wire to reach the left ventricle of the heart where they are directly deployed to draw blood out of the ventricle and deliver it to the circulation, thereby reducing ventricular work (resting the heart) and providing flow to the rest of the organs. The Impella 2.5 is implanted percutaneously, while the Impella 5.0 is implanted via a small cut-down of the femoral artery in the groin. The Impella 2.5 can pump up to 2.5 liters of blood per minute, and the Impella 5.0 can pump up to 5.0 liters of blood per minute. The Impella 5.0 has been used to treat patients in need of cardiac support resulting from post-cardiotomy cardiogenic shock, myocarditis, low cardiac output after a heart attack, or post-coronary intervention procedures, or as a bridge to other circulatory support devices, including our AB5000 and BVS 5000 systems. Our Impella RD is a right heart support pump, and our Impella LD is a left heart pump. Both are surgically implanted.

Our Impella 2.5 and 5.0 catheters and Impella RD and LD heart pumps are already available in Europe under CE mark approval. We are pursuing FDA approval for our Impella 2.5 and 5.0 products. The Impella 2.5 pilot clinical trial was designed to study the use of the Impella 2.5 to support high-risk angioplasty as a left ventricular assist device. The Impella 2.5 patient enrollment has been completed through enrollment of 20 patients at the following hospitals: Brigham & Women's Hospital, Massachusetts General Hospital, Columbia Presbyterian, Scripps Clinic, Cedars-Sinai Medical Center, Texas Heart Institute, William Beaumont Hospital and Academic Medical Centre of the University of Amsterdam. The trial will be completed after we have concluded all necessary post-enrollment patient monitoring. Angioplasty, performed in the cath lab, is the insertion of a catheter-guided balloon and is used to open a narrowed coronary artery. A stent, or a wire-mesh tube that expands to hold the artery open, is usually placed at the narrowed section. According to the American Heart Association, there are approximately 1.3 million in-patient angioplasty procedures in the U.S. annually, of which only a fraction are high-risk. For purposes of our clinical trials, high-risk angioplasty is generally defined as a procedure on patients undergoing angioplasty on an unprotected left main coronary artery lesion, or the last patent coronary conduit, and who have poor cardiac function. The Impella 5.0 pilot clinical trial includes post-cardiotomy patients who have been weaned from the heart-lung machine. In addition, we are seeking 510(k) clearance of our Impella 2.5

catheter for short duration use. Regardless of the outcome of our 510(k) submission, we plan to pursue PMA approval for other clinical indications. We cannot assure you that we will receive PMA approval or 510(k) clearance for either of our Impella 2.5 or 5.0 or that we will be able to sell them at anticipated prices.

### ***IAB and iPulse***

We recently introduced our percutaneous intra-aortic balloon, or IAB. An IAB is typically used in the cath lab as an initial line of therapy for patients with diminished heart function, although a substantial number of IABs are used in the surgery suite. Our IAB is easy to insert and is designed to enhance blood flow to the heart and other organs for patients with diminished heart function. Our IAB is inserted percutaneously into a patient's descending aorta and inflates and deflates in counterpulsation to the patient's heart rhythm. The IAB extends our clinical and market reach further upstream in the care of acute heart disease patients, including direct usage in the intensive care unit, cath lab and surgery suite. We began selling IABs in the fourth quarter of fiscal 2007.

To support the IAB, we developed our iPulse combination console. The iPulse console is also designed to support our AB5000 and BVS 5000 systems, other manufacturers' intra-aortic balloons and products we may offer in the future. We believe the ability of the iPulse console to support multiple devices will make it more attractive than consoles designed to operate a single device. The new iPulse console will support procedures with associated Medicare reimbursement that extends across four diagnostic related groups, which further enhances its attractiveness to customers.

We received 510(k) clearance from the FDA for our new IAB in December 2006 and CE Mark approval in January 2007. The iPulse console has CE mark approval in Europe but has not been approved for commercial sale in the United States. To obtain FDA approval of the iPulse console, we have filed a supplement to our PMA application for our existing AB5000 console. We believe there will be U.S. market demand for our iPulse console following FDA supplement approval anticipated later this summer; however, we cannot guarantee approval.

### ***AbioCor***

Our AbioCor Implantable Replacement Heart is the first completely self-contained artificial heart. The complete AbioCor system consists internally of a thoracic unit, a rechargeable battery, an electronics package and a power receiver coil, and externally, a power transmitter coil, power and battery pack, handheld alarm monitor, patient home electronics and an in hospital console. Once implanted, the AbioCor system does not penetrate the skin, reducing the chance of infection. This technology provides patients with mobility and remote diagnostics.

Designed to sustain the body's circulation, the AbioCor is intended for end-stage biventricular heart failure patients whose other treatment options have been exhausted. Patients with advanced age, impaired organ function or cancer are, in most circumstances, ineligible for a heart transplant and are potential candidates to receive the AbioCor implantable heart.

We received Humanitarian Device Exemption, or HDE, approval from the FDA for the AbioCor in September 2006. HDE approval signifies that no comparable alternative therapy exists for patients facing imminent death without the technology. Under this approval, only a limited number of patients may receive the AbioCor per year. Under HDE approval, the FDA may request a panel review of the post-approval study data.

We expect to begin selling the AbioCor in late calendar 2007 in a controlled roll-out to approximately five heart centers in the U.S. We expect eventually to expand availability to up to ten hospitals in the U.S., including qualified clinical trial sites and additional qualified centers once they have completed a comprehensive and rigorous training program. We expect this training period to take six to eight months. We are unable to determine how many patient procedures will be performed after the respective centers are trained. We do not expect that revenues from sales of the AbioCor will be a material portion of our total revenues for the foreseeable future.

### ***Cannulae***

Each of our AB5000 and BVS 5000 systems requires two cannulae, or tubes that connect the ventricle or blood pump to the heart and an associated artery. We offer a variety of cannulae. We recently introduced our new integrated cannula system, which was approved by the FDA in July 2006. The new cannula, which is easier to implant and can be removed through a small incision, has the potential for use off-pump (also called beating heart) with minimally invasive procedures. For example, although removal of the cannulae requires a surgical procedure, it does not require a sternotomy, a substantially more invasive procedure that separates the breastbone in order to access the heart. Moreover, because the AB5000 and the BVS 5000 blood pumps use the same cannulae, clinicians can seamlessly transfer patients from one device to another without requiring an additional surgical procedure.

## **Research and Product Development**

Our research and development efforts are focused on developing a broader portfolio of products across the continuum of care in heart recovery, primarily focused in the area of circulatory care. In the past few years, our research and development efforts have helped us to significantly expand our product portfolio, and we have eight disposable products that have either been approved or cleared by the FDA or have received CE mark approval. In addition, we have a number of new products at various stages of development.

In January 2007 we announced that we are conducting pre-clinical trials for a catheter-based heart pump to provide left-ventricular support to pediatric patients. This device is similar to the Impella 2.5 and is intended to provide support to patients requiring preconditioning before a cardiac intervention, or to recover patients who cannot be weaned from bypass, or who have myocarditis. We have designed the technology to operate as either a pulsatile device that can provide up to 120 beats per minute or as a continuous flow device. We estimate that the device will provide circulatory support for approximately two weeks.

Over the last 25 years, we have gained substantial expertise in circulatory support while developing our AbioCor Implantable Replacement Heart, the first completely self-contained artificial heart. We used this expertise to develop the AB5000, and we intend to continue to use this experience to develop additional circulatory care products. We are also working on our next-generation implantable replacement heart, the AbioCor II, which is approximately 30% smaller than the existing AbioCor and is being designed with a goal of five-year reliability.

We cannot assure you that any of our products under development will achieve the intended clinical goals or that any of them will receive regulatory approval for commercial sale in the United States or abroad.

As of March 31, 2007, research and development staff consisted of 82 professional and technical personnel, including 28 engineers with advanced degrees, covering disciplines such as electrical engineering, mechanical engineering, computer science, reliability engineering, fluid mechanics, materials and physiology.

We expended \$13.4 million, \$16.7 million, and \$22.3 million on research and development in fiscal years 2005, 2006, and 2007, respectively. Our research and development expenditures include costs related to clinical trials, including ongoing pilot clinical trials for our Impella products.

## **Sales, Clinical Support, Marketing and Field Service**

As of March 31, 2007, our worldwide sales, clinical support, marketing and field service teams included 87 full-time employees, 64 of whom are in the U.S. and 23 of whom are in Europe. Since March 31, 2004, we have increased the number of our direct sales and clinical personnel from 17 to 60 employees covering the U.S., France and Germany. In the U.S., we now have 26 direct sales representatives and 17 clinical support personnel.

Our clinical support personnel consist primarily of registered nurses with experience in either the surgery suite or the cath lab, and they play a critical role in training current and prospective customers in the use of our products. To enhance our global distribution and to augment our efforts to establish recovery as the goal for all acute cardiac attacks, we intend to increase our global sales and clinical headcount by approximately two to four sales and clinical employees per quarter during fiscal year 2008.

As of March 31, 2007, we have international sales and distribution agreements for select products in Australia, China, Italy, Japan, Latin America and Spain. We also use distributors in certain European and Middle Eastern countries where we have chosen not to sell directly to medical centers. In fiscal years 2005, 2006, and 2007, approximately 8%, 13%, and 11%, respectively, of our product revenues were derived from international sales.

We recently entered into a five-year distribution agreement with Medix Japan Inc. The agreement provides for distribution of our AB5000, BVS 5000, and Impella 2.5 and 5.0 products following regulatory approval in Japan. Medix intends to initiate clinical trials in Japan during our fiscal year 2008. The agreement includes a minimum purchase commitment of \$11 million for the Impella products within the first 18 months following Impella regulatory approvals in Japan. The agreement also includes a minimum purchase commitment of \$5 million for our other products that begins in our first quarter of fiscal year 2008. If the purchase commitments are not met, our available remedy is to terminate the agreement.

## **Manufacturing**

We manufacture our products in Danvers, Massachusetts and Aachen, Germany. Our United States operations manufacture the BVS 5000, AB5000, AbioCor, IAB, iPulse, and other products under development. Our Aachen, Germany facility manufactures all of our Impella

products and other products under development. In addition, we rely on third-party suppliers to provide us with some components used in our existing products and products under development. For example, we outsource the manufacturing of all of our consoles, other than final assembly and testing.

We believe our existing manufacturing facilities give us the physical capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months. However, we will continue to monitor market conditions and demand and evaluate the potential need for expanded capacity in the future. Both of our manufacturing facilities are ISO 13485:2003 certified and operate under the FDA's good manufacturing practice requirements set forth in the current quality system regulation, known as QSR.

## **Intellectual Property**

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

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

As of May 31, 2007, we own or have rights to 69 U.S. patents and at least 95 foreign patents. Of our U.S. patents, 19 are related to the AbioCor Implantable Replacement Heart, 17 are related to Impella products and 23 are related to other technologies. Our portfolio also includes ten patents related to an artificial heart developed by the Pennsylvania State University, to which we have an exclusive worldwide license. Our U.S. patents have expiration dates ranging from June 17, 2007 to October 24, 2026. Of our foreign patents, one is related to the BVS 5000 Biventricular Support System and 94 are related to Impella products. Our foreign patents have expiration dates ranging from April 4, 2016 to August 8, 2023. We also own or have rights to certain pending U.S. and foreign patent applications. We believe patents will issue pursuant to such applications, but cannot guarantee it. Moreover, neither the timing of any issuance, the scope of protection, nor the actual issue date of these pending applications can be forecasted with precision. Where we have licensed patent rights from third parties, we are generally required to pay royalties.

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

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

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

## **Competition**

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

Our customers frequently have limited budgets. As a result, our products compete against a broad range of medical devices and other therapies for these limited funds. Our success will depend in large part upon our ability to enhance our existing products, to develop new products to meet regulatory and customer requirements, and to achieve market acceptance. We believe that important competitive factors with

respect to the development and commercialization of our products include the relative speed with which we can develop products, establish clinical utility, complete clinical trials and regulatory approval processes, obtain reimbursement, and supply commercial quantities of the product to the market.

The AB5000 and BVS 5000 systems can assume the full pumping function of the heart. The FDA approved these systems as recovery devices for the treatment of patients with potentially reversible heart failure. These products compete with a temporary cardiac assist device from Thoratec Corporation, which is also capable of assuming the full pumping function of the heart and is today approved for post-cardiotomy support only. The Thoratec device was originally approved for bridge-to-transplant indications, and we believe bridge-to-transplant continues to be the primary use of the device. In addition, the AB5000 and BVS 5000 compete with other blood pumps that are used in medical centers for a variety of applications, such as intra-aortic balloon pumps, including those offered by Datascope and Arrow International, and centrifugal pumps. Levitronix is conducting clinical trials in the U.S. for a device that may compete with our heart assist products in some applications. Levitronix has licensed this product to Thoratec Corporation for distribution in the U.S. To our knowledge, these pumps are not FDA approved. These pumps are cleared under a 510(k) in which their labeling does not allow for specific indications beyond 6 hours of use. These pumps are limited to either providing partial pumping support of failing hearts, or are non-pulsatile, or are not recommended for the duration of support generally required for recovery. The FDA provided 510(k) clearance for a product designed by CardiacAssist, Inc. that may compete with our products. Approval by the FDA of products that compete directly with our products could increase competitive pricing and other pressures. We believe that we will compete with such products based primarily on clinical effectiveness based on scientific evidence, global customer relationships, and customer relations.

We are aware of other heart replacement device research efforts in the U.S., Canada, Europe and Japan, but we are not aware of any plans for any other totally implantable replacement heart to commence clinical trials in the U.S. or anywhere in the world. 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 biventricular failure. Unlike our AbioCor, the CardioWest heart is not fully implantable. In addition, there are a number of companies—including Thoratec Corporation, Jarvik Heart, HeartWare, World Heart Corporation, MicroMed Technology, Ventracor and several early-stage companies—that are developing permanent heart assist products, including implantable left ventricular assist devices, or LVADs, and miniaturized rotary ventricular assist devices, that may address markets that overlap with certain segments of the markets targeted by our products. In addition to these devices, several companies and institutions have been for many years investigating xenotransplantation, the transplantation of a heart from another species, as a potential therapy. Research is also being conducted by others to develop gene and cell therapy potentially to reverse the disease process or to supplant diseased heart cells.

### **Third-Party Reimbursement**

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

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

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

Coverage and reimbursements for procedures to implant, remove, replace or repair the AB5000 and BVS 5000 are well-established in the United States market. For instance, Medicare covers the use of VADs, such as our AB5000 and BVS 5000 devices, when used for support of blood circulation post-cardiotomy, as a temporary life-support system until a human heart becomes available for transplant, or as therapy for patients who require permanent mechanical cardiac support. Medicare does not, however, cover the use of VADs as a permanent replacement

for the human heart or artificial heart. CMS recently increased Medicare reimbursement for patients that recover during an in-patient stay using external VADs, such as our AB5000 and BVS 5000 devices, to levels similar to those for patients who undergo heart transplants. Reimbursements for patients who do not recover remain at lower levels.

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

Coverage and reimbursement in the United States for our other products will depend upon, among other things, our ability to obtain the FDA approvals or clearances to market such products. If and when we obtain FDA approval or clearance for our new products, such as our Impella products and iPulse console, we anticipate that third-party payers, including both CMS and commercial insurance companies, will reimburse hospitals and physicians under existing billing codes or general procedural codes for newer technologies and we believe that procedures targeted for use with our products are generally already reimbursable under governmental programs and most private plans. Although certain costs associated with the use of our Impella 2.5 and 5.0 products in qualifying clinical trials are reimbursed, we cannot assure you that, if these products receive FDA approval or clearance, the commercial use of these products will also be reimbursed.

Medicare does not cover the use of artificial hearts, either as a permanent replacement for a human heart or as a temporary life-support system until a human heart becomes available for transplant. This means that our AbioCor system, when used as a replacement for the human heart, is not covered by Medicare. In December 2006, the Medicare Evidence Development and Coverage Advisory Committee, a Medicare advisory group that offers expert clinical advice, recommended to CMS that Medicare cover and reimburse the costs of HDE-approved technologies, such as our AbioCor system, when used in qualifying clinical studies. However, CMS is not required to follow the recommendations of its advisory group or otherwise incorporate their recommendations into coverage policy. In April 2007, CMS issued a draft of its clinical trial policy that did not include this recommendation. The policy is subject to public comment and a final decision is expected in July 2007. If the final coverage policy does not include the recommendation of the committee, we intend to seek other potential avenues for reimbursement of our AbioCor system.

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

## **Government Regulation**

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

### ***Premarket Regulation***

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

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

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

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

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

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

Certain Class III devices that were on the market before May 28, 1976, known as preamendments Class III devices, and devices that are determined to be substantially equivalent to them, can be brought to market through the 510(k) process until the FDA, by regulation, calls for PMA applications for the devices. In addition, the FDCA requires the FDA either to down-classify preamendments Class III devices to Class I or Class II, or to publish a classification regulation retaining the devices in Class III. Manufacturers of preamendments Class III devices that the FDA retains in Class III must have PMA applications accepted by the FDA for filing within 90 days after the publication of a final regulation in which the FDA calls for PMA applications. Failure to meet the deadline can lead the FDA to prevent continued marketing of the device during the PMA application review period. The IAB received 510(k) clearance as a preamendments Class III device. The Impella 2.5 for short duration use would also be a preamendments Class III device, if 510(k) clearance is obtained. If the FDA calls for a PMA for a preamendments Class III device, a PMA must be submitted for the device even if the device has already received 510(k) clearance; however, if the FDA down-classifies a preamendments Class III device to Class I or Class II, a PMA application will not be required.

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

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

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

In addition, certain devices can be distributed under a Humanitarian Device Exemption, or HDE, rather than a PMA. In order for a device to be eligible for an HDE, a qualifying target patient population of less than 4,000 patients per year for which there is no other available therapy must be approved by the FDA. The FDA's approval of an HDE to treat that qualifying patient population then requires

demonstration that the device is safe for its intended application, that it is potentially effective, and that the probable benefits outweigh the associated risks.

Our AB5000 and BVS 5000 systems are approved by the FDA for heart recovery for patients who have undergone successful cardiac surgery and subsequently develop low cardiac output, or patients who suffer from acute cardiac disorders leading to hemodynamic instability. In 1992, the FDA approved our PMA for the BVS 5000. In 1996 and 1997, the FDA approved the use of the BVS 5000 for additional indications, expanding its use to the treatment of all patients with potentially reversible heart failure. In April 2003, the AB5000 Circulatory Support System Console was approved under a PMA supplement, and in September 2003 a PMA supplement for the AB5000 blood pump was approved.

To support applications for premarket approval, we have begun pilot clinical trials for our Impella 2.5 and 5.0 products in the U.S. In the Impella 2.5 pilot trial, the proposed indication for use of our Impella 2.5 is support during high-risk angioplasty and subsequent to the procedure for up to five days. In the Impella 5.0 pilot trial, the proposed indication for use includes post-cardiotomy patients who have been weaned from the heart-lung machine but could potentially benefit from some hemodynamic support. We may conduct additional clinical trials in the future to address additional indications for use.

In May 2006, we announced that our primary regulatory pathway for the Impella 2.5 will be to seek PMA approval. Based on our current clinical trial, we expect that we will initially seek approval of the device for the support of high-risk angioplasty. In April 2007, we announced the completion of the enrollment of 20 patients in the pilot clinical trial of the Impella 2.5. The trial will be completed after we have concluded all necessary post-enrollment patient monitoring. In addition, we announced in February 2007 that we had also made a submission seeking 510(k) clearance for the Impella 2.5 for short duration use (up to six hours). The FDA recently responded to our 510(k) submission 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. 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 to the FDA attempting to demonstrate that the device does not raise a new question of safety or effectiveness, and we believe that our response 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. We will continue our primary regulatory pathway of seeking PMA approval of the Impella 2.5 while we respond to current and any future inquiries from the FDA on the pending 510(k) clearance submission. If we receive 510(k) clearance from the FDA for short duration use, we intend to launch the Impella 2.5 for commercial sale in the U.S. for that use while continuing the PMA pathway for the Impella 2.5 to obtain FDA approval to promote the Impella 2.5 for high-risk angioplasty and/or other specific indications for longer-term support.

We received FDA clearance for our new IAB in December 2006. We have submitted our iPulse console for FDA approval by filing a PMA supplement to the PMA for our existing AB5000 console.

In January 2001, the FDA granted an IDE providing us with regulatory permission to commence the initial clinical trial of the AbioCor. In September 2003, a Humanitarian Use Device designation was approved by the Office of Orphan Product Development, paving the way for our HDE submission in September 2004. In September 2006 we received HDE approval from the FDA for the AbioCor.

### ***Postmarket Regulation***

The medical devices that we manufacture and distribute pursuant to FDA clearances or approvals are subject to continuing regulation by the FDA and other regulatory authorities. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. Among other FDA requirements, we must comply with the FDA's good manufacturing practice regulations. These QSR regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of all finished medical devices intended for human use. We must also comply with Medical Devices Reporting, or MDR, which requires that a firm report to the FDA any incident in which its product may have caused or contributed to a death or serious injury, or in which its product malfunctioned and, if the malfunction were to recur, it would be likely to cause or contribute to a death or serious injury. Labeling, advertising, and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

We are subject to routine inspection by the FDA and other regulatory authorities for compliance with QSR and MDR requirements, as well as other applicable regulations. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, and require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also impose

operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal fines and penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice.

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

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

### ***International Regulation***

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

### **Fraud and Abuse Laws**

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

### ***Anti-Kickback Statute***

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

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

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

We have various arrangements with customers and physicians 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 protections, 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 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.

If our operations are found to be in violation 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. Any penalties, damages, fines, or curtailment or restructuring of our operations 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 some 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 could 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.

#### ***Federal False Claims Act***

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

#### ***HIPAA***

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

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

#### **Employees**

As of March 31, 2007, we had 324 full-time employees, including:

- 82 in product engineering, research and development, and regulatory;
- 87 in sales, clinical support, marketing and field service;
- 91 in manufacturing and quality control; and
- 64 in general and administration.

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

**Our Corporate Information**

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

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

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

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

### **Risks Related to Our Business**

***We have not operated at a profit and do not expect to be profitable in our fiscal year 2008.***

We have had net losses in each of the past three fiscal years. We plan to make significant expenditures in fiscal 2008 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 2008 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. 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. 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 that our response 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 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 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;
- 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 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 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:

- developing our global sales and marketing infrastructure and capabilities;
- expanding manufacturing capacity, maintaining quality and increasing production;
- expansion of foreign regulatory compliance capabilities;

- implementing appropriate operational and financial systems and controls;
- identifying, attracting and retaining qualified personnel, particularly experienced clinical staff; and
- training, managing and supervising our personnel worldwide.

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

***The markets for most of our products and products under development are 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, AbioCor, AbioCor II and other new 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;
- 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 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, and 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, and 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 principal products and current primary source of revenues, the AB5000 and BVS 5000, are vulnerable to competitive pressures.***

To date, we have derived most of our product revenues from sales of the AB5000 and BVS 5000. We believe that we will continue to rely heavily on these products for at least the next several years until we obtain U.S. regulatory approval for new products, including our Impella products and iPulse console. Moreover, we expect to rely increasingly on sales of the AB5000, as sales of the BVS 5000 have been declining. 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. 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 AB5000 consoles have a disproportionate effect on our revenues, because the price of the console is substantially greater than the price of our disposable blood pumps. 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.

***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. We do not have experience in manufacturing our Impella products in the commercial quantities that might be required if we receive FDA approval of those products, nor do we have experience manufacturing our AB5000, IAB and AbioCor 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.

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

We manufacture our Impella micro heart pumps at our facility in Aachen, Germany, and we manufacture our other products at our facility in Danvers, Massachusetts. 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.

***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 and our iPulse consoles 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 current commercial 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. The cost of our AB5000 systems, BVS 5000 systems, Impella micro heart pumps, and iPulse consoles is substantial, and the cost of implanting the AbioCor in a patient will also be substantial. 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. With regard to the AbioCor, there is a Medicare noncoverage decision for artificial hearts that would prevent Medicare coverage of the services related to the implantation of that device, and that may deter coverage by private insurers. We cannot be sure that third-party payers will cover and/or adequately reimburse sales of our Impella products, iPulse console, AbioCor 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 health care 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 and iPulse consoles. Any reduction in the amount of this reimbursement could harm our business.

***Changes in health care reimbursement systems in the United States and abroad could reduce our revenues and profitability.***

The federal government has considered ways to change, and has changed, the manner in which healthcare services are provided and paid for in the U.S. Occasionally, 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. Future legislative and regulatory initiatives could be introduced that adversely affect demand for our products and have a material adverse impact on our revenues. Our business and results of operations could therefore be adversely affected by future healthcare reforms.

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.

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.

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 the 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. 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. 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 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 with required components when we need them. These factors could make it more difficult for us to effectively and efficiently manufacture our products, and could adversely impact our results of operations.

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, BVS 5000 and Impella circulatory assist systems, as well as our iPulse console, by recruiting direct sales and support teams in Germany and France. Our international operations 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.

***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;
- 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 micro heart pumps, IAB, iPulse console, AbioCor, AbioCor II and other new products or product enhancements;
- costs we incur in anticipation of future sales, such as inventory purchases, expansion of manufacturing facilities, or establishment of international sales offices;
- economic conditions in the health care 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 experimentation credit carryforwards.***

At March 31, 2007, we had federal and state net operating loss carryforwards of approximately \$79.2 million and \$36.9 million, respectively, which begin to expire in fiscal 2008. At March 31, 2007, we also had foreign net operating loss carryforwards of approximately \$20.6 million that can be carried forward indefinitely. Additionally, at March 31, 2007, we had federal and state research and experimentation credit carryforwards of approximately \$6.3 million and \$4.3 million, respectively, which begin to expire in fiscal 2008. Ownership changes, as defined in Section 382 of the Internal Revenue Code, may have limited the amount of net operating loss carryforwards and research and experimentation credit carryforwards that we can use each year to offset future taxable income and taxes payable. Subsequent ownership changes could impose additional limitations. We have not done a complete analysis to determine whether changes in the composition of our stockholders, including as a result of our acquisition of Impella or our recent public offering, have resulted or will result in an ownership change for purposes of Section 382. We cannot assure you that we will obtain any benefit from any of our net operating loss carryforwards and research and experimentation credit carryforwards.

***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 micro heart pumps, iPulse console, AbioCor, AbioCor II 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.

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

The development, manufacture and sale of any medical device in the United States 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 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 the AB5000, BVS 5000, Impella products, AbioCor or AbioCor II could adversely affect our business and our prospects.

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, and 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. Finally, 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.

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.

***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.

***Future milestone payments relating to our acquisition of Impella could harm our financial position or result in dilution.***

We may be required to make additional contingent payments of up to \$11.2 million under the terms of our acquisition of Impella, based on our future stock price performance and milestones related to FDA approval of Impella's products. If we pay any milestone payment in shares of our common stock, our stockholders may experience dilution. If we use cash to make any such payment, our financial resources will be diminished and we may be unable to pursue other activities, such as research and development, the expansion of our sales force or the acquisition of other new products.

***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 for post-cardiotomy support. In addition, the AB5000 and BVS 5000 compete with other blood pumps that are used in medical centers for a variety of applications, such as intra-aortic balloon pumps, including those offered by 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 Corporation 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 biventricular failure. In addition, there are a number of companies—including Thoratec Corporation, Jarvik Heart, Heartware, World Heart Corporation, MicroMed Technology, Ventracor and several early-stage companies—that are developing permanent heart assist products, including implantable left ventricular assist devices and miniaturized rotary ventricular assist devices.

***If we acquire other companies or businesses, we will be subject to risks that could hurt our business.***

We may pursue acquisitions to obtain complementary businesses, products or technologies. Any such acquisition may not produce the revenues, earnings or business synergies that we anticipate, and an acquired business, product or technology might not perform as we expect. Our management could spend a significant amount of time, effort and money in identifying, pursuing and completing the acquisition. If we complete an acquisition, we may encounter significant difficulties and incur substantial expenses in integrating the operations and personnel of the acquired company into our operations while striving to preserve the goodwill of the acquired company. In particular, we may lose the services of key employees of the acquired company, and we may make changes in management that impair the acquired company's relationships with employees and customers.

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use our stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced. We may be required to capitalize a significant amount of intangibles, including goodwill, which may lead to significant amortization charges. In addition, we may incur significant, one-time write-offs and amortization charges, such as our \$13.3 million write-off of in-process research and development expenses in connection with the Impella acquisition in fiscal 2006. These amortization charges and write-offs could decrease our future earnings or increase our future losses.

***Fluctuations in foreign currency exchange rates could result in declines in our reported sales and earnings.***

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign currency exchange rates, primarily the Euro. The functional currency of Abiomed Europe is the Euro. At present, we do not hedge our exposure to foreign currency fluctuations. As a result, sales occurring in the future that are denominated in foreign currencies may be translated into U.S. dollars at less favorable rates, resulting in reduced revenues and earnings.

**Risks Related to Our Common Stock**

***The market price of our common stock is volatile.***

The market price of our common stock has fluctuated widely and may continue to do so. For example, from March 31, 2006 to March 31, 2007 the price of our stock ranged from a high of \$16.19 per share to a low of \$11.48 per share. Many factors could cause the market price of our common stock to rise and fall. Some of these factors are:

- variations in our quarterly results of operations;
- the status of regulatory approvals for our products;
- the introduction of new products by us or our competitors;
- acquisitions or strategic alliances involving us or our competitors;

- changes in accounting principles;
- changes in health care policy or third-party reimbursement practices;
- changes in estimates of our performance or recommendations by securities analysts;
- the hiring or departure of key personnel;
- future sales of shares of common stock in the public market; and
- market conditions in the industry and the economy as a whole.

In addition, the stock market in general and the market for shares of medical device companies in particular have experienced extreme price and volume fluctuations in recent years. These fluctuations are often unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the market price of our common stock. When the market price of a company's stock drops significantly, stockholders often institute securities class action litigation against that company. Any litigation against us could cause us to incur substantial costs, divert the time and attention of our management and other resources, or otherwise harm our business.

***The sale of additional shares of our common stock, or the exercise of outstanding options and warrants to purchase our common stock, could dilute our stockholders' ownership interest.***

We have issued a substantial number of options and warrants to acquire our common stock, and we expect to continue to issue options to our employees and others. If all outstanding stock options and warrants were exercised, our stockholders would suffer dilution of their ownership interest. In addition, in connection with our acquisition of Impella CardioSystems AG in 2005, we may be obligated to make certain milestone payments. These payments may be made in stock, which would also result in a dilution of our stockholders' ownership interest.

***The sale of material amounts of common stock could encourage short sales by third parties and depress the price of our common stock. As a result, our stockholders may lose all or part of their investment.***

The downward pressure on our stock price caused by the sale of a significant number of shares of our common stock, or the perception that such sales could occur by any of our significant stockholders could cause our stock price to decline, thus allowing short sellers of our stock an opportunity to take advantage of any decrease in the value of our stock. The presence of short sellers in our common stock may further depress the price of our common stock.

***Our rights distribution, certificate of incorporation and Delaware law could make it more difficult for a third party to acquire us and may prevent our stockholders from realizing a premium on our stock.***

Our rights distribution and provisions of our certificate of incorporation and of the Delaware General Corporation Law may make it more difficult for a third party to acquire us, even if doing so would allow our stockholders to receive a premium over the prevailing market price of our stock. Our rights distribution and those provisions of our certificate of incorporation and Delaware law are intended to encourage potential acquirers to negotiate with us and allow our Board of Directors the opportunity to consider alternative proposals in the interest of maximizing stockholder value. However, such provisions may also discourage acquisition proposals or delay or prevent a change in control, which could negatively affect our stock price.

***The market value of our common stock could vary significantly, based on market perceptions of the status of our development efforts.***

The perception of securities analysts regarding our product development efforts could significantly affect our stock price. As a result, the market price of our common stock has and could in the future change substantially when we or our competitors make product announcements. Many factors affecting our stock price are industry related and beyond our control.

***We have not paid and do not expect to pay dividends, and any return on our stockholders' investment will likely be limited to the value of our common stock.***

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic

factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on our stockholders' investment will only occur if our stock price appreciates.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our headquarters are in an industrial office park located 22 miles north of Boston. This facility, located at 22 Cherry Hill Drive in Danvers, Massachusetts, consists of approximately 80,000 square feet of space under an operating lease that expires in 2010. This facility houses all of our U.S. operations, including research and development, manufacturing, sales and marketing and general and administrative departments. Under the terms of the lease, we have two five-year options to extend our lease term beyond 2010 at market rates. We have also recently entered into a short-term lease for office space in Washington, DC.

Our European headquarters are located in Aachen, Germany in a leased facility of approximately 33,000 square feet. Our lease expires in December 2012. The building houses all of the research and development and manufacturing operations for our Impella product line as well as the sales, marketing and general and administrative functions for most of our product lines sold in Europe and the Middle East. In addition, we recently leased an approximately 270 square foot office in France, which will focus on the sales and marketing of our product lines sold in France.

**ITEM 3. LEGAL PROCEEDINGS**

On May 15, 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a Demand for Arbitration (subsequently amended) with the Boston office of the American Arbitration Association. The claim arises out of our purchase of intellectual property rights relating to the Penn State Heart and the acquisition of BeneCor Heart Systems. The claim seeks 600,000 unrestricted shares of Abiomed common stock and attorneys' fees for an alleged breach of our obligation to fund development of the Penn State Heart program and an alleged cancellation of the Penn State Heart development project. We instituted a legal action in Federal Court to determine the arbitrability of the claims asserted and the Federal Court has stayed the arbitration of a portion of the claim. The arbitration hearings have been completed and we are awaiting a decision.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended March 31, 2007.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Market Price

Our common stock is traded on the Nasdaq Global Market under the symbol "ABMD." The following table sets forth the range of high and low sales prices per share of common stock, as reported by the Nasdaq Global Market for our two most recent fiscal years:

<b>Fiscal Year Ended March 31, 2006</b>	<b>High</b>	<b>Low</b>
First Quarter	\$11.91	\$ 7.75
Second Quarter	10.97	8.31
Third Quarter	10.15	7.81
Fourth Quarter	13.40	9.12
<b>Fiscal Year Ended March 31, 2007</b>	<b>High</b>	<b>Low</b>
First Quarter	\$14.14	\$11.48
Second Quarter	16.19	12.25
Third Quarter	15.65	12.07
Fourth Quarter	15.10	12.12

#### Number of Stockholders

As of June 6, 2007, we had approximately 739 holders of record of our common stock and approximately 10,624 beneficial holders of our common stock. Many beneficial holders hold their stock through depositories, banks and brokers included as a single holder in the single "street" name of each respective depository, bank, or broker.

#### Dividends

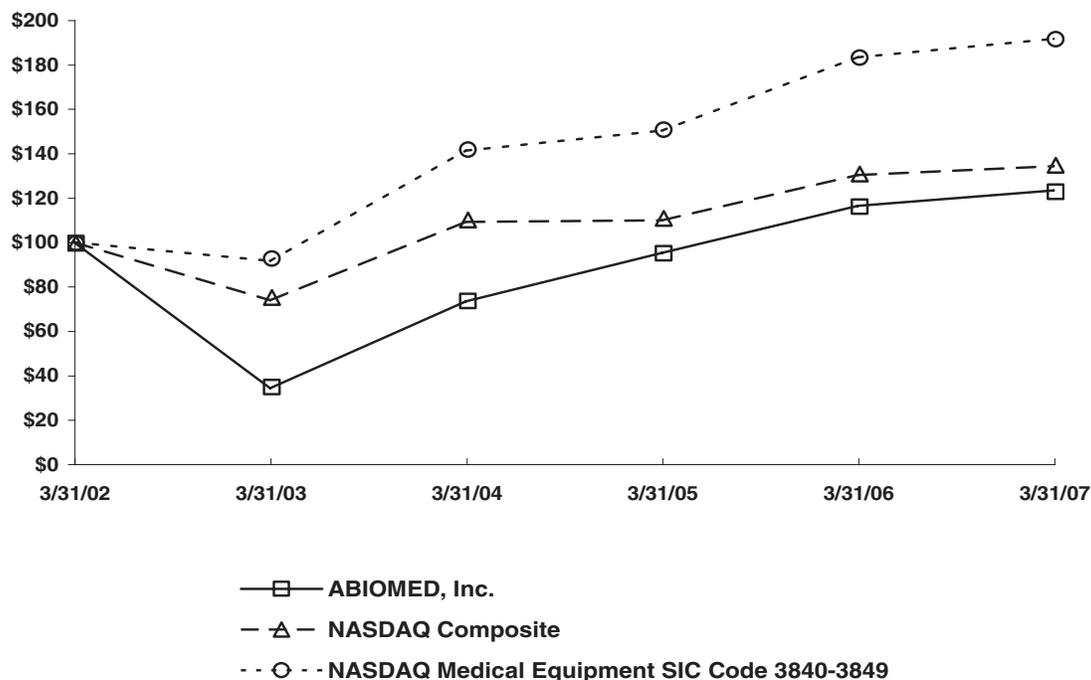
We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We anticipate that we will retain all of our future earnings, if any, to support operations and to finance the growth and development of our business. Our payment of any future dividends will be at the discretion of our board of directors and will depend upon our financial condition, operating results, cash needs and growth plans.

## Performance Graph

The following graph compares the yearly change in the cumulative total stockholder return for our last five full fiscal years, based upon the market price of our common stock, with the cumulative total return on a Nasdaq Composite Index (U.S. Companies) and a peer group, the Nasdaq Medical Equipment-SIC Code 3840-3849 Index, which is comprised of medical equipment companies, for that period. The performance graph assumes the investment of \$100 on March 31, 2002 in our Common Stock, the Nasdaq Composite Index (U.S. Companies) and the peer group index, and the reinvestment of any and all dividends.

### COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\*

Among ABIOMED, Inc., The NASDAQ Composite Index  
And The NASDAQ Medical Equipment SIC Code 3840-3849 Index



\* \$100 invested on 3/31/02 in stock or index-including reinvestment of dividends.  
Fiscal year ending March 31.

	Cumulative Total Return (\$)					
	3/31/02	3/31/03	3/31/04	3/31/05	3/31/06	3/31/07
ABIOMED, Inc.	100.00	35.14	73.78	95.32	116.22	123.06
Nasdaq Composite Index	100.00	74.26	109.10	109.77	129.91	133.87
Nasdaq Medical Equipment SIC Code 3840-3849	100.00	91.78	140.83	149.72	182.27	190.47

This graph is not "soliciting material" under Regulation 14A or 14C of the rules promulgated under the Securities Exchange Act of 1934, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference in any of our filings under the Securities Act of 1933, as amended, or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

## Sales of Unregistered Securities

As described in our current report on Form 8-K dated January 30, 2007 and filed on February 5, 2007, on January 30, 2007 we issued 402,279 shares of our common stock to the former shareholders of Impella CardioSystems AG.

## Transfer Agent and Rights Agent

American Stock Transfer & Trust Company, 59 Maiden Lane, New York, NY 10038, is our stock Transfer Agent and Rights Agent.

**ITEM 6. SELECTED FINANCIAL DATA**

**SELECTED CONSOLIDATED FINANCIAL DATA**

(In thousands, except per share data)

	Fiscal Years Ended March 31,				
	2003	2004	2005	2006	2007
<b>Statement of Operations Data:</b>					
Revenue:					
Products	\$ 23,127	\$ 25,070	\$ 37,945	\$ 43,322	\$ 50,408
Funded research and development	183	669	271	348	241
	<u>23,310</u>	<u>25,739</u>	<u>38,216</u>	<u>43,670</u>	<u>50,649</u>
Costs and expenses:					
Cost of product revenue excluding amortization of intangibles	7,501	7,591	9,366	11,685	12,012
Research and development	20,206	14,150	13,350	16,739	22,292
Selling general and administrative	14,667	14,037	18,566	30,923	42,448
Expensed in-process research and development	—	—	—	13,306	800
Amortization of intangibles	427	213	187	1,308	1,608
	<u>42,801</u>	<u>35,991</u>	<u>41,469</u>	<u>73,961</u>	<u>79,160</u>
Loss from operations	(19,491)	(10,252)	(3,253)	(30,291)	(28,511)
Interest and other income, net	1,320	806	911	1,198	1,105
Loss before provision before income taxes	(18,171)	(9,446)	(2,342)	(29,093)	(27,406)
Provision for income taxes	—	—	—	356	475
Net loss	<u>\$(18,171)</u>	<u>\$ (9,446)</u>	<u>\$ (2,342)</u>	<u>\$(29,449)</u>	<u>\$(27,881)</u>
Basic and diluted net loss per share	<u>\$ (0.87)</u>	<u>\$ (0.45)</u>	<u>\$ (0.11)</u>	<u>\$ (1.15)</u>	<u>\$ (1.03)</u>
Weighted average shares outstanding	<u>20,994</u>	<u>21,153</u>	<u>21,845</u>	<u>25,649</u>	<u>27,124</u>
<b>Balance Sheet Data:</b>					
	March 31,				
	2003	2004	2005	2006	2007
Cash, cash equivalents, marketable securities and long-term investments	\$ 54,449	\$ 45,483	\$ 43,617	\$ 30,835	\$ 75,125
Working capital	56,987	32,096	50,342	37,704	83,485
Total assets	68,516	59,161	61,061	78,537	136,183
Stockholders' equity	62,090	54,336	56,179	69,488	122,095
Dividends	—	—	—	—	—

*Note: Fiscal year 2006 and fiscal year 2007 include the results of operations attributable to Impella from the date of acquisition, May 10, 2005. Information about our acquisition of Impella is set forth in Note 8 of our consolidated financial statements included in this report.*

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*All statements, trend analysis and other information contained in the following discussion relative to markets for our products and trends in sales, gross profit and anticipated expense levels, as well as other statements, including words such as "may," "anticipate," "believe," "plan," "estimate," "expect," and "intend" and other similar expressions constitute forward-looking statements. These forward-looking statements are subject to business and economic risks and uncertainties, and our actual results of operations may differ materially from those contained in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under Item 1A Risk Factors as well as other risks and uncertainties referenced in this report.*

### Overview

We are a leading provider of medical devices in circulatory support and we offer a continuum of care in heart recovery to acute heart failure patients. Our 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 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 in pre-shock or in need of prophylactic support in the cardiac catheterization lab, or cath lab. We are focused on increasing awareness of heart recovery and establishing it as the goal for patients with failing but potentially recoverable hearts. We expect recovery awareness and utilization of our products will 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 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.

### Critical Accounting Policies

#### *Estimates*

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, inventories, impairment of intangible assets and goodwill, income taxes including the valuation allowance for deferred tax assets, stock based compensation, valuation of long-lived assets and investments, contingencies and litigation. We base our estimates on historical experiences and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimated or assumed.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

#### *Revenue Recognition*

We recognize revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable, and collectibility is reasonably assured in accordance with the SEC Staff Accounting Bulletin No. 104 ("SAB 104"). Revenue from product sales to new customers is deferred until training on the use of the products has occurred. All costs related to product shipment are recognized at time of shipment. We do not provide for rights of return to customers on product sales.

Maintenance and service support contract revenues are recognized ratably over the term of the service contracts based upon the elapsed term of the service contract. In limited instances, we also rent console medical devices on a month-to-month basis or for a longer specified period of time to customers for which revenue is recognized as earned.

Government-sponsored research and development contracts and grants generally provide for payment on a cost-plus-fixed-fee basis. Revenues from these contracts and grants are recognized as work is performed, provided the government has appropriated sufficient funds for the work. Under contracts in which we elect to spend significantly more on the development project during the term of the contract than the

total contract amount, we prospectively recognize revenue on such contracts ratably over the term of the contract as related research and development costs are incurred, provided the government has appropriated sufficient funds for the work.

#### *Intangibles*

We estimate the fair value of acquisition-related intangible assets principally based on projections of cash flows that will arise from identifiable intangible assets of acquired businesses. The projected cash flows are discounted to determine the present value of the assets at the dates of acquisition. We review intangible assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Factors considered important which could trigger an impairment review include significant changes relative to: (i) projected future operating results; (ii) the use of the assets or the strategy for the overall business; (iii) business collaborations; and (iv) industry, business, or economic trends and developments. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If it is determined that the carrying value of intangible assets may not be recoverable, the asset is written down to its estimated fair value on a discounted cash flow basis. The net book value of intangible assets at March 31, 2007 was approximately \$7.3 million.

#### *Goodwill*

We periodically evaluate goodwill for impairment using forecasts of discounted future cash flows. Estimates of future cash flows require assumptions related to revenue and operating income growth, asset-related expenditures, working capital levels and other factors. Different assumptions from those made in our analysis could materially affect projected cash flows and our evaluation of goodwill for impairment. Should the fair value of goodwill decline because of reduced operating performance, market declines, delays in regulatory approval, or other indicators of impairment, or as a result of changes in the discount rate, charges for impairment of goodwill may be necessary. We performed our annual impairment review for fiscal 2007 as of October 31, 2006 and determined that goodwill was not impaired. The carrying amount of goodwill at March 31, 2007 was \$26.7 million.

#### *Allowance for Doubtful Accounts*

We regularly monitor collections and payments from our customers and maintain a provision for estimated losses based upon our historical experience and any specific customer collection issues that we have identified. Although such credit losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same credit loss rates that we have in the past. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances would be required.

#### *Warranties*

Our products are subject to rigorous regulation and quality standards. Although we have established extensive product quality programs and processes, including monitoring and evaluating the quality of our component suppliers, we record a warranty obligation related to anticipated product failure rates and product recalls. Our Consoles are covered by a one-year limited manufacturer's warranty. We estimate and record a warranty obligation in cost of revenue at the time of shipment and we record any additional amounts when we determine that such costs are probable and we can reasonably estimate them. Historically, our warranty provision has not been substantial; however, our operating results could be adversely affected if the actual cost of any product failures, including product recalls, exceeds our estimated warranty provision.

#### *Inventories*

We value our inventory of products held for sale at the lower of cost or current estimated market value. We regularly review inventory quantities on hand and write down to its net realizable value any inventory believed to be impaired. If actual demand or market conditions are less favorable than projected demand, additional inventory write-downs may be required that could adversely impact financial results for the period in which the additional excess or obsolete inventory is identified. We recorded write-downs of inventory in the amount of \$0.0 million, \$0.4 million, and \$0.2 million for fiscal 2005, 2006 and 2007, respectively.

#### *Stock-Based Compensation*

In fiscal 2007, in accordance with Statements of Financial Accounting Standards ("SFAS") No. 123(R) *Share-Based Payment*, we began recording stock-based compensation in our statement of operations based on the fair value method, rather than the intrinsic method. This expense is determined after consideration of several significant judgments and estimates. The fair value of each stock option we granted is

estimated using the Black-Scholes option pricing model. Use of a valuation model requires us to make certain assumptions with respect to selected model inputs. The risk-free interest rate is based on the United States Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on a combination of the historical volatility of our stock and adjustments for factors not reflected in historical volatility that are more indicative of future volatility. By using this combination, we are taking into consideration estimates of future volatility that we believe will differ from historical volatility as a result of product diversification and our acquisition of Impella. The average expected life was estimated using the simplified method for determining the expected term as prescribed by the SEC's Staff Accounting Bulletin No. 107 *Share-based Payment*. The calculation of the fair value of the options is net of estimated forfeitures. Forfeitures are estimated based on an analysis of actual option forfeitures, adjusted to the extent historic forfeitures may not be indicative of forfeitures in the future. In addition, an expected dividend yield of zero is used in the option valuation model, because we do not pay dividends and do not expect to pay any cash dividends in the foreseeable future.

Prior to April 1, 2006, we accounted for stock-based compensation plans in accordance with the provisions of APB No. 25. We followed the disclosure-only alternative requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, we did not recognize compensation expense for the issuance of options with fixed exercise prices at least equal to the fair market value at the date of the grant.

### *Income Taxes*

As part of the process of preparing our consolidated financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. In addition, as of March 31, 2007, we had federal and state tax net operating loss carryforwards of approximately \$79.2 million and \$36.9 million, respectively, that begin to expire in fiscal 2008. At March 31, 2007, we also had foreign net operating loss carryforwards of approximately \$20.6 million that can be carried forward indefinitely. We have federal and state research and development credit carryforwards of approximately \$6.3 million and \$4.3 million, respectively, that begin to expire in fiscal 2008. We have recorded a valuation allowance of \$80.1 million as an offset against these net deferred tax assets due to the uncertainty surrounding the timing of the realization of the tax benefit. In the event that we determine in the future that we will be able to realize all or a portion of our net deferred tax benefit, an adjustment to deferred tax valuation allowance would increase net income in the period such a determination was made. Ownership changes, as defined in Section 382 of the Internal Revenue Code, may have limited the amount of net operating loss carryforwards and research and experimentation credit carryforwards that we can use each year to offset future taxable income and taxes payable. Subsequent ownership changes could impose additional limitations. We have not done a complete analysis to determine whether changes in the composition of our stockholders, including as a result of our acquisition of Impella or our recent public offering, have resulted or will result in an ownership change for purposes of Section 382.

### **Recent Accounting Pronouncements**

#### *FIN No. 48*

In June 2006, the Financial Accounting Standards Board ("FASB") released FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the company has taken or expects to take on a tax return. Under FIN 48, the financial statements will reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without discounting for the time value of money. FIN 48 also revises disclosure requirements and introduces a prescriptive, annual, tabular roll-forward of the unrecognized tax benefits. FIN 48 will become effective with our fiscal year beginning April 1, 2007. We are evaluating the effect that the adoption of FIN 48 may have on our consolidated financial statements.

#### *SFAS No. 157*

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. Among other requirements, SFAS No. 157 defines fair value and establishes a framework for measuring fair value and also expands disclosure requirements regarding fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. We are evaluating the impact that the adoption of SFAS No. 157 may have on our consolidated financial statements.

#### *SFAS No. 159*

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which provides companies with an option to report selected financial assets and liabilities at fair value in an attempt to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. This Statement is effective

as of the beginning of an entity's first fiscal year beginning after November 15, 2007. We are evaluating the impact that the adoption of SFAS No. 159 may have on our consolidated financial statements.

## Results of Operations

The following table sets forth certain consolidated statements of operations data for the periods indicated as a percentage of total revenues (which includes revenues from products and funded research and development):

	Year Ended March 31,		
	2005	2006	2007
<b>Revenues:</b>			
Products	99.3%	99.2%	99.5%
Funded research and development	0.7	0.8	0.5
Total revenues	100.0	100.0	100.0
<b>Costs and expenses:</b>			
Cost of product revenues excluding amortization of intangibles	24.5	26.8	23.7
Research and development	34.9	38.3	44.0
Selling, general and administrative	48.6	70.7	83.8
Expensed in-process research and development	—	30.5	1.6
Amortization of intangibles	0.5	3.0	3.2
Total costs and expenses	108.5	169.3	156.3
Loss from operations	(8.5)	(69.3)	(56.3)
Other income, net	2.4	2.7	2.2
Loss before income taxes	(6.1)	(66.6)	(54.1)
Tax provision	—	0.8	0.9
Net loss	(6.1)%	(67.4)%	(55.0)%

### *Fiscal Years Ended March 31, 2007 and March 31, 2006 ("fiscal 2007" and "fiscal 2006")*

#### Product Revenues

Product revenues for fiscal 2007 increased by \$7.1 million, or 16%, to \$50.4 million from \$43.3 million for fiscal 2006. Revenues from disposables, service and other programs (non-console revenues) comprised approximately 84% and 86% of total revenues for fiscal 2007 and fiscal 2006, respectively. For fiscal 2007 compared to fiscal 2006, revenues from Impella disposables increased 112%, AB5000 disposables revenue increased 37% and revenues from BVS declined approximately 22%. Comparing total revenues for fiscal 2007 to fiscal 2006, total sales of our Impella products (consoles and disposables) increased approximately 87%, total sales of our AB 5000 products (consoles and disposables) increased approximately 38%, and total sales of our BVS 5000 products declined by approximately 22%. In summary, the increase in fiscal 2007 revenues compared to fiscal year 2006 is primarily due to higher volume from our Impella and AB5000 products, partially offset by declines in sales of our BVS 5000 products during the period.

The dollar increase in revenue for fiscal 2007 as compared to fiscal 2006 is primarily due to the effects of our strategy to increase global distribution and our ongoing efforts to increase recovery awareness globally in hospitals, open heart centers and transplant centers. Our sales and clinical teams are focused on stimulating demand for our products by educating surgeons and cardiologists about both the clinical benefits of recovery and the increased reimbursement available for our heart recovery products. We expect to continue to increase sales and clinical headcount throughout fiscal 2008 with particular focus on expertise in the cath lab and also plan to increase our marketing, service and training personnel and investments to support the efforts of the sales and clinical teams to drive recovery awareness and revenue growth globally.

In December 2006, we announced the new iPulse Console and 510(k) clearance of our Intra-Aortic Balloon. We believe there will be U.S. market demand for our iPulse console (combination driver for the Intra-Aortic Balloon, BVS and AB5000) following FDA supplement approval anticipated later in the summer of calendar 2007; however, we cannot guarantee approval. This may cause a potential shift in console revenue from the AB5000 console to our newer iPulse console in future quarters.

#### Cost of Product Revenues

Cost of product revenues for fiscal 2007 increased \$0.3 million or 3%, to \$12.0 million from \$11.7 million for fiscal 2006. In fiscal 2007, utilization of our German manufacturing capacity was higher than it was in fiscal 2006. Additionally, the lower cost of goods sold from

disposable products offset increased cost of goods sold from consoles, and our SAP implementation in July 2006 resulted in improved efficiencies that lowered cost of goods sold during fiscal 2007 compared to fiscal 2006. The aggregate effect of these factors resulted in cost of goods sold during fiscal 2007 being approximately flat as compared to fiscal 2006, and decreasing as a percentage of product revenue as compared to fiscal 2006.

#### **Research and Development Expenses**

Research and development expenses increased by \$5.6 million, or 34%, to \$22.3 million in fiscal 2007, from \$16.7 million in fiscal 2006. Research and development expenses for fiscal 2007 included stock compensation expense of \$1.7 million and clinical trial expenses associated with our Impella 2.5 and 5.0 pilot trials of \$1.6 million. Our increases in product development costs reflect our efforts to expand and enhance our product lines across a clinical spectrum of care in the cath lab and surgery suite. During fiscal 2007, we invested in new product development to broaden our portfolio of products in the circulatory care markets. In addition, our research and development expenditures include costs related to clinical trials, including pilot trials for our Impella products.

#### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses increased by \$11.5 million, or 37%, to \$42.4 million in fiscal 2007, from \$30.9 million in fiscal 2006. The increase is due primarily to increased costs of \$4.6 million associated with our strategy to increase our global distribution, specifically our global sales, marketing and clinical specialist organizations. Total global sales and clinical headcount at the end of fiscal 2007 was 60 compared to 45 at the end of fiscal 2006, representing an increase of 33%. Selling, general and administrative expenses for fiscal 2007 also included \$3.8 million of stock-based compensation expense, costs associated with our ERP implementation and increased professional fees.

We expect to continue to increase sales and clinical headcount throughout fiscal 2008 and also plan to increase our marketing, service and training personnel and investments to support the efforts of the sales and clinical teams to drive recovery awareness globally.

#### **Expensed In-Process Research and Development Expenses**

We recorded a charge of \$0.8 million during the quarter ended June 30, 2006 in connection with the acquisition of certain circulatory care device patents and know-how. This charge relates to costs to acquire in-process research and development projects and technologies, which had not reached technological feasibility at the date of the asset acquisition and had no alternative future use.

We recorded a \$13.3 million non-cash charge to in-process research and development expense during the quarter ended June 30, 2005 in connection with our acquisition of Impella on May 10, 2005. This charge relates to costs to acquire in-process research and development projects and technologies, which had not reached technological feasibility at the date of the business acquisition and had no alternative future use.

#### **Other Income, Net**

Other income, net consists primarily of interest earned on our cash and investments. Other income, net was \$1.1 million for fiscal 2007, representing a decrease of \$0.1 million from \$1.2 million for fiscal 2006. The decrease in other income, net is primarily driven by lower investment income as a result of cash used in operations throughout the fiscal year.

#### **Tax Provision**

As of March 31, 2007, we have accumulated a net deferred tax liability in the amount of \$1.2 million which is primarily the result of a difference in accounting for our goodwill associated with the acquisition of Impella which is amortized over 15 years for tax purposes but not amortized for book purposes. The net deferred tax liability cannot be offset against our deferred tax assets under U.S. generally accepted accounting principles since it relates to an indefinite-lived asset and is not anticipated to reverse in the same period. For fiscal 2007, we have recorded a deferred tax provision related to amortization of goodwill in the amount of \$0.5 million. Differences between amounts recorded as a deferred tax liability on the balance sheet versus amounts recorded in the statement of operations result from deferred tax adjustments for foreign currency fluctuations. Other than this provision, we have not recorded an income tax benefit on our operating loss because it was more likely than not that we would not realize the benefits of our deferred tax assets.

#### **Net Loss**

During fiscal 2007, we incurred a net loss of \$27.9 million, or \$1.03 per share, including the effects of stock-based compensation expense. This compares to a net loss of \$29.4 million, or \$1.15 per share, for the prior fiscal year which represents a decrease in net loss of

\$1.5 million. The decrease in the net loss in fiscal 2007 compared to fiscal 2006 is due primarily to increased revenue of \$6.9 million and \$12.5 million in decreases of acquired in-process research and development, partially offset by increased selling, general and administrative expenses of \$11.5 million for the expansion of our global distribution; and an increase of \$5.6 million in research and development expenses to expand our portfolio of circulatory care products. Included in the amounts reflected above for fiscal 2007 is stock-based compensation expense of \$5.8 million, or approximately \$0.21 per share, as a result of our adoption of SFAS No. 123(R) in the first quarter of fiscal 2007.

#### *Fiscal Years Ended March 31, 2006 and March 31, 2005 (“fiscal 2006” and “fiscal 2005”)*

##### **Product Revenues**

Product revenues for fiscal 2006 increased by \$5.4 million, or 14%, to \$43.3 million from \$37.9 million for fiscal 2005. Revenues from disposables, service and other programs (non-console revenues) comprised approximately 86% of total revenues for fiscal 2006 and fiscal 2005. For fiscal 2006 compared to fiscal 2005, revenues from AB5000 disposables revenue increased 30% and revenues from BVS declined approximately 6%. Comparing total revenues for fiscal 2006 to fiscal 2005, total sales of our AB 5000 products (consoles and disposables) increased approximately 26%, and total sales of our BVS 5000 products declined by approximately 9%. In summary, the increase in fiscal 2006 revenues compared to fiscal 2005 is primarily due to higher volume from our AB5000 products and the addition of Impella product revenues since our acquisition in May 2005, partially offset by declines in sales of our BVS 5000 products during the period.

The higher revenue during fiscal 2006 compared to fiscal 2005 is due to the effects of the increased global distribution during fiscal 2006 versus fiscal 2005 as headcount for our sales and clinical teams was 45 at the end of fiscal 2006, up nearly 70% since the end of fiscal 2005. These sales and clinical teams have been focused on increasing recovery awareness in the hospitals and open heart centers globally. On October 1, 2005, the Centers for Medicare & Medicaid Services (CMS) increased reimbursement for our recovery VADs to an average of \$140,000, an increase of 70% from prior levels, and now at the same level of reimbursement as transplant VADs sold by other medical device companies. We believe that this change in reimbursement, an increase in published recovery data using our products, together with the increased global distribution teams, generated the increase in revenues in fiscal 2006 compared to fiscal 2005.

##### **Cost of Product Revenues**

Cost of product revenues increased by \$2.3 million, or 25%, to \$11.7 million in fiscal 2006 from \$9.4 million in fiscal 2005. As a percentage of product revenues, cost of product revenues was 27% in fiscal 2006 compared to 25% in fiscal 2005. The increase year over year is due primarily to the inclusion of cost of product revenues for Impella products in fiscal 2006 and increased costs of product revenues for our AB 5000 and BVS 5000 as we sold more of these products in fiscal 2006 compared to fiscal 2005. Additionally, during fiscal 2006 we recorded a non-cash charge of approximately \$0.4 million primarily as a result of determining that certain inventory had no future net realizable value.

##### **Research and Development Expenses**

Research and development expenses increased by \$3.3 million, or 25%, to \$16.7 million in fiscal 2006, from \$13.4 million in fiscal 2005. The increase is primarily the result of including Impella's research and development expense since our acquisition in May 2005 and also reflects our efforts to expand and enhance our product lines across a clinical spectrum of care in the cath lab and surgery suite. During fiscal 2006, we invested in new product development to broaden our portfolio of products in the circulatory care market.

##### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses increased by \$12.3 million, or 67%, to \$30.9 million in fiscal 2006, from \$18.6 million in fiscal 2005. The increase is primarily due to the inclusion of Impella expenses during fiscal 2006 and also due to our strategy to increase our global distribution, specifically our global sales, service, marketing and clinical specialists organizations. Total global sales and clinical headcount at the end of fiscal 2006 was 45 compared to 27 at the end of fiscal 2005, representing an increase of 67%.

##### **Expensed In-Process Research and Development Expenses**

We recorded a \$13.3 million non-cash charge to in-process research and development expense during the quarter ended June 30, 2005 in connection with our acquisition of Impella on May 10, 2005. This charge relates to costs to acquire in-process research and development projects and technologies, which had not reached technological feasibility at the date of the business acquisition and had no alternative future use.

## **Other Income, Net**

Other income, net consists primarily of interest earned on our cash and investments. Other income, net was \$1.2 million for fiscal 2006 compared to \$0.9 million for fiscal 2005. This increase was primarily due to higher investment income.

## **Tax Provision**

In fiscal 2005, we had no tax provision as we were in a loss position and it was more likely than not that we would not recognize the benefit of the net operating losses. As part of the Impella acquisition in May 2005, we obtained tax-deductible goodwill amounting to \$13.9 million. The difference between tax and financial statement cumulative amortization on tax-deductible goodwill gave rise to a long-term deferred tax liability of \$0.3 million. This deferred tax liability cannot be used as a source of taxable income in the determination of the valuation allowance. Valuation allowances for deferred tax assets are established when necessary to reduce deferred tax assets to the amount expected to be realized. Based on future operating results, expected at the end of fiscal 2006, we believed that it was more likely than not that we would not realize the benefits of our deferred tax assets.

## **Net Loss**

During fiscal 2006 we incurred a net loss of \$29.4 million, or \$1.15 per share. This compares to a net loss of \$2.3 million, or \$0.11 per share for fiscal 2005. The \$27.1 million change in the net loss in fiscal 2006 compared to fiscal 2005 is due primarily to: a \$13.3 million non-cash in-process research and development charge; increased selling, general and administrative expenses of \$12.3 million as we expanded our global distribution; and an increase of \$3.3 million in research and development expenses as we drove our strategy to expand our product portfolio across a clinical spectrum.

## **Liquidity and Capital Resources**

We have supported our operations primarily with revenues from sales of our AB5000, BVS 5000 and Impella circulatory product lines, government contracts, proceeds from equity financings and stock option exercises. At March 31, 2007, our cash and investments totaled \$75.1 million, an increase of \$44.3 million compared to \$30.8 million in cash and investments at March 31, 2006.

During fiscal 2007, cash used by operating activities was \$19.8 million as compared to \$9.3 million during the same period in the prior year. Our net loss of \$27.9 million is the primary cause of our cash use from operations. Our net loss is primarily attributed to increased investments in our global distribution as we continue to pursue initiatives to increase recovery awareness as well as our investments in research and development intended to broaden our portfolios of circulatory care products. In addition, our inventories increased by \$4.1 million from March 31, 2006, reflecting our inventory build-up to support anticipated increases in global demand for our products and our accounts receivable also increased by \$1.9 million as a result of higher volume. Amounts partially offsetting cash used from our net loss, inventory build up and increased accounts receivable are increases in accounts payable of \$1.6 million, non-cash adjustments of \$5.8 million related to stock-based compensation expense as a result of our adoption of SFAS No. 123(R), \$3.9 million of depreciation and amortization, and \$0.5 million for changes in our deferred tax liability.

Investment activities for fiscal 2007 provided \$15.1 million, comprised primarily of \$35.2 million of proceeds from the sale and maturity of short-term securities offset by purchases of short-term securities of \$17.7 million, and expenditures for property and equipment of \$2.4 million.

Cash provided by financing activities for fiscal 2007 is primarily attributed to \$63.6 million in net proceeds received from our March 2007 equity financing and proceeds received from the exercise of stock options and our ESPP in the amount of \$2.8 million and \$0.3 million, respectively.

Capital expenditures for fiscal 2008 are estimated to be in the range of \$2.5 million to \$3.5 million which will support the international phase of our ERP (SAP) implementation as well as our plans to build manufacturing capacity.

We believe that our revenue from product sales together with existing resources will be sufficient to fund our operations during the next twelve months.

## Contractual Obligations and Commercial Commitments

The following table (in thousands) summarizes our contractual obligations at March 31, 2007 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Contractual Obligations	Payments Due By Fiscal Year				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Lease Obligations	\$ 7,669	\$ 1,960	\$ 3,441	\$ 1,652	\$ 616
Purchase Obligations	6,421	6,421	—	—	—
Total Obligations	<u>\$14,090</u>	<u>\$ 8,381</u>	<u>\$ 3,441</u>	<u>\$ 1,652</u>	<u>\$ 616</u>

We have no long-term debt, capital leases or material commitments at March 31, 2007 other than those shown in the table above.

In May 2005, we acquired all the shares of outstanding capital stock of Impella CardioSystems AG, a company headquartered in Aachen, Germany. The aggregate purchase price excluding a contingent payment in the amount of \$5.6 million made on January 30, 2007 in the form of common stock, was approximately \$45.1 million, which consisted of \$42.2 million of our common stock, \$1.6 million of cash paid to certain former shareholders of Impella, and \$1.3 million of transaction costs, consisting primarily of fees paid for financial advisory and legal services. We may make additional contingent payments to Impella's former shareholders based on additional milestone payments related to FDA approvals in the amount of up to \$11.2 million. These contingent payments may be made in a combination of cash or stock under circumstances described in the purchase agreement. If any contingent payments are made, they will result in an increase to the carrying value of goodwill.

We apply the disclosure provisions of FIN No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others, and Interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34* (FIN No. 45) to our agreements that contain guarantee or indemnification clauses. These disclosure provisions expand those required by SFAS No. 5 by requiring that guarantors disclose certain types of guarantees, even if the likelihood of requiring the guarantor's performance is remote. The following is a description of arrangements in which we are a guarantor.

We enter into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited. We have never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, we have no liabilities recorded for these agreements as of March 31, 2007.

Clinical study agreements – In our clinical study agreements, we have agreed to indemnify the participating institutions against losses incurred by them for claims related to any personal injury of subjects taking part in the study to the extent they relate to use of our devices in accordance with the clinical study agreement, the protocol for the device and our instructions. The indemnification provisions contained within our clinical study agreements do not generally include limits on the claims. We have never incurred any material costs related to the indemnification provisions contained in our clinical study agreements.

Product warranties—We routinely accrue for estimated future warranty costs on our product sales at the time of shipment. All of our products are subject to rigorous regulation and quality standards. While we engage in extensive product quality programs and processes, including monitoring and evaluating the quality of our component suppliers, our warranty obligations are affected by product failure rates. Our operating results could be adversely affected if the actual cost of product failures exceeds the estimated warranty provision.

Patent indemnifications—In many sales transactions, we indemnify customers against possible claims of patent infringement caused by our products. The indemnifications contained within sales contracts usually do not include limits on the claims. We have never incurred any material costs to defend lawsuits or settle patent infringement claims related to sales transactions. Under the provisions of FIN No. 45, intellectual property indemnifications require disclosure only.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

### ***Derivative Financial Instruments and Derivative Commodity Instruments***

We do not participate in derivative financial instruments or derivative commodity instruments.

### ***Primary Market Risk Exposures***

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio, which consists primarily of money market funds, commercial paper and corporate bonds with maturities of one year or less at March 31, 2007. The primary objective of our investment activities is to preserve principal while maximizing yields without significantly increasing risk. This is accomplished by investing in high investment grade securities with ratings of at least AA by Moody's or Standard & Poor's as well as investment portfolio diversification. Our held-to-maturity securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10 percent from levels at March 31, 2007, we believe the decline in fair market value of our investment portfolio would be immaterial. We believe, however, that we have the ability to hold our fixed income investments until maturity and therefore would not expect our operating results or cash flows to be affected to any significant degree by a change in market interest rates on our securities portfolio.

### ***Currency Exchange Rates***

Our Impella subsidiary's functional currency is the Euro. Therefore, our investment in Impella is sensitive to fluctuations in currency exchange rates. The effect of a change in currency exchange rates on our net investment in international subsidiaries is reflected in the "accumulated other comprehensive income (loss)" component of stockholders' equity. Had a 10% depreciation in the Euro occurred relative to the U.S. dollar as of March 31, 2007, the result would have been a reduction of stockholders' equity of approximately \$3.7 million.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our Consolidated Financial Statements and Supplementary Data are provided under Part IV, Item 15 of this Form 10-K.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

On November 9, 2006, the audit committee of Abiomed, Inc. approved the dismissal of PricewaterhouseCoopers LLP, effective as of November 9, 2006 and approved the selection of Deloitte & Touche LLP as our independent registered public accounting firm for the fiscal year ending March 31, 2007. In connection with our change in accountants, there were no disagreements or reportable events required to be disclosed pursuant to Regulation S-K, Item 304(a)(1)(iv) and Item 304(a)(1)(v).

## **ITEM 9A. CONTROLS AND PROCEDURES**

### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of March 31, 2007. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2007, these disclosure controls and procedures were effective to provide reasonable assurance that material information required to be disclosed by us, including our consolidated subsidiaries, in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

### ***Evaluation of Changes in Internal Control over Financial Reporting***

During the fourth quarter of our fiscal year ended March 31, 2007, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### ***Management's Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we assessed the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of March 31, 2007.

### ***Important Considerations***

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Deloitte & Touche LLP, an independent registered public accounting firm that audited our financial statements for the year ended March 31, 2007, included in this annual report, has issued an attestation report on management's assessment of our internal control over financial reporting. This report is set forth below:

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of  
ABIOMED, Inc.  
Danvers, Massachusetts

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that ABIOMED, Inc. and subsidiaries (the "Company") maintained effective internal control over financial reporting as of March 31, 2007, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of March 31, 2007, is fairly stated, in all material respects, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2007, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedule as of and for the year ended March 31, 2007 of the Company and our report dated June 12, 2007 expressed an unqualified opinion on those financial statements and financial statement schedule and includes an explanatory paragraph relating to the change in method of accounting for share-based payments upon the adoption of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, on April 1, 2006.

/s/ Deloitte & Touche LLP

Boston, Massachusetts  
June 12, 2007

**ITEM 9B. OTHER INFORMATION**

Not applicable.

### **PART III**

#### **ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE***

The information required by Item 10 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year captioned:

- “Proposal No. 1: Election of Directors,”
- “Executive Officers,”
- “Audit Committee Report,”
- “Corporate Governance,” and
- “Section 16(a) Beneficial Ownership Reporting Compliance.”

We have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions. A paper copy of our code of ethics may be obtained free of charge by writing to us care of our Compliance Officer at our principal executive office located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, or by email at IR@abiomed.com.

#### **ITEM 11. *EXECUTIVE COMPENSATION***

The information required by Item 11 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year end captioned:

- “Executive Compensation”
- “Compensation Discussion and Analysis,”
- “Compensation Committee Interlocks and Insider Participation,” and
- “Compensation Committee Report.”

#### **ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS***

The information required by Item 12 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year end captioned:

- “Security Ownership of Certain Beneficial Owners and Management.”
- “Equity Compensation Plans”

#### **ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE***

The information required by Item 13 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year end captioned:

- “Executive Compensation,” and
- “Proposal No. 1: Election of Directors,” and
- “Certain Relationships and Related Transactions.”

#### **ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES***

The information required by Item 14 of Form 10-K is incorporated by reference to the information in our definitive proxy statement to be filed within 120 days after the close of our fiscal year end captioned:

- “Principal Accountant Fees and Services.”

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this report:

(1) The financial statements from our Annual Report for our fiscal year ending March 31, 2007 are attached hereto.

Reports of Independent Registered Public Accounting Firms	F-1
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Stockholders' Equity	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

(2) Consolidated financial statement schedule

Schedule II: Valuation and qualifying accounts

(3) Exhibits

**EXHIBIT INDEX**

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
2.1	Share Purchase Agreement for the acquisition of Impella Cardio Systems AG, dated April 26, 2005.		8-K	May 16, 2005	2.1
3.1	Restated Certificate of Incorporation.		S-3	September 29, 1997	3.1
3.2	Restated By-Laws, as amended.		10-K	May 27, 2004	3.2
3.3	Certificate of Designations of Series A Junior Participating Preferred Stock—filed as Exhibit 3.3 to the 1997 Registration Statement.*		S-3	September 29, 1997	3.3
3.4	Amendment to the Company's Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000.		8-K	March 21, 2007	3.4
4.1	Specimen Certificate of common stock.		S-1	June 5, 1987	4.1
4.2	Rights Agreement between ABIOMED and its transfer agent, as Rights Agent dated as of August 13, 1997 (including Form of Rights Certificate attached thereto as Exhibit A).		8-K	August 25, 1997	4
10.1	Form of Indemnification Agreement for Directors and Officers.		S-1	June 5, 1987	10.13
10.2*	1992 Combination Stock Option Plan.		10-Q	October 27, 1995	10.2
10.3*	Amendment to 1992 Combination Stock Option Plan.		10-Q	October 14, 1997	10.2
10.4*	1988 Employee Stock Purchase Plan, as amended.		10-Q	February 8, 2005	10.11
10.5*	1989 Non-Qualified Stock Option Plan for Non-Employee Directors.		10-Q	October 27, 1995	10.1

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
10.6	Facility Lease dated January 8, 1999 for the premises at 22 Cherry Hill Drive. filed as Exhibit 10 to our Form 10-Q for the fiscal quarter ended December 31, 1998.		10-Q	February 12, 1999	10
10.7*	1998 Equity Incentive Plan.		10-Q/A	January 8, 1999 (for the quarter ended September 30, 1998)	10
10.8*	Form of Change of Control Agreement.		10-Q	November 9, 1999	10(b)
10.9*	Schedule related to Change of Control Agreement.		10-Q	November 9, 1999	10(c)
10.10*	2000 Stock Incentive Plan Agreement, as amended.		Def 14A	July 15, 2005	Appendix A
10.11	Employment Agreement of Michael R. Minogue dated April 5, 2004.		10-Q	August 9, 2004	10.10
10.12	Inducement stock option granted to Michael R. Minogue dated April 5, 2004.		10-Q	August 9, 2004	10.11
10.13	Registration Rights and Stock Restriction Agreement between Abiomed, Inc. and Stockholders of Impella CardioSystems AG.		8-K	May 16, 2005	10.1
10.14	Consulting Agreement between Abiomed, Inc. and Dr. David M. Lederman dated October 17, 2005.		8-K	October 21, 2005	10.1
10.15*	Restricted Stock Agreement between Abiomed, Inc. and Michael R. Minogue.		10-Q	October 9, 2005	10.15
10.16*	Offer letter with Daniel Sutherby dated December 13, 2005.		10-Q	February 9, 2006	10.15
10.17*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Directors.		10-Q	February 9, 2006	10.16
10.18*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Employees or Consultants.		10-Q	February 9, 2006	10.17
10.19*	Summary of Executive Compensation.	X			
10.20*	Summary of Director Compensation.	X			
10.21*	Form of Employment, Nondisclosure and Non Competition Agreement—as filed as Exhibit to our Form for the fiscal year ended March 31, 2006.		10-K	June 14, 2006	10.20
10.22	Software License Agreement between Abiomed, Inc. and AnswerThink, Inc. dated November 30, 2005.		10-Q	February 9, 2006	10.20
10.23	Consulting Agreement between Abiomed, Inc. and AnswerThink, Inc. dated September 15, 2006.		10-Q	February 8, 2007	10.23
10.24	Distribution Agreement between Abiomed, Inc. and MEDIX Japan, Inc. dated November 4, 2006.		10-Q	February 8, 2007	10.24
11.1	Statement regarding computation of Per Share Earnings (see Note 2, Notes to Consolidated Financial Statements).	X			
21.1	Subsidiaries of the Registrant.	X			
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm.	X			
23.2	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.	X			

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
31.1	Rule 13a—14(a)/15d—14(a) certification of principal executive officer.	X			
31.2	Rule 13a—14(a)/15d—14(a) certification of principal accounting officer.	X			
32.1	Section 1350 certification.	X			

\* Management contract or compensatory plan.



**ABIOMED, INC. AND SUBSIDIARIES**

**Consolidated Financial Statements**

**Index**

	<u>Page</u>
Reports of Independent Registered Public Accounting Firms	F-1
Consolidated Balance Sheets at March 31, 2006 and 2007	F-3
Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2005, 2006 and 2007	F-4
Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended March 31, 2005, 2006 and 2007	F-5
Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2005, 2006 and 2007	F-6
Notes to Consolidated Financial Statements	F-7 to F-24

[THIS PAGE INTENTIONALLY LEFT BLANK]

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
ABIOMED, Inc.  
Danvers, Massachusetts

We have audited the accompanying consolidated balance sheet of ABIOMED, Inc. and its subsidiaries (the "Company") as of March 31, 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. Our audit also included the 2007 financial statement schedule listed in the Index at Item 15. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of ABIOMED, Inc. and its subsidiaries at March 31, 2007, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for share-based payments upon the adoption of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, on April 1, 2006.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of March 31, 2007, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated June 12, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Deloitte & Touche LLP

Boston, Massachusetts  
June 12, 2007

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of ABIOMED, Inc.:

In our opinion, the accompanying consolidated balance sheet as of March 31, 2006 and the related consolidated statements of operations, of stockholders' equity and of cash flows for each of two years in the period ended March 31, 2006 present fairly, in all material respects, the financial position of ABIOMED, Inc. and its subsidiaries at March 31, 2006 and the results of their operations and their cash flows for each of the two years in the period ended March 31, 2006, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the Index appearing under Item 15(a)(2) for each of the two years in the period ended March 31, 2006 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
Boston, Massachusetts  
June 12, 2006

**ABIOMED, INC. AND SUBSIDIARIES**

**Consolidated Balance Sheets  
(in thousands, except share data)**

	<b>March 31,</b>	
	<b>2006</b>	<b>2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 7,832	\$ 69,646
Short-term marketable securities	23,003	5,479
Accounts receivable, net	8,880	10,932
Inventories	4,868	8,567
Prepaid expenses and other current assets	1,860	1,758
Total current assets	46,443	96,382
Property and equipment, net	4,824	5,764
Intangible assets, net	8,164	7,329
Goodwill	19,106	26,708
Total Assets	<u>\$ 78,537</u>	<u>\$ 136,183</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,070	\$ 5,185
Accrued expenses	5,185	7,017
Deferred revenue	484	695
Total current liabilities	8,739	12,897
Long-term deferred tax liability	310	1,191
Total Liabilities	9,049	14,088
Commitments and Contingencies		
Stockholders' equity:		
Class B Preferred stock, \$.01 par value	—	—
Authorized—1,000,000 shares; Issued and outstanding—none		
Common Stock, \$.01 par value—		
Authorized—100,000,000 shares; Issued—26,474,270 shares at March 31, 2006		
and 32,254,577 at March 31, 2007		
Outstanding—26,468,091 at March 31, 2006 and 32,243,558 at March 31, 2007	265	323
Additional paid-in capital	214,666	292,467
Deferred stock-based compensation	(171)	—
Accumulated deficit	(143,308)	(171,189)
Treasury stock, at cost		
6,179 shares at March 31, 2006 and 11,019 shares at March 31, 2007	(66)	(116)
Accumulated other comprehensive (loss) income	(1,898)	610
Total stockholders' equity	69,488	122,095
Total liabilities and stockholders' equity	<u>\$ 78,537</u>	<u>\$ 136,183</u>

*See notes to consolidated financial statements*

**ABIOMED, INC. AND SUBSIDIARIES**

**Consolidated Statements of Operations**  
(in thousands, except per share data)

	<u>Fiscal Years Ended March 31,</u>		
	<u>2005</u>	<u>2006</u>	<u>2007</u>
Revenue:			
Products	\$ 37,945	\$ 43,322	\$ 50,408
Funded research and development	271	348	241
	<u>38,216</u>	<u>43,670</u>	<u>50,649</u>
Costs and expenses:			
Cost of product revenue excluding amortization of intangibles	9,366	11,685	12,012
Research and development	13,350	16,739	22,292
Selling, general and administrative	18,566	30,923	42,448
Expensed in-process research and development	—	13,306	800
Amortization of intangibles	187	1,308	1,608
	<u>41,469</u>	<u>73,961</u>	<u>79,160</u>
Loss from operations	(3,253)	(30,291)	(28,511)
Other income, net:			
Investment income	801	1,194	1,045
Foreign exchange gain (loss)	91	(116)	(27)
Other income, net	19	120	87
	<u>911</u>	<u>1,198</u>	<u>1,105</u>
Loss before provision for income taxes	(2,342)	(29,093)	(27,406)
Provision for income taxes	—	356	475
Net loss	<u>\$ (2,342)</u>	<u>\$(29,449)</u>	<u>\$(27,881)</u>
Basic and diluted net loss per share	\$ (0.11)	\$ (1.15)	\$ (1.03)
Weighted average shares outstanding	21,845	25,649	27,124

*See notes to consolidated financial statements*

**ABIOMED, INC. AND SUBSIDIARIES**

**Consolidated Statements of Stockholders' Equity**  
(in thousands, except share data)

	Common Stock						Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity	Comprehensive (Loss)
	Number of Shares	Par Value	Additional Paid-in Capital	Deferred Stock-based Compensation	Accumulated Deficit	Treasury Stock			
Balance, March 31, 2004	21,386,919	\$214	\$165,696	\$ (57)	\$(111,517)	\$ —	\$ 54,336	\$ —	
Stock options exercised	665,437	7	3,919	—	—	—	3,926	—	
Stock issued under employee stock purchase plan	21,287	—	161	—	—	—	161	—	
Stock issued to directors	5,668	—	60	—	—	—	60	—	
Deferred compensation related to employee stock option grants	—	—	259	(259)	—	—	—	—	
Amortization of deferred compensation	—	—	—	38	—	—	38	—	
Net loss	—	—	—	—	(2,342)	—	(2,342)	\$( 2,342)	
<b>Balance, March 31, 2005</b>	<b>22,079,311</b>	<b>221</b>	<b>170,095</b>	<b>(278)</b>	<b>(113,859)</b>	<b>—</b>	<b>56,179</b>	<b>—</b>	
Stock issued to acquire Impella CardioSystems AG	4,029,004	40	42,160	—	—	—	42,200	—	
Restricted stock	24,000	1	—	86	—	—	87	—	
Stock options exercised	313,628	3	1,952	—	—	—	1,955	—	
Stock issued under employee stock purchase plan	23,970	—	204	—	—	—	204	—	
Stock issued to directors	4,357	—	56	—	—	—	56	—	
Amortization of deferred compensation	—	—	(9)	21	—	—	12	—	
Stock compensation related to stock options	(6,179)	—	208	—	—	—	208	—	
Return of common stock from escrow	—	—	—	—	(66)	—	(66)	—	
Net loss	—	—	—	—	(29,449)	—	(29,449)	\$(29,449)	
Foreign currency translation	—	—	—	—	—	—	(1,898)	(1,898)	
Comprehensive loss	—	—	—	—	—	—	—	\$(31,347)	
<b>Balance, March 31, 2006</b>	<b>26,468,091</b>	<b>265</b>	<b>214,666</b>	<b>(171)</b>	<b>(143,308)</b>	<b>(66)</b>	<b>69,488</b>	<b>(1,898)</b>	
Stock issued to acquire Impella CardioSystems AG	402,279	4	5,570	—	—	—	5,574	—	
Common stock issued	5,000,000	50	63,501	—	—	—	63,551	—	
Restricted stock	—	—	(80)	171	—	—	91	—	
Stock options exercised	350,933	4	2,747	—	—	—	2,751	—	
Stock issued under employee stock purchase plan	27,095	—	305	—	—	—	305	—	
Stock compensation expense	—	—	5,758	—	—	—	5,758	—	
Return of common stock from escrow	(4,840)	—	—	—	(50)	—	(50)	—	
Net loss	—	—	—	—	(27,881)	—	(27,881)	\$(27,881)	
Foreign currency translation, net	—	—	—	—	—	—	2,508	2,508	
Comprehensive loss	—	—	—	—	—	—	—	\$(25,373)	
<b>Balance, March 31, 2007</b>	<b>32,243,558</b>	<b>\$323</b>	<b>\$292,467</b>	<b>\$ —</b>	<b>\$(171,189)</b>	<b>\$(116)</b>	<b>\$ 122,095</b>	<b>\$ 610</b>	

See notes to consolidated financial statements

**ABIOMED, INC. AND SUBSIDIARIES**

**Consolidated Statements of Cash Flows  
(in thousands)**

	<b>Fiscal Years Ended March 31,</b>		
	<b>2005</b>	<b>2006</b>	<b>2007</b>
<b>Operating activities:</b>			
Net loss:	\$ (2,342)	\$(29,449)	\$(27,881)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,529	3,030	3,915
Bad debt expense (recovery)	(67)	193	7
Loss on abandonment of patents	49	—	—
Loss on impairment of fixed assets	—	—	75
Write-down of inventory	36	423	207
Deferred tax provision	—	310	475
Stock-based compensation	98	371	5,848
Expensed in-process research and development	—	13,306	—
Changes in assets and liabilities, net of acquisition:			
Accounts receivable	(2,563)	258	(1,920)
Inventories	(1,491)	(465)	(4,095)
Prepaid expenses, other current assets and other assets	(465)	173	159
Accounts payable	(238)	1,326	1,572
Accrued expenses	355	827	1,618
Deferred revenue	(65)	358	200
Net cash used in operating activities	<u>(5,164)</u>	<u>(9,339)</u>	<u>(19,820)</u>
<b>Investing activities:</b>			
Proceeds from the sale and maturity of short and long-term securities	42,169	42,016	35,187
Purchases of short and long-term securities	(39,520)	(29,021)	(17,663)
Costs of acquisition, net of cash acquired	—	(2,573)	(9)
Proceeds from disposal of equipment	—	11	—
Additions to patents	(36)	(133)	(47)
Expenditures for property and equipment	(697)	(2,931)	(2,373)
Net cash provided by investing activities	<u>1,916</u>	<u>7,369</u>	<u>15,095</u>
<b>Financing activities:</b>			
Proceeds from exercise of stock options	3,926	1,955	2,751
Proceeds from employee stock purchase plan	161	204	305
Proceeds from public offering, net of expenses	—	—	63,551
Return of common stock from escrow	—	(66)	(50)
Net cash provided by financing activities	<u>4,087</u>	<u>2,093</u>	<u>66,557</u>
Exchange rate effect on cash	(56)	91	(18)
Net increase in cash and cash equivalents	783	214	61,814
Cash and cash equivalents at beginning of fiscal year	6,835	7,618	7,832
Cash and cash equivalents at end of fiscal year	<u>\$ 7,618</u>	<u>\$ 7,832</u>	<u>\$ 69,646</u>
<b>Supplemental disclosures:</b>			
Taxes paid, net of refunds	\$ 82	\$ 59	\$ 18
Common shares issued for business acquisition	\$ —	\$ 42,200	\$ 5,574

*See notes to consolidated financial statements*

## **ABIOMED, INC. AND SUBSIDIARIES**

### **Notes to Consolidated Financial Statements (In thousands, except share data)**

#### **Note 1. Nature of Operations**

Abiomed, Inc. (the “Company” or “Abiomed”) is a leading provider of medical devices in circulatory support that offers a continuum of care in heart recovery to acute heart failure patients. The Company’s strategy is focused on establishing heart recovery as the goal for all acute cardiac attacks. The Company’s 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. Abiomed is focused on increasing awareness of heart recovery and establishing it as the goal for patients with failing but potentially recoverable hearts. The Company expects that recovery awareness and utilization of its products will significantly increase the number of patients able to return home from the hospital with their own hearts.

Prior year amounts have been reclassified to conform with the current year presentation. Specifically, the Company has included amortization expense associated with inventory used for demonstration purposes in depreciation and amortization reflected in the Company’s statements of cash flows in the amount of \$0.3 million for both fiscal year 2005 and 2006. Such amounts were previously reflected as changes in inventories in the statements of cash flows.

#### **Note 2. Summary of Significant Accounting Policies**

The accompanying consolidated financial statements reflect the application of certain significant accounting policies described below.

##### **Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries, all of which are wholly owned. All significant intercompany accounts and transactions have been eliminated in consolidation. The financial statements include the financial results of Abiomed Europe, GMBH (formerly Impella CardioSystems AG) from its date of acquisition on May 10, 2005.

##### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, inventories, impairment of intangible assets and goodwill, income taxes including the valuation allowance for deferred tax assets, stock based compensation, valuation of long-lived assets and investments, contingencies and litigation. Abiomed bases its estimates on historical experiences and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimated or assumed.

##### **Major Customers and Concentrations of Credit Risk**

Abiomed primarily sells its products to large hospitals and distributors. No customer accounted for more than 10% of total product revenues in fiscal year 2005, 2006, and 2007. No distributor customer or other customer had an accounts receivable balance greater than 10% of total accounts receivable at the end of fiscal 2006, or 2007.

Credit is extended based on an evaluation of a customer’s financial condition and generally collateral is not required. To date, credit losses have not been significant and the Company maintains an allowance for doubtful accounts based on its assessment of the collectibility of accounts receivable. Receivables are geographically dispersed, primarily throughout the United States, as well as in Europe and other foreign countries where formal distributor agreements exist.

Financial instruments which potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, and short-term investments. Although the Company maintains cash balances at financial institutions that exceed federally insured limits, these balances are placed with high credit quality financial institutions.

##### **Cash, Cash Equivalents and Marketable Securities**

The Company classifies any marketable security with a maturity date of 90 days or less at the time of purchase as a cash equivalent. Cash equivalents are carried on the balance sheet at fair market value.

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 2. Summary of Significant Accounting Policies (Continued)

The Company classifies any security with a maturity date of greater than 90 days at the time of purchase as marketable securities and classifies marketable securities with a maturity date of greater than one year from the balance sheet date as long-term investments. In accordance with Statements of Financial Accounting Standards (“SFAS”) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, securities that the Company has the positive intent and ability to hold to maturity are reported at amortized cost and classified as held-to-maturity securities. At March 31, 2007 the held-to-maturity investment portfolio consisted primarily of commercial paper and corporate bonds with maturities of one year or less.

#### Inventories

Inventories are stated at the lower of cost or market. Cost is based on the first in, first out method. The Company regularly reviews inventory quantities on hand and writes down to its net realizable value any inventory believed to be impaired. If actual demand or market conditions are less favorable than projected demand, additional inventory write-downs may be required that could adversely impact financial results for the period in which the additional excess or obsolete inventory is identified.

#### Property and equipment

Property and equipment is recorded at cost less accumulated depreciation. Depreciation is computed using the straight line method based on estimated useful lives of two to ten years for machinery and equipment and four to ten years for furniture and fixtures. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful lives of the related assets. Expenditures for maintenance and repairs are expensed as incurred. Expenditures for renewals or betterments are capitalized.

The Company capitalizes the cost of software used for internal operations once technological feasibility of the software has been demonstrated in accordance with Statement of Position No. 98-1. Such costs consist primarily of custom-developed and packaged software and the direct labor costs of internally developed software. All capitalized software costs are depreciated on a straight-line basis over a period of three to seven years.

#### Impairment of Long-Lived Assets

Long-lived assets (primarily property, equipment and intangible assets) are reviewed for impairment losses whenever events or changes in circumstances indicate the carrying amount may not be recoverable. An impairment loss would be recognized based on the amount by which the carrying value of the asset exceeds its fair value. Fair value is determined primarily using the estimated future cash flows associated with the asset under review, discounted at a rate commensurate with the risk involved and other valuation techniques.

#### Intellectual Property

The Company capitalizes intellectual property costs relating to patenting its technology as they are incurred, excluding costs associated with Company personnel. Capitalized costs, the majority of which represent legal costs, reflect the cost of both awarded patents and patents pending. The Company amortizes the cost of these patents over the estimated useful life of the patents, generally up to seven years. If the Company elects to stop pursuing a particular patent application, determines that a patent application is not likely to be awarded for a particular patent, or elects to discontinue payment of required maintenance fees for a particular patent, the Company at that time records as expense the net capitalized amount of such patent application or patent.

#### Goodwill and Intangible Assets

In accordance with the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, the Company assesses the realizability of goodwill annually, at October 31<sup>st</sup>, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. These events or circumstances generally include operating losses or a significant decline in earnings associated with the acquired business or asset. The Company’s ability to realize the value of the goodwill will depend on the future cash flows of the business. If the Company is not able to realize the value of goodwill, the Company may be required to incur material charges relating to the impairment of those assets. The Company completed its annual review of goodwill as of October 31, 2006 and has determined that no write-down for impairment is necessary.

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 2. Summary of Significant Accounting Policies (Continued)

Acquisition-related intangible assets include the costs of acquired product technology, patents, trademarks and other specifically identifiable intangible assets. Intangible assets are amortized on a straight-line basis over their estimated useful lives of seven years.

#### Fair Value of Financial Instruments

SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*, requires disclosure for estimates of the fair value of financial instruments. The Company's financial instruments were comprised of cash and cash equivalents, marketable securities, accounts receivable and accounts payable, the carrying amounts of which approximated fair market value.

#### Revenue Recognition and Product Warranty

The Company recognizes revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable, and collectibility is reasonably assured in accordance with the SEC Staff Accounting Bulletin No. 104 ("SAB 104"). The Company also follows the guidance of EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables* when transactions include multiple elements. Revenue from product sales to new customers is deferred until training on the use of the products has occurred. All costs related to product shipment are recognized at time of shipment. The Company does not provide for rights of return to customers on product sales.

Maintenance and service support contract revenues are recognized ratably over the term of the service contracts based upon the elapsed term of the service contract. In limited instances, the Company also rents its console medical devices on a month-to-month basis or for a longer specified period of time to customers for which revenue is recognized as earned.

Government-sponsored research and development contracts and grants generally provide for payment on a cost-plus-fixed-fee basis. Revenues from these contracts and grants are recognized as work is performed, provided the government has appropriated sufficient funds for the work. Under contracts in which the Company elects to spend significantly more on the development project during the term of the contract than the total contract amount, the Company prospectively recognizes revenue on such contracts ratably over the term of the contract as it incurs related research and development costs, provided the government has appropriated sufficient funds for the work.

Consoles sold are covered by a one-year warranty for which estimated contractual warranty obligations are recorded in cost of revenue at the time of shipment. The Company's products are subject to rigorous regulation and quality standards

#### Translation of Foreign Currencies

All assets and liabilities of the Company's non-U.S. subsidiaries are translated at year-end exchange rates, and revenues and expenses are translated at average exchange rates for the year in accordance with SFAS No. 52, *Foreign Currency Translation*. Resulting translation adjustments are reflected in the accumulated other comprehensive (loss) income component of stockholders' equity. Currency transaction gains and losses are included in the accompanying statement of operations and are not material for the three years presented.

#### Net Loss Per Share

In accordance with SFAS No. 128, *Earnings Per Share*, basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the fiscal year. Diluted net loss per share is computed by dividing net loss by the weighted-average number of dilutive common shares outstanding during the fiscal year. Dilutive shares outstanding are calculated by adding to the weighted shares outstanding any potential (unissued) shares of common stock and warrants based on the treasury stock method. In fiscal years when net income is reported, the calculation of diluted net income per share typically results in lower earnings per share than is calculated using the basic method. In fiscal years when a net loss is reported, such as the fiscal years ended March 31, 2005, 2006 and 2007, all common stock equivalents are excluded from the calculation because they would have an anti-dilutive effect, meaning the loss per share would be reduced. Therefore, in fiscal years when a loss is reported the calculation of basic and dilutive loss per share results in the same value.

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 2. Summary of Significant Accounting Policies (Continued)

The calculation of diluted weighted average shares outstanding for the fiscal years ended, March 31, 2005, 2006, and 2007 excludes warrants to purchase up to 400,000 shares of common stock issued in connection with the purchase of intellectual property (Note 12). Also excluded from the calculation of diluted weighted average shares outstanding for the fiscal years ended, March 31, 2005, 2006, and 2007 are stock options outstanding in the amount of 3,617,506, 3,961,643, and 4,305,920, respectively and unvested shares of restricted stock in the amount of 24,000 shares, 16,000 shares and 8,000 shares, respectively.

#### Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive (loss) income. Other comprehensive (loss) income includes certain changes in equity that are excluded from net loss, such as translation adjustments.

#### Accounting for Stock-Based Compensation

In December 2004, the FASB issued SFAS No. 123(R), *Share-based Payment*. SFAS No. 123(R) requires entities to recognize compensation costs for all share-based payments, including grants of employee stock options, based on the grant-date fair value of those share-based payments (with limited exceptions), adjusted for expected forfeitures.

Effective April 1, 2006, the Company adopted the provisions of SFAS No. 123(R) using the modified prospective application transition method. Under this transition method, the compensation cost recognized beginning April 1, 2006 includes compensation cost for (i) all share-based payments granted prior to, but not yet vested as of April 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (ii) shares issued in offerings under the Employee Stock Purchase Plan with offering periods commencing April 1, 2006 and stock options granted subsequent to March 31, 2006 based on the grant-date fair value estimated using the Black-Scholes valuation model in accordance with the provisions of SFAS No. 123(R). Compensation cost is recognized on a straight-line basis over the requisite service period for share-based payments issued subsequent to the adoption of SFAS No. 123(R). For stock options issued prior to the adoption of SFAS No. 123(R), the accelerated method is used for expense recognition.

Prior to April 1, 2006, the Company accounted for stock-based compensation in accordance with the provisions of APB No. 25. The Company elected to follow the disclosure-only alternative requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, the Company did not recognize the compensation expense for the issuance of options with fixed exercise prices at least equal to the fair market value at the date of the grant. Under the modified prospective transition method of SFAS No. 123(R), results for prior periods are not restated; however, the presentation of pro forma net income (loss) and net income (loss) per share as if the Company had accounted for its stock plans under the fair value method of SFAS No. 123 is required for periods presented prior to the adoption of SFAS No. 123(R).

#### Recent Accounting Pronouncements

##### *FIN No. 48*

In June 2006, the Financial Accounting Standards Board ("FASB") released FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 prescribes a comprehensive model for how a company should recognize, measure, present, and disclose in its financial statements uncertain tax positions that the Company has taken or expects to take on a tax return. Under FIN 48, the financial statements will reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts, but without discounting for the time value of money. FIN 48 also revises disclosure requirements and introduces a prescriptive, annual, tabular roll-forward of the unrecognized tax benefits. FIN 48 will become effective with the Company's fiscal year beginning April 1, 2007. The Company is evaluating the effect that the adoption of FIN 48 may have on its consolidated financial statements.

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 2. Summary of Significant Accounting Policies (Continued)

##### *SFAS No. 157*

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. Among other requirements, SFAS No. 157 defines fair value and establishes a framework for measuring fair value and also expands disclosure requirements regarding fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those years. The Company is evaluating the impact that the adoption of SFAS No. 157 may have on its consolidated financial statements.

##### *SFAS No. 159*

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which provides companies with an option to report selected financial assets and liabilities at fair value in an attempt to reduce both complexity in accounting for financial instruments and the volatility in earnings caused by measuring related assets and liabilities differently. This Statement is effective as of the beginning of an entity's first fiscal year beginning after November 15, 2007. The Company is evaluating the impact that the adoption of SFAS No. 159 may have on its consolidated financial statements.

#### Note 3. Restricted Cash

The Company had restricted cash of approximately \$0.3 million included in prepaid expenses and other current assets at March 31, 2006 and March 31, 2007. This cash represents security deposits held in the Company's European banks for certain facility and auto leases.

#### Note 4. Marketable Securities

The amortized cost, including interest receivable approximates market value of held-to-maturity short-term marketable securities and was \$16.9 million and \$5.5 million at March 31, 2006 and 2007, respectively.

The Company has classified its portion of the investment portfolio consisting of corporate asset-backed securities as available-for-sale securities for fiscal 2006. The cost of these securities approximates market value and was \$6.1 million at March 31, 2006. Principal payments of these available-for-sale securities are typically made on an expected pre-determined basis rather than on the longer contractual maturity date. There were no available-for-sale securities at March 31, 2007.

#### Note 5. Accounts Receivable

The components of accounts receivable are as follows:

	March 31,	
	2006	2007
Trade receivables	\$ 9,091	\$11,135
Allowance for doubtful accounts	(211)	(203)
	<u>\$ 8,880</u>	<u>\$10,932</u>

**ABIOMED, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—(Continued)**

**Note 6. Inventories**

The components of inventories are as follows:

	March 31,	
	2006	2007
Raw materials and supplies	\$ 1,764	\$ 3,755
Work-in-process	659	1,771
Finished goods	2,445	3,041
	<u>\$ 4,868</u>	<u>\$ 8,567</u>

All of the Company's inventories relate to circulatory care product lines that include the AB5000, BVS 5000, AbioCor and Impella products. Finished goods and work-in-process inventories consist of direct material, labor and overhead. From time to time, the Company loans finished goods inventory on a short-term basis to customers for demonstration purposes or clinical trial purposes which are amortized over a three-year life. The cost of "demo" inventory and the net carrying value are reflected in the table below:

	March 31,	
	2006	2007
Cost of inventory used for demo purposes	\$ 1,066	\$ 2,082
Accumulated amortization	(498)	(904)
	<u>\$ 568</u>	<u>\$ 1,178</u>

**Note 7. Property and equipment**

The components of property and equipment are as follows:

	March 31,	
	2006	2007
Machinery and equipment	\$ 12,519	\$ 15,513
Furniture and fixtures	1,340	1,367
Leasehold improvements	2,545	2,522
Construction in progress	989	654
Total cost	17,393	20,056
Less accumulated depreciation	(12,569)	(14,292)
	<u>\$ 4,824</u>	<u>\$ 5,764</u>

Depreciation expense related to property and equipment was \$1.1 million, \$1.4 million and \$1.9 million for the fiscal years ended March 31, 2005, 2006 and 2007, respectively.

**Note. 8 Acquisition**

In May 2005, the Company acquired all of the shares of outstanding capital stock of Impella CardioSystems AG ("Impella") in exchange for approximately \$1.6 million in cash and 4,029,004 shares of Abiomed common stock. As of March 31, 2007, 11,019 of the shares have been returned to the Company as a result of Abiomed's settlement of undisclosed pre-acquisition liabilities. Impella develops, manufactures and markets percutaneous micro heart pumps with integrated motors and sensors for use in interventional cardiology and heart surgery. These devices are designed primarily for use by interventional cardiologists to support pre-shock patients in the cath lab who may not require as much support as patients in the surgery suite. The Impella catheters are designed to provide ventricular support for patients requiring hemodynamic stabilization or suffering from reduced cardiac output, and can aid in recovering the hearts of patients following a heart attack. The Impella 2.5 and 5.0 catheters and Impella RD and LD heart pumps are already available in Europe under CE mark approval. In the U.S., both the Impella 2.5 and 5.0 are in pilot clinical trials.

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note. 8 Acquisition (Continued)

The aggregate purchase price, excluding a contingent payment in the amount of \$5.6 million made on January 30, 2007 in the form of common stock, was approximately \$45.1 million, which consisted of \$42.2 million of the Company's common stock, \$1.6 million of cash paid to certain former shareholders of Impella, and \$1.3 million of transaction costs, consisting primarily of fees paid for financial advisory and legal services. The Company issued 4,029,004 shares of common stock, the fair value of which was based upon a five-day average of the closing price two days before and two days after the terms of the acquisition were agreed to and publicly announced.

In addition, the purchase agreement for the acquisition of Impella provides that the Company may be required to make additional contingent payments to Impella's former shareholders of up to \$16.75 million. If the average market price per share of Abiomed's common stock, as determined in accordance with the purchase agreement, as of the date of any of the milestones is achieved is \$22 or more, no additional contingent consideration will be required with respect to the milestones. If the average market price is between \$18 and \$22 on the date of the Company's achievement of a milestone, the relevant milestone payment will be reduced ratably. The following are the potential milestone payments notwithstanding the foregoing:

- upon FDA approval of Impella's 2.5 liter pump system, a payment of \$5,583,333,
- upon FDA approval of Impella's 5.0 liter pump system, a payment of \$5,583,333, and
- upon the sale of 1,000 units of Impella's products worldwide between the closing and December 31, 2007, a payment of \$5,583,334.

These milestone payments may be made, at the Company's option, by a combination of cash or stock, except that no more than an aggregate of \$15 million of these milestone payments may be made in the form of stock. If any contingent payments are made, they will result in an increase in the carrying value of goodwill. The Company reached the 1,000 unit milestone in the third quarter of fiscal 2007. On January 30, 2007, 402,279 shares of common stock were issued to satisfy this milestone obligation of \$5.6 million which was accounted for by increasing both goodwill and stockholder's equity.

The acquisition of Impella was accounted for under the purchase method of accounting and the results of operations of Impella have been included in the consolidated results of the Company from the acquisition date. The purchase price of the acquisition was allocated to tangible and intangible assets and assumed liabilities based on their estimated fair values at the date of acquisition. The Company allocated approximately \$9.5 million of the purchase price to intangible assets comprised of existing technology, patents, trademarks and other purchased intangibles (Note 9). In addition, approximately \$13.3 million of the purchase price was allocated to in-process research and development. The excess purchase price of approximately \$20.3 million after this allocation was accounted for as goodwill.

The following table presents the fair values of assets and liabilities initially recorded in connection with the Impella acquisition:

Cash	\$ 535
Accounts receivable	805
Inventories	1,335
Prepaid expenses and other current assets	514
Property and equipment	589
Intangible assets:	
Patents (estimated useful life of 7 years)	6,179
Developed technology (estimated useful life of 7 years)	2,175
Distributor agreements (estimated useful life of 7 years)	800
Trademarks and tradenames (estimated useful life of 7 years)	314
Acquired in-process R&D Charge ("IPR&D")	13,306
Total intangible assets	22,774
Goodwill	20,268
Accrued expenses and other current liabilities	(1,749)
Total consideration paid	<u>\$45,071</u>

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 8 Acquisition (Continued)

Of the \$22.8 million of acquired intangible assets, \$13.3 million was allocated to IPR&D and was written off at the date of acquisition as a non-cash acquisition charge to operations because the IPR&D had no alternative uses and had not reached technological feasibility. This non-cash acquisition charge is reflected in the accompanying statement of operations for the fiscal year ended March 31, 2006.

The amount of the IPR&D charge was determined by identifying IPR&D activities that have reached the “substance” stage of development and for which no alternative future use exists. In addition, the fair value of existing technology for U.S. based sales is included in expensed IPR&D due to the additional risks and expense incurred by the combined entity in obtaining regulatory approval for U.S. based market sales.

Management determined the valuation of the IPR&D using a number of factors. The value was based primarily on the discounted cash flow method. This valuation included consideration of (i) the stage of completion of each of the projects, (ii) the technological feasibility of each of the projects, (iii) whether the projects had an alternative future use, (iv) the estimated future residual cash flows that could be generated from the various projects and technologies over their respective projected economic lives, and (v) whether additional product development costs or regulatory risks would be incurred to bring the technology to completion.

The primary basis for determining the technological feasibility of these projects was whether the product has obtained approval from the FDA for commercial sales in the U.S. As of the acquisition date, the IPR&D projects, as well as the existing technologies and products have not completed or obtained sufficient clinical data to support an application to the FDA seeking commercial approval.

The economic benefit stream or annual cash flow generated for each of the IPR&D projects and existing technology product sales were determined based upon management’s estimate of future revenue and expected profitability of the various products and technologies involved. These projected cash flows were then discounted to their present values taking into account management’s estimate of future expenses that would be necessary to bring the projects to completion. The discount rates include a rate of return, which accounts for the time value of money, as well as risk factors that reflect the economic risk that the cash flows projected may not be realized. The cash flows were discounted at discount rates ranging from 23% to 25% per annum, depending on the project’s stage of completion and the type of complex functionality needed. This discounted cash flow methodology for the various projects included in the purchased IPR&D resulted in a total valuation of \$13.3 million. Although work on the projects related to the IPR&D is anticipated to continue after the acquisition, the amount of the purchase price allocated to IPR&D was written off because the projects underlying the IPR&D that was being developed were considered technologically feasible as of the acquisition date, however the assets utilized in these projects, excluding the patents, have no alternative future use.

#### Note 9. Intangible Assets and Goodwill

The carrying amount of goodwill was recorded in connection with the Company’s acquisition of Impella (Note 8):

Balance at May 10, 2005 (date of acquisition)	\$ 20,129
Purchase price adjustments	131
Exchange rate impact	(1,154)
Balance at March 31, 2006	19,106
Purchase price adjustments-milestone payment	5,583
Exchange rate impact	2,019
Balance at March 31, 2007	<u>\$ 26,708</u>

The components of intangible assets are as follows:

	March 31, 2006			March 31, 2007		
	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Patents	\$ 6,990	\$ 1,564	\$ 5,426	\$ 7,625	\$ 2,681	\$ 4,944
Trademarks and Tradenames	407	109	298	444	175	269
Distribution Agreements	754	99	655	655	179	476
Acquired Technology	2,054	269	1,785	2,258	618	1,640
	<u>\$10,205</u>	<u>\$ 2,041</u>	<u>\$ 8,164</u>	<u>\$10,982</u>	<u>\$ 3,653</u>	<u>\$ 7,329</u>

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

Amortization expense for intangible assets was \$0.1 million, \$1.3 million and \$1.6 million for the years ending March 31, 2005, 2006 and 2007, respectively. Assuming no future acquisitions, the estimated annual amortization expense for fiscal years 2008 through 2009, fiscal years 2010 through 2012, and thereafter is \$1.5 million, \$1.4 million, and \$0.1 million, respectively.

#### Note 10. Warranties

The following table summarizes the activities in the warranty reserve for the fiscal years ended March 31, 2006 and 2007:

	March 31,	
	2006	2007
Balance at the beginning of the year	\$ 231	\$ 167
Accrual for warranties issued	193	132
Settlements made	(257)	(142)
Balance at the end of the year	\$ 167	\$ 157

#### Note 11. Stock Award Plans and Stock Based Compensation

In December 2004, the FASB issued SFAS No. 123(R), *Share-based Payment*. SFAS No. 123(R) requires entities to recognize compensation costs for all share-based payments, including grants of employee stock options, based on the grant-date fair value of those share-based payments (with limited exceptions), adjusted for expected forfeitures.

Effective April 1, 2006, the Company adopted the provisions of SFAS No. 123(R) using the modified prospective application transition method. Under this transition method, the compensation cost recognized beginning April 1, 2006 includes compensation cost for (i) all share-based payments granted prior to, but not yet vested as of April 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (ii) shares issued in offerings under the Employee Stock Purchase Plan with offering periods commencing April 1, 2006 and stock options granted subsequent to March 31, 2006 based on the grant-date fair value estimated using the Black-Scholes valuation model in accordance with the provisions of SFAS No. 123(R). Compensation cost is recognized on a straight-line basis over the requisite service period for share-based payments issued subsequent to the adoption of SFAS No. 123(R). For stock options issued prior to the adoption of SFAS No. 123(R), the accelerated method is used for expense recognition.

The Company has elected to calculate the available additional paid-in capital pool for purposes of determining the impact of tax deficiencies using the alternative transition method described in FSP 123(R)-3, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*.

#### Stock Option Plans

With the exception of 3,557 outstanding options that were granted to certain employees during our fiscal year ended March 31, 2004, with an exercise price of \$0.01 per share, all outstanding stock options of the Company as of March 31, 2007 were granted with an exercise price equal to the fair market value on the date of grant. For the options and restricted stock granted below fair market value, compensation expense is recognized ratably over the vesting period. Outstanding stock options, if not exercised, expire 10 years from the date of grant.

The 1992 Combination Stock Option Plan (the "Combination Plan"), as amended, was adopted in September 1992 as a combination and amendment of the Company's then outstanding Incentive Stock Option Plan and Nonqualified Plan. A total of 2,670,859 options were awarded from the Combination Plan during its ten-year restatement term that ended on May 1, 2002. As of March 31, 2007, 141,300 of these options remain outstanding, fully vested and eligible for future exercise.

The 1998 Equity Incentive Plan, (the "Equity Incentive Plan"), was adopted by the Company in August 1998. The Equity Incentive Plan provides for grants of options to key employees, directors, advisors and consultants as either incentive stock options or nonqualified stock options as determined by the Company's Board of Directors. A maximum of 1,000,000 shares of common stock may be awarded under this plan. Options granted under the Equity Incentive Plan are exercisable at such times and subject to such terms as the Board of Directors may specify at the time of each stock option grant. Options outstanding under the Equity Incentive Plan have vesting periods of 3 to 5 years from the date of grant and options awarded expire ten years from the date of grant.

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 11. Stock Award Plans and Stock Based Compensation (Continued)

The 2000 Stock Incentive Plan, (the “2000 Plan”), as amended, was adopted by the Company in August 2000. The 2000 Plan provides for grants of options to key employees, directors, advisors and consultants to the Company or its subsidiaries as either incentive or nonqualified stock options as determined by the Company’s Board of Directors. Up to 4,900,000 shares of common stock may be awarded under the 2000 Plan and are exercisable at such times and subject to such terms as the Board of Directors may specify at the time of each stock option grant. Options outstanding under the 2000 Plan generally vest 4 years from the date of grant and options awarded expire ten years from the date of grant.

The Company has a nonqualified stock option plan for non-employee directors (the “Directors’ Plan”). The Directors’ Plan, as amended, was adopted in July 1989 and provides for grants of options to purchase shares of the Company’s common stock to non-employee Directors of the Company. Up to 400,000 shares of common stock may be awarded under the Directors’ Plan. Options outstanding under the Director’s Plan have vesting periods of 1 to 5 years from the date of grant and options expire ten years from the date of grant

#### Grant-Date Fair Value

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model, consistent with the provisions of SFAS No. 123(R), SEC SAB No. 107 *Share-based Payment* and the Company’s prior period pro forma disclosure of net loss, including stock-based compensation (determined under a fair value method as prescribed by SFAS No. 123). The fair value of options granted during the fiscal years 2005, 2006 and 2007 were calculated using the following weighted average assumptions:

	2005	2006	2007
Risk-free interest rate	3.87%	4.14%	4.97%
Expected option life (in years)	7.5	7.3	6.25
Expected Volatility	84%	73%	65%

The risk-free interest rate is based on the United States Treasury yield curve in effect at the time of grant for a term consistent with the expected life of the stock options. Volatility assumptions are calculated based on a combination of the historical volatility of our stock and adjustments for factors not reflected in historical volatility that are more indicative of future volatility. By using this combination, the Company is taking into consideration estimates of future volatility that the Company believes will differ from historical volatility as a result of product diversification and the Company’s acquisition of Impella. The average expected life was estimated using the simplified method for determining the expected term as prescribed by the SEC’s Staff Accounting Bulletin No. 107. The calculation of the fair value of the options is net of estimated forfeitures. Forfeitures are estimated based on an analysis of actual option forfeitures, adjusted to the extent historic forfeitures may not be indicative of forfeitures in the future. In addition, an expected dividend yield of zero is used in the option valuation model, because the Company does not pay cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The weighted average grant-date fair value for options granted during fiscal years 2005, 2006, and 2007 was \$8.05, \$6.91, and \$8.75 per share, respectively.

The application of SFAS No. 123(R) resulted in expense of \$5.8 million, or \$0.21 per share for the 2007 fiscal year which is recorded within the applicable operating expense where the Company reports the option holders’ compensation cost in the consolidated statements of operations. The remaining unrecognized stock-based compensation expense for unvested stock option awards at March 31, 2007 was approximately \$9.0 million, net of forfeitures, and the weighted average time over which this cost will be recognized is 1.9 years. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow. Because the Company does not recognize the benefit of tax deductions in excess of recognized compensation cost due to its net operating loss position, this change had no impact on the Company’s consolidated statement of cash flows for the twelve months ended March 31, 2007.

#### Accounting Prior to Adoption of SFAS No. 123 (R)

Prior to April 1, 2006, the Company accounted for stock-based compensation in accordance with the provisions of APB No. 25. The Company elected to follow the disclosure-only alternative requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*. Accordingly, the Company did not recognize the compensation expense for the issuance of options with fixed exercise prices at least equal to

**ABIOMED, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—(Continued)**

**Note 11. Stock Award Plans and Stock Based Compensation (Continued)**

the fair market value at the date of the grant. Under the modified prospective transition method of SFAS No. 123(R), results for prior periods are not restated; however, the presentation of pro forma net income (loss) and net income (loss) per share as if the Company had accounted for its stock plans under the fair value method of SFAS No. 123 is required for periods presented prior to the adoption of SFAS No. 123(R).

In the process of adopting SFAS No. 123(R), the Company determined that the historical estimated forfeiture rates used in the SFAS No. 123 pro forma disclosure in the previously issued financial statements were higher than the Company's actual historical forfeiture rates, resulting in an understatement of the Company's pro forma stock compensation expense. The Company has revised its pro forma disclosure for the years ended March 31, 2005 and 2006 to reflect estimated forfeiture rates that are consistent with the Company's historical forfeiture rates. This revision resulted in an increase in pro forma expense and pro forma net loss in the amount of \$2.3 million and \$1.8 million and an increase in net loss per share of \$0.11 and \$0.07 for the fiscal years ended March 31, 2005, and 2006, respectively, which is reflected in the table below.

	<u>2005</u>	<u>2006</u>
Net loss, as reported	\$ (2,342)	\$ (29,449)
Add: Stock-based employee compensation included in reported net loss	98	340
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	<u>(5,145)</u>	<u>(6,307)</u>
Pro forma net loss	\$ (7,389)	\$ (35,416)
Basic and diluted loss per share		
As reported	\$ (0.11)	\$ (1.15)
Pro forma	\$ (0.34)	\$ (1.38)

**Stock Option Activity**

The following table summarized stock option activity for the years ended March 31, 2005 and 2006:

	<u>2005</u>		<u>2006</u>	
	<u>Options</u>	<u>Weighted-Average Exercise Price</u>	<u>Options</u>	<u>Weighted-Average Exercise Price</u>
Outstanding at beginning of year	3,076,839	\$ 9.05	3,617,506	\$10.11
Granted	1,487,400	10.34	1,108,882	9.42
Exercised	(665,437)	5.90	(317,985)	6.33
Cancelled	(244,821)	8.16	(292,687)	8.15
Expired	<u>(36,475)</u>	19.48	<u>(154,073)</u>	16.69
Outstanding at end of year	<u>3,617,506</u>	\$10.11	<u>3,961,643</u>	\$10.11
Exercisable at end of year	<u>1,423,805</u>	\$10.99	<u>1,637,702</u>	\$11.10

The following table summarizes the stock option activity for the year ended March 31, 2007:

	<u>Options</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (Years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at March 31, 2006	3,961,643	\$10.11		
Granted	1,102,850	13.57		
Exercised	(350,933)	7.84		
Cancelled	(347,949)	10.85		
Expired	<u>(59,691)</u>	15.95		
Outstanding at March 31, 2007	<u>4,305,920</u>	\$11.04	<u>7.03</u>	<u>\$13,648,205</u>
Exercisable at March 31, 2007	<u>1,997,012</u>	\$10.72	<u>5.42</u>	<u>\$ 8,151,352</u>

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 11. Stock Award Plans and Stock Based Compensation (Continued)

The total intrinsic value of options exercised (i.e. the difference between the market price at exercise and the price paid by the employee to exercise the options) for the fiscal years 2005, 2006, and 2007 was \$5.1 million, \$1.2 million, and \$2.0 million, respectively. The total fair value of options vested in fiscal years 2005, 2006, and 2007 was \$2.0 million, \$5.1 million, and \$5.3 million, respectively.

#### *Variable Options*

The Company has a consulting agreement with David M. Lederman, Ph.D., its former Chief Executive Officer and former Chairman of its Board of Directors. Under this consulting agreement, Dr. Lederman has agreed to serve as a senior advisor for four years in exchange for \$0.2 million of annual compensation, starting on April 2, 2005. Dr. Lederman's existing non-qualified stock options that were awarded in the past during his tenure as the Company's CEO remain unmodified and will continue to vest during the term of his service as a non-employee advisor. He has the ability to exercise the options during this term. These options are considered variable options, the fair value of which will be expensed over the vesting period of the options, subject to adjustment based on the market price of the Company's common stock at the close of each financial reporting period.

#### *Restricted Stock*

On March 1, 2005, the Company granted 24,000 shares of restricted stock to an officer of the Company, of which 16,000 shares vested in 8,000 increments on March 1, 2006 and March 1, 2007. The remaining 8,000 shares will vest on March 1, 2008. The fair value of this grant per share, \$10.80, was calculated based upon the fair market value of the Company's stock price at the date of grant. The restricted stock grant compensation expense is recognized on a straight-line basis over a vesting period of three years. At March 31, 2007, there was \$0.1 million of unrecognized compensation cost related to these restricted shares.

#### *Employee Stock Purchase Plan*

In March of 1988, the Company adopted the 1988 Employee Stock Purchase Plan ("the Purchase Plan" or "ESPP"), as amended. Under the Purchase Plan, eligible employees (including officers and directors) who have completed three months of employment with the Company or its subsidiaries who elect to participate in the Purchase Plan instruct the Company to withhold a specified amount from each payroll period during a six-month payment period (the periods April 1 – September 30 and October 1 – March 31). On the last business day of each payment period, the amount withheld is used to purchase common stock at an exercise price equal to 85% of the lower of its market price on the first business day or the last business day of the payment period. Up to 500,000 shares of common stock may be issued under the Purchase Plan, of which 232,998 shares are available for future issuance as of March 31, 2007. During the fiscal years ended March 31, 2005, 2006 and 2007, 21,287, 23,970, and 27,095 shares of common stock, respectively, were sold pursuant to the Purchase Plan. Compensation expense recognized related to the Company's ESPP was \$0.1 million for fiscal 2007. Compensation expense for the Company's ESPP was valued using the Black-Scholes option valuation model using the following assumptions: an expected life of six months, a weighted average volatility of 39.75% and a weighted average risk free rate of 4.84%.

#### Note 12. Capital Stock

Each share of common stock has a voting right of one vote per share.

The Company has authorized 1,000,000 shares of Class B Preferred Stock, \$0.01 par value, of which the Board of Directors can set the designation, rights and privileges. No shares of Class B Preferred Stock have been issued or are outstanding.

In August 1997, the Company declared a dividend of one Preferred Share Purchase Right (the Right) for each outstanding share of common stock to its stockholders of record at August 28, 1997. Each right entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock with a par value of \$0.01 per share, at a price of \$45.00 per one one-thousandth of a share, subject to amendment. In accordance with the terms set forth in the Rights Agreement, the Rights are not exercisable until the occurrence of certain events, as defined. In addition, the registered holders of the Rights will have no rights as a common stockholder of the Company until the Rights are exercised. The Company's Board of Directors may amend the terms of the Rights. The Rights expire on August 13, 2007.

**ABIOMED, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—(Continued)**

**Note 12. Capital Stock (Continued)**

In September 2000, the Company issued common stock and warrants to acquire the exclusive rights to the Penn State Heart together with complete ownership of a company incorporated to commercialize the Penn State Heart called BeneCor Heart Systems, Inc. The terms of this transaction consisted of payment of 110,000 shares of the Company's common stock, plus the issuance of warrants to purchase up to 400,000 additional shares of the Company's common stock at an exercise price of \$0.01 per share. Exercise of the warrants is contingent on the achievement of certain clinical and regulatory milestones with the Penn State Heart by specified dates, the last of which is September 30, 2007. Warrants not vested and exercised by September 30, 2007 will expire. The value of the common stock and warrants issued in connection with the transaction are included in stockholders' equity in the amount of \$3.1 million each for a total of \$6.2 million, which represents the fair value of the stock and warrants based on the closing market price for the Company's stock on the closing date for this transaction. These amounts were fully expensed as in-process research and development on the date of acquisition because the technology had no future alternate use. As of March 31, 2007, approximately 400,000 warrants were outstanding and none were exercisable.

See Note 8 to these consolidated financial statements for the effect on the Company's capital structure from the May 10, 2005 acquisition of Impella CardioSystems AG.

In March 2007, the Company issued 5,000,000 shares of common stock in a public offering for use in expanding the Company's global sales and distribution, completion of clinical studies and regulatory processes, investments in research and development to broaden the Company's portfolio of products across the continuum of care and for general corporate processes. In April of 2007, an additional 80,068 shares of common stock were issued in connection with the offering upon the partial exercise of the underwriters' over-allotment option.

**Note 13. Income Taxes**

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates. A valuation reserve is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. The tax benefit associated with the stock option compensation deductions will be credited to equity when realized.

At March 31, 2007, the Company had federal and state net operating loss (NOL) carryforwards of approximately \$79.2 million and \$36.9 million, respectively, which begin to expire in fiscal 2008. At March 31, 2007, the Company also had foreign NOL carryforwards of approximately \$20.6 million that can be carried forward indefinitely. Additionally, at March 31, 2007, the Company had federal and state research and experimentation credit carryforwards of approximately \$6.3 million and \$4.3 million, respectively, which begin to expire in fiscal 2008. Ownership changes, as defined in Section 382 of the Internal Revenue Code, may have limited the amount of net operating loss carryforwards and research and experimentation credit carryforwards that the Company can use each year to offset future taxable income and taxes payable. Subsequent ownership changes could impose additional limitations. The Company has not done a complete analysis to determine whether changes in the composition of its stockholders, including the Company's acquisition of Impella or the Company's recent public offering, have resulted or will result in an ownership change for purposes of Section 382.

Loss before income taxes is as follows for the years ended March 31:

	<u>2005</u>	<u>2006</u>	<u>2007</u>
Loss before income taxes:			
United States	\$ (1,761)	\$(10,599)	\$(15,660)
Foreign	(581)	(18,494)	(11,746)
Income (loss) before income taxes	<u>\$ (2,342)</u>	<u>\$(29,093)</u>	<u>\$(27,406)</u>
Provision for income taxes:			
Current:			
Federal		\$ 46	\$ —
State		—	—
Foreign		—	—
Total current		<u>46</u>	<u>—</u>
Deferred:			
Federal		264	404
State		46	71
Foreign		—	—
Total deferred		<u>310</u>	<u>475</u>
Total tax provision		<u>\$ 356</u>	<u>\$ 475</u>

**ABIOMED, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—(Continued)**

**Note 13. Income Taxes (Continued)**

There was no current or deferred tax provision for the fiscal year ended March 31, 2005. Differences between the federal statutory income tax rate and the effective tax rates for the years ended March 31, 2006 and 2007, are summarized as follows:

	<u>2006</u>	<u>2007</u>
Statutory income tax rate	34.0%	34.0%
Increase (decrease) resulting from:		
State taxes, net of federal tax benefit	—	—
Change in valuation allowance	(42.0)	(42.5)
Credits	2.5	2.7
Rate differential on foreign operations	4.7	2.3
Stock based compensation	—	2.2
Alternative minimum tax	(0.2)	—
Other, net	(0.2)	(0.4)
Effective tax rate	<u>(1.2)%</u>	<u>(1.7)%</u>

For fiscal year 2005 the effective tax rate of zero differs from the statutory rate of 34% primarily due to the inability of the Company to recognize deferred tax assets as a result of its net operating loss position.

The components of the Company's net deferred taxes were as follows at March 31:

	<u>2006</u>	<u>2007</u>
<b>Assets</b>		
NOL carryforwards and tax credit carryforwards	\$ 32,700	\$ 38,366
Foreign NOL carryforwards	7,119	8,237
Stock based compensation	—	2,303
Nondeductible reserves and accruals	1,070	338
Deferred revenue	132	263
Depreciation	505	489
Amortizable intangibles other than goodwill	5,284	5,180
Other, net	1,079	959
Capitalized research and development	23,721	26,801
	<u>71,610</u>	<u>82,936</u>
<b>Liabilities</b>		
Identified intangibles	(3,108)	(2,805)
Indefinite lived intangible	(310)	(784)
Cumulative foreign currency translation gain	—	(407)
	<u>(3,418)</u>	<u>(3,996)</u>
Net deferred tax asset	68,192	78,940
Valuation allowance	(68,502)	(80,131)
Net deferred taxes	<u>\$ (310)</u>	<u>\$ (1,191)</u>

The change in the valuation allowance of \$11.6 million is primarily due to the impact of the current year operating losses without current tax benefit.

Management has determined that the Company is not likely to realize the income tax benefit of its net deferred tax assets. To the extent the Company generates income in future years, the tax provision will reflect the realization of such benefits, with the exception of benefits attributable to acquired deferred tax assets. The recognition of such amount in future years will be allocated to reduce the excess of the purchase price over the net assets acquired and other non-current intangible assets.

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 13. Income Taxes (Continued)

As a result of the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets* and the fiscal year 2006 acquisition of Impella, the Company has recorded a valuation allowance in excess of its net deferred tax assets to the extent the difference between the book and tax basis of indefinite lived intangible assets is not expected to reverse during the net operating loss carryforward period.

The net deferred tax liability of \$1.2 million at March 31, 2007 is primarily due to the difference in accounting for the Company's goodwill, which is amortizable over 15 years for tax purposes but not amortized for book purposes, in accordance with SFAS No. 142. It is also due to an unrealized gain from fluctuations in foreign currency with respect to our European operations which are treated as disregarded entities for tax purposes. These net deferred tax liabilities cannot be offset against the Company's deferred tax assets under U.S. generally accepted accounting principals since they relate to indefinite-lived assets and are not anticipated to reverse in the same period.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* ("FIN 48"). FIN 48 clarifies the accounting for uncertainties in income taxes recognized in an enterprise's financial statements. The Interpretation requires that the Company determines whether it is more likely that a tax position will be sustained upon examination by the appropriate taxing authority. If a tax position meets the more likely than not recognition criteria, FIN 48 requires the tax position be measured at the largest amount of benefit greater than 50% likely of being realized upon ultimate settlement. FIN 48 must be applied to all existing tax positions upon initial adoption. This accounting standard is effective for fiscal years beginning after December 15, 2006. The Company will adopt FIN 48 on April 1, 2007. The Company is evaluating the impact that the adoption of FIN 48 will have on its consolidated financial statements.

#### Note 14. Commitments and Contingencies

The Company's acquisition of Impella provides that Abiomed may be required to make additional contingent payments to Impella's former shareholders (see Note 8). The Company may make additional contingent payments to Impella's former shareholders based on additional milestones related to FDA approvals in the amount of up to \$11.2 million. These contingent payments may be made in a combination of cash or stock under circumstances described in the purchase agreement.

On May 15, 2006, Richard A. Nazarian, as Selling Stockholder Representative, filed a Demand for Arbitration (subsequently amended) with the Boston office of the American Arbitration Association. The claim seeks 600,000 unrestricted shares of Abiomed common stock for an alleged breach of our obligation to fund development of the Penn State Heart program and an alleged cancellation of the Penn State Heart development project. The Company instituted a legal action in Federal Court to determine the arbitrability of the claims asserted and the Federal Court has stayed the arbitration of a portion of the claim. The arbitration hearings have been completed and the Company is awaiting a decision. The Company has applied the concepts of SFAS No. 5, *Accounting for Contingencies*, and has determined that no accrual is warranted.

The Company applies the disclosure provisions of FIN No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Guarantees of Indebtedness of Others, and Interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34* (FIN No. 45) to its agreements that contain guarantee or indemnification clauses. These disclosure provisions expand those required by SFAS No. 5, *Accounting for Contingencies*, by requiring that guarantors disclose certain types of guarantees, even if the likelihood of requiring the guarantor's performance is remote. The following is a description of arrangements in which the Company is a guarantor.

**Product warranties**—The Company routinely accrues for estimated future warranty costs on its product sales at the time of sale. Abiomed's products are subject to rigorous regulation and quality standards. Operating results could be adversely effected if the actual cost of product failures exceeds the estimated warranty provision.

**Patent indemnifications**—In many sales transactions, the Company indemnifies customers against possible claims of patent infringement caused by the Company's products. The indemnifications contained within sales contracts usually do not include limits on the claims. The Company has never incurred any material costs to defend lawsuits or settle patent infringement claims related to sales transactions. Under the provisions of FIN No. 45, intellectual property indemnifications require disclosure only.

The Company enters into agreements with other companies in the ordinary course of business, typically with underwriters, contractors, clinical sites and customers that include indemnification provisions. Under these provisions the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of its activities. These indemnification

**ABIOMED, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—(Continued)**

**Note 14. Commitments and Contingencies (Continued)**

provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. Abiomed has never incurred any material costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the estimated fair value of these agreements is minimal. Accordingly, the Company has no liabilities recorded for these agreements as of March 31, 2007.

Clinical study agreements – In the Company’s clinical study agreements, Abiomed has agreed to indemnify the participating institutions against losses incurred by them for claims related to any personal injury of subjects taking part in the study to the extent they relate to uses of the Company’s devices in accordance with the clinical study agreement, the protocol for the device and Abiomed’s instructions. The indemnification provisions contained within the Company’s clinical study agreements do not generally include limits on the claims. The Company has never incurred any material costs related to the indemnification provisions contained in its clinical study agreements

As of March 31, 2007, the Company had entered into leases for its facilities, including its primary operating facility in Danvers, Massachusetts, with terms through fiscal 2010. The Danvers lease may be extended, at the Company’s option, for two successive additional periods of five years each with monthly rent charges to be determined based on then current fair rental values. The Company’s lease for its Aachen location expires in December 2012. In December 2005 we closed our office facility in The Netherlands, recording a charge of approximately \$0.1 million for the remaining lease term. Total rent expense under these leases, included in the accompanying consolidated statements of operations approximated \$0.8 million, \$1.3 million, and \$1.6 million for the fiscal years ended March 31, 2005, 2006 and 2007, respectively.

Future minimum lease payments under all significant non-cancelable operating leases as of March 31, 2007 are approximately as follows:

Fiscal Year Ending March 31,	Operating Leases
2008	1,960
2009	1,850
2010	1,590
2011	831
2012	822
Thereafter	616
Total future minimum lease payments	<u>\$ 7,669</u>

From time-to-time, the Company is involved in legal and administrative proceedings and claims of various types. While any litigation contains an element of uncertainty, management presently believes that the outcome of each such other proceedings or claims which are pending or known to be threatened, or all of them combined, is not expected to have a material adverse effect on the Company’s financial position, cash flow and results.

**Note 15. Research and Development**

Research and development is a significant portion of the Company’s operations. The Company’s research and development efforts are focused on the development of new products related to cardiac assist, recovery and heart replacement and to continually enhance and improve our existing products. Research and development costs are expensed when incurred and include direct materials and labor, depreciation, contracted services and other costs associated with developing new products and significant enhancements to existing products. Research and development expense for the fiscal years ended March 31, 2005, 2006 and 2007 are reflected in the table below:

	2005	2006	2007
Internally funded	\$ 13,100	\$ 16,480	\$ 22,123
Incurred under government contracts and grants	250	259	169
	<u>\$ 13,350</u>	<u>\$ 16,739</u>	<u>\$ 22,292</u>

## ABIOMED, INC. AND SUBSIDIARIES

### Notes to Consolidated Financial Statements—(Continued)

#### Note 16. Expensed In-Process Research and Development

The Company recorded a charge of \$0.8 million during the quarter ended June 30, 2006 in connection with the acquisition of certain circulatory care device patents and know-how. This charge relates to costs to acquire in-process research and development projects and technologies, which have not reached technological feasibility at the date of the asset acquisition and have no alternative future use.

The Company recorded a \$13.3 million non-cash charge to in-process research and development expense during the quarter ended June 30, 2005 in connection with the Company's acquisition of Impella on May 10, 2005. This charge relates to costs to acquire in-process research and development projects and technologies, which have not reached technological feasibility at the date of the business acquisition and have no alternative future use.

#### Note 17. 401(k) Plan

The Company has a 401(k) Plan that covers all employees who are at least 20 years of age. Amounts paid by the Company to match a portion of employees' contributions and discretionary amounts determined by the Company's Board of Directors totaled approximately \$0.2 million for each of the fiscal years ended March 31, 2005, 2006 and 2007, respectively.

#### Note 18. Accrued Expenses

Accrued expenses consisted of the following:

	March 31,	
	2006	2007
Salaries and benefits	\$ 3,432	\$ 4,214
Warranty	167	157
Professional, accounting and auditing fees	1,224	1,611
Other	362	1,035
	<u>\$ 5,185</u>	<u>\$ 7,017</u>

#### Note 19. Segment and Enterprise Wide Disclosures

The Company operates in one business segment—the research, development and sale of medical devices to assist or replace the pumping function of the failing heart. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results. Approximately 71% of the Company's total consolidated assets are located within the United States as of March 31, 2007. Remaining assets are located in Europe, primarily related to our Impella production facility, and include goodwill and intangibles of \$33.7 million at March 31, 2007 associated with the Impella acquisition from May 2005 as discussed in Note 8. Total assets in Europe excluding goodwill and intangibles were \$5.8 million at March 31, 2007 and amounted to 4% of total consolidated assets. International sales (sales outside the United States and primarily in Europe) accounted for 8%, 13% and 11% of total product revenue during the fiscal years ended March 31, 2005, 2006 and 2007, respectively.

**ABIOMED, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements—(Continued)**

**Note 20. Quarterly Results of Operation (Unaudited)**

The following is a summary of our unaudited quarterly results of operations for the fiscal years ending March 31, 2006 and 2007.

	<b>1<sup>st</sup> Quarter</b>	<b>2<sup>nd</sup> Quarter</b>	<b>3<sup>rd</sup> Quarter</b>	<b>4<sup>th</sup> Quarter</b>	<b>Total Year</b>
<b>Fiscal Year 2006</b>					
Total revenues	\$ 8,423	\$ 10,936	\$ 10,515	\$ 13,796	\$ 43,670
Cost of product revenue excluding amortization of intangibles	2,333	2,448	3,070	3,834	11,685
Total expenses (1)	24,824	11,527	11,985	13,940	62,276
Other income, net	226	260	313	399	1,198
Loss before provision for income taxes	(18,508)	(2,779)	(4,227)	(3,579)	(29,093)
Provision for income taxes	—	—	253	103	356
Net loss	<u>\$(18,508)</u>	<u>\$ (2,779)</u>	<u>\$ (4,480)</u>	<u>\$ (3,682)</u>	<u>\$(29,449)</u>
Basic and diluted loss per share	<u>\$ (0.77)</u>	<u>\$ (0.11)</u>	<u>\$ (0.17)</u>	<u>\$ (0.14)</u>	<u>\$ (1.15)</u>
<b>Fiscal Year 2007</b>					
Total revenues	\$ 13,008	\$ 10,886	\$ 12,904	\$ 13,851	\$ 50,649
Cost of product revenues excluding amortization of intangibles	3,483	2,925	2,873	2,731	12,012
Total expenses (1)	15,977	16,835	16,915	17,421	67,148
Other income, net	459	301	262	83	1,105
Loss before provision for income taxes	(5,993)	(8,573)	(6,622)	(6,218)	(27,406)
Provision for income taxes	138	103	103	131	475
Net loss	<u>\$(6,131)</u>	<u>\$ (8,676)</u>	<u>\$ (6,725)</u>	<u>\$ (6,349)</u>	<u>\$(27,881)</u>
Basic and diluted loss per share	<u>\$ (0.23)</u>	<u>\$ (0.33)</u>	<u>\$ (0.25)</u>	<u>\$ (0.22)</u>	<u>\$ (1.03)</u>

(1) Total expenses in the first quarter above include an in-process research and development charge of \$13.3 million and \$0.8 million for fiscal 2006 and fiscal 2007, respectively.

ABIOMED, INC. AND SUBSIDIARIES

SCHEDULE II

Valuation and Qualifying Accounts  
(in thousands)

Description	Balance at Beginning of Year	Additions	Deductions	Balance at End of Year
Allowance for Doubtful Accounts				
Fiscal year ended March 31, 2005	\$ 131	\$ 1	\$ 68	\$ 64
Fiscal year ended March 31, 2006	\$ 64	\$ 186	\$ 39	\$ 211
Fiscal year ended March 31, 2007	\$ 211	\$ 106	\$ 114	\$ 203

[THIS PAGE INTENTIONALLY LEFT BLANK]

## OFFICES

Abiomed, Inc.  
22 Cherry Hill Drive  
Danvers, Massachusetts 01923, USA  
Phone: (978) 777-5410  
Fax: (978) 777-8411  
Email: ir@abiomed.com

Abiomed Europe GmbH  
Neuenhofer Weg 3  
52074 Aachen, Germany  
Voice: +49 (241) 8860-0  
Facsimile: +49 (241) 8860-111

## NASDAQ GLOBAL MARKET

Trading symbol: ABMD

## DIVIDENDS

The Company has never paid any cash dividends on its capital stock and does not plan to pay any cash dividends in the foreseeable future. The current policy of the Company is to retain our cash flows and any future earnings to finance future growth.

## AVAILABLE PUBLICATIONS

The Company's annual report is distributed regularly to stockholders. Additional publications are available to stockholders, including the Company's annual report on Form 10-K, and quarterly reports on Form 10-Q, as filed with the Securities and Exchange Commission, news releases issued by the Company and brochures on specific products. Such publications are available on our website at [www.abiomed.com](http://www.abiomed.com) or by writing us at:

Abiomed, Inc., 22 Cherry Hill Drive,  
Danvers, Massachusetts 01923, USA.

## TRANSFER AGENT AND REGISTRAR

American Stock Transfer & Trust Company  
59 Maiden Lane  
New York, New York 10038

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Deloitte & Touche LLP  
200 Berkeley Street  
Boston, MA 02116

## FACTORS THAT MAY AFFECT FUTURE RESULTS

Certain statements in this annual report, including statements made in the letter to the shareholders, employees, customers and their patients, narrative text, captions and graphics, constitute "forward-looking statements," such as statements regarding the Company's plans, objectives, expectations and intentions. These statements can often be identified by the use of forward-looking terminology such as "may," "will," "should," "expect," "anticipate," "believe," "plan," "intend," "could," "estimates," "is being," "goal," "schedule" or other variations of these terms or comparable terminology. All forward-looking statements, including statements regarding timing and results of the AbioCor roll-out and Impella trials, AB5000 and BVS revenue growth and introduction of new products, involve risks and uncertainties. Actual results, events or performance could differ materially from those set forth in the forward-looking statements. Factors that could cause or contribute to such differences are discussed under the heading "Risk Factors" in the Company's annual report on Form 10-K for the fiscal year ended March 31, 2007, and the Company's other filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this annual report. The Company undertakes no obligation to publicly release the results of any revision to these forward-looking statements that might be made to reflect any change in the Company's expectations or in events, conditions or circumstances on which any statement is based.

## DEFINITIONS

**510(k) Clearance:** required by the FDA for any device intended for human use that does not have a PMA or HDE. A 510(k) submission must demonstrate that a device is substantially equivalent to one or more similar devices legally marketed in the United States.

**Acute Myocardial Infarction (AMI):** also called heart attack, usually caused by a blocked coronary artery, which prevents blood and oxygen from nourishing the heart muscle.

**Angioplasty:** performed in the catheterization lab in which a catheter-guided balloon is used to open a narrowed coronary artery. A stent (a wire-mesh tube that expands to hold the artery open) is usually placed at the narrowed section during angioplasty.

**Cardiogenic Shock (CS):** a condition that often takes place after a heart attack when cells in the heart start to die, due to the failure of the heart to pump an adequate amount of blood to the heart and the rest of the body.

**CE Mark:** a mandatory European approval or marking for devices showing essential health and safety requirements.

## EXECUTIVE OFFICERS

(As determined by the Abiomed Board of Directors and pursuant to the Rules and Regulations of the Securities and Exchange Act of 1934)

### Michael R. Minogue

Chairman, Chief Executive Officer and President

### Daniel J. Sutherby

Chief Financial Officer

### David Weber, Ph.D.

Chief Operating Officer

### William J. Bolt

Sr. Vice President, Quality and Regulatory Affairs

### Andrew J. Greenfield

Vice President, Healthcare Solutions

## BOARD OF DIRECTORS

### Michael R. Minogue

Chairman, Chief Executive Officer and President

### W. Gerald Austen, M.D.

Edward D. Churchill Professor of Surgery,  
Harvard Medical School and the  
Massachusetts General Hospital

### Ronald W. Dollens

Retired Chief Executive Officer and  
President, Guidant Corporation

### David Gottlieb

Managing Partner,  
Noble Bridge Group, LLC

### Louis E. Lataif

Dean, Boston University  
School of Management

### Desmond H. O'Connell, Jr.

Former Chairman, Serologicals Corporation;  
Management Consultant

### Dorothy E. Puhly

Lead Director, Abiomed Board of Directors;  
Executive Vice President, Chief Financial Officer and  
Assistant Treasurer, Dana-Farber Cancer Institute, Inc.

### Eric A. Rose, M.D.

Former Chairman of Columbia University,  
Department of Surgery  
Chief Executive Officer and Chairman of the Board,  
SIGA Technologies, Inc.

### Henri A. Termeer

Chairman, Chief Executive Officer and President,  
Genzyme Corporation

**Myocarditis:** inflammation of the heart muscle brought on by viruses or bacteria, may even result from allergic reaction.

**Post Cardiotomy Cardiogenic Shock (PCCS):** cardiogenic shock that takes places during open-heart surgery, often as a result the patient cannot come off a heart-lung support machine.

**Premarket Approval (PMA):** the process of scientific and regulatory review of the safety and effectiveness of Class III medical devices. It is the most stringent type of device regulation required by the FDA.



**RECOVERING  
HEARTS.  
SAVING LIVES.**



**LEADING IN  
TECHNOLOGY  
& INNOVATION**

TM



**GROWING  
SHAREHOLDER  
VALUE**



**WINNING CULTURE**

- Patients and Customers Come First
- Honor and Integrity in All Actions



Recovering hearts. Saving lives.™

**Abiomed, Inc.**  
22 Cherry Hill Drive  
Danvers, MA 01923, USA

**Abiomed Europe GmbH**  
Neuenhofer Weg 3  
52074 Aachen, Germany

**[www.abiomed.com](http://www.abiomed.com)**