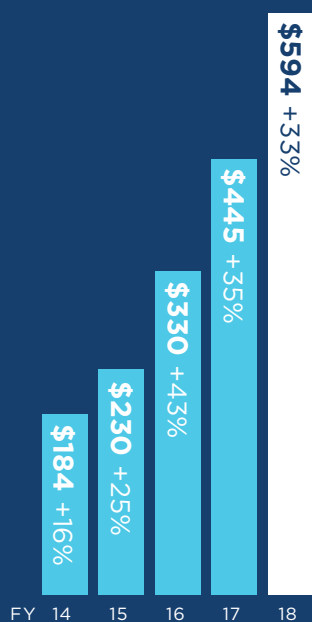




# FINANCIAL PERFORMANCE

FY 2018



## TOTAL REVENUE

DOLLARS IN MILLIONS

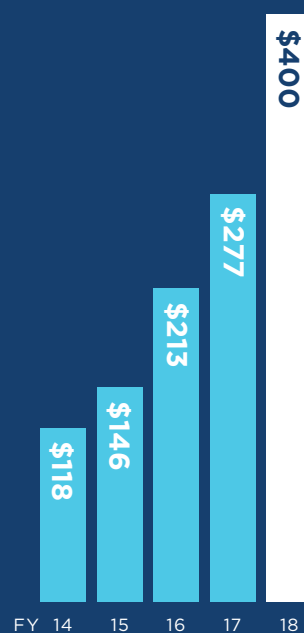


## GROSS MARGIN



## GAAP OPERATING INCOME

DOLLARS IN MILLIONS



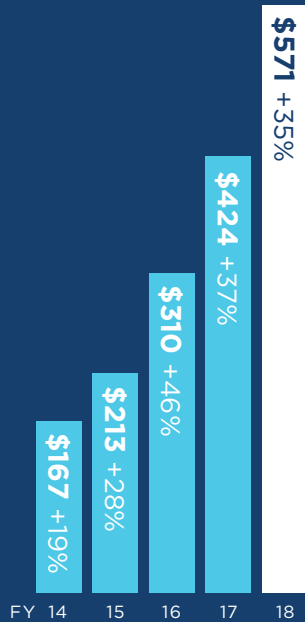
## NET CASH BALANCES\*

DOLLARS IN MILLIONS

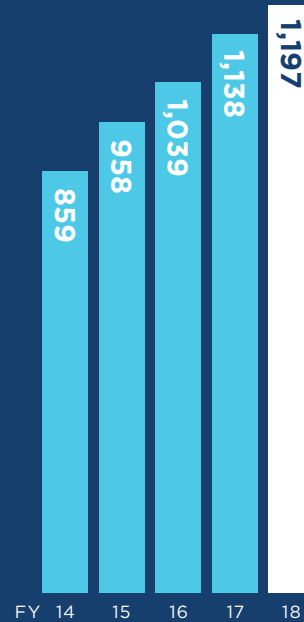
\* Net cash balances are defined as total cash, short-term and long-term marketable securities. The Company currently has no debt.

# IMPELLA® DEVICE PROGRESS

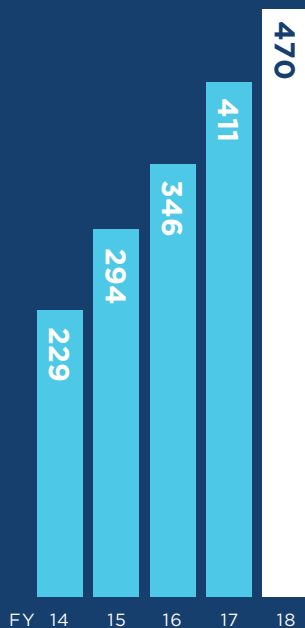
FY 2018



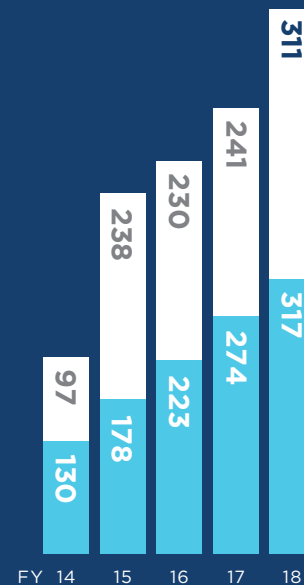
**IMPELLA REVENUE**  
DOLLARS IN MILLIONS



**IMPELLA U.S. SITES**



**IMPELLA PUBLICATIONS**



**TOTAL ABIOMED PATENT PORTFOLIO**

■ PATENTS ■ PATENTS PENDING

## DEAR SHAREHOLDERS,

ABIOMED achieved many significant milestones and expanded the field of Heart Recovery in FY 2018. Our outstanding results are built on our mission to recover hearts and save lives, lead in technology and innovation, grow shareholder value and sustain our winning culture of integrity and Patients First. We finished the year with record results on nearly every clinical and business metric and fortified our leadership position with expanded FDA indications, global distribution, training facilities, manufacturing capacity and patent portfolio.

We are grateful to our patients, customers, employees and shareholders who have enabled ABIOMED to continue our mission and advance the standard of care for hemodynamic support.

ABIOMED remains one of the fastest growing profitable medical technology companies with total reported sales of \$594 million in FY 2018, representing an increase of \$149 million or 33% growth over the prior year. This translated to an improvement in operating income of 74% to \$157 million and an operating margin of 27% all while continuing to invest in future growth initiatives. Our balance sheet remains strong as we ended the year with no debt and approximately \$400 million in cash. The installed base of the Impella 2.5®, Impella CP®, Impella 5.0® and Impella RP® heart pumps grew by more than 400 new hospital sites and our team has now supported more than 70,000 patients in the U.S. alone. Outside the U.S., revenue in Germany increased 70% over the prior year and we executed a successful second half launch in Japan, solidifying reimbursement and treating our first set of Japanese patients at 14 hospitals.



Impella CP patient Bill Asper and his wife with several members of the ABIOMED Board of Directors.

## FY 2018 HIGHLIGHTS

- **FDA Approval for Impella RP® for Right Heart Failure**
- **First Patient Treated with Impella® in Japan**
- **Expanded FDA Indication for High-Risk Percutaneous Coronary Intervention (PCI)**
- **Expanded FDA Indication for Cardiomyopathy with Cardiogenic Shock**
- **Women's Initiative for Heart Recovery Launched**
- **FDA Approval for Impella CP® with SmartAssist™ and Optical Sensor**
- **European Approval (CE Marking) for Impella 5.5™ and First Patient Treated at University Heart Center Hamburg**

### Transforming the Standard of Care

In FY 2018, ABIOMED received expanded FDA indications and launched initiatives including:

- FDA approval for the Impella RP heart pump, which is now commercially launching in the U.S.
- Expanded FDA approval to treat patients undergoing a high-risk percutaneous coronary intervention (PCI) with complex anatomy, severe coronary artery disease and high-risk comorbidities, with or without depressed ejection fraction. This further validates Protected PCI as a “first of its kind” high-risk PCI indication for Impella-supported intervention that enables an interventional cardiologist to perform a more complete, minimally invasive revascularization in a single session.
- Expanded FDA approval for cardiomyopathy, a disease or virus of the heart muscle, leading to cardiogenic shock. The expanded indication includes post and peripartum cardiomyopathy, spontaneous coronary artery dissection (SCAD) and myocarditis, inflammation of the heart wall. Cardiogenic shock is the number one cardiac risk in hospitals, carries an approximate 50% mortality rate and is a growing risk in the moderately aged population.
- A Women's Initiative for Heart Recovery with the goal of increasing awareness, education and research on cardiovascular disease in women. Cardiovascular disease, including coronary artery disease, is the number one killer of men and women. Enabling all patients, specifically young and otherwise healthy mothers with peripartum cardiomyopathy or SCAD, to return home with their recovered, native heart is the ideal solution and cost-effective medicine.



ABIOMED employees in red to celebrate Go Red for Women Day.

ABIOMED is dedicated to partnering with our customers and hospitals to improve outcomes and simultaneously reduce the cost of care. This year, two independent physician-led initiatives expanded the awareness of treating both elective and emergent high-risk PCI patients. For the elective high-risk PCI population, a prestigious research group further advanced the CHIP (Complex, High-Risk Indicated Patients) training and education including hemodynamic science and complete revascularization publications. For emergent patients, another physician-led, independent group of dedicated experts launched a “call to arms” with the National Cardiogenic Shock Initiative to improve patient outcomes in cardiogenic shock.

While we remain focused on the 231,000 U.S. high-risk patient population and increasing our penetration rate from 9%, we acknowledge that with the expanded indications and physician-led initiatives, the total addressable population of appropriate and approved patients that may benefit from Impella therapy is likely larger.

### **A Long Runway for Growth**

As we enter FY 2019, we are in the early innings of adoption with the early majority of customers in the U.S., Germany and Japan, and we have an increasing pipeline of new products, new indications and new geographies on the horizon.

In March, we received European approval, or CE mark, for the Impella 5.5™ heart pump, which is a heart recovery pump providing physicians with a minimally-invasive, 30-day, ambulatory, wean-able, forward-flow unloading heart device with peak flows of more than 6 liters per minute. We believe that the Impella 5.5, and in the future the Impella BTR™ (Bridge to Recovery) heart pumps, will revolutionize the treatment of targeted Class III heart failure patients (~100,000) with unloading therapy combined with

adjunctive therapies. Our innovation will continue with new FDA approved product enhancements, including SmartAssist™ with optical sensor and Impella Connect™ technologies that allow for real time in the “cloud” review of Impella ICU patients. We believe this type of real-time tracking combined with hemodynamic algorithms will improve patient outcomes and heart recovery while improving ease of use and productivity for our customers and our clinical team. Lastly, the Impella ECP™ heart pump continues its development to become the smallest profile (9 French) higher flow catheter heart pump for Protected PCI.

We continue our quest to improve patient outcomes and to collect and analyze clinical data to identify best practices in the largest dataset of high-risk patients incorporated in the IQ Quality Assurance Database and cVAD Registry study. While we maintain several ongoing studies both inside and outside of the cVAD Registry, we completed our FDA feasibility STEMI DTU study, in May 2018, targeting a new population of approximately 200,000 U.S. STEMI patients. We expect to publish the results regarding our hypothesis that unloading the heart with Impella before revascularization may reduce reperfusion injury in the setting of AMI STEMI without cardiogenic shock.



ABIOMED's newly expanded headquarters and Heart Recovery Institute in Danvers, Massachusetts.



Governor Charlie Baker joins Mike Minogue and Impella patients for the grand opening celebration of the Danvers, Massachusetts Heart Recovery Institute.

These important investments in our pipeline and clinical research will continue to lay the groundwork for improving clinical outcomes and sustaining long-term adoption and growth of the Impella platform.

As a result of our execution and operational discipline, ABIOMED is financially secure and operationally prepared to continue our global mission of recovering hearts and saving lives. ABIOMED has amassed a library of over 400 clinical publications and a patent portfolio of 317 patents with an additional 311 pending. We have invested in our state-of-the-art Heart Recovery Institutes in both Danvers, Massachusetts and Aachen, Germany and have trained hundreds of physicians and ABIOMED clinical staff this fiscal

year. We are prepared for the clinical demand of Impella and our new clean rooms are ramping up in Danvers and Aachen as we continue to increase our manufacturing capacity. In FY 2019, we will continue our expansion by opening our new Innovation Center in Danvers, which will be home to our scientists and engineers who have created the foundation of the technology. ABIOMED has now grown to over 1,100 employees worldwide with offices in Danvers, Massachusetts, Aachen and Berlin, Germany and Tokyo, Japan.

In closing, our company culture is driven by our ability to prioritize and serve Patients First. We are the new standard of care for hemodynamic support validated by the regulatory agencies around the world. Recovering hearts, saving lives is our guiding compass and the foundation of our technology and success. I would like to recognize and thank our employees, customers and regulators for their dedication, clinical research and support. We enter FY 2019 with purpose and confidence in our mission and each other. The rising tide of Heart Recovery is growing and we are positioned for another outstanding year.

Sincerely,

A handwritten signature in black ink that reads "Mike Minogue".

Michael R. Minogue  
Chairman, President and Chief Executive Officer



ABIOMED Field Team at the ABIOMED Annual Meeting.

# IMPELLA® HEART PUMP PLATFORM



IMPELLA 2.5®



IMPELLA CP®



IMPELLA 5.0®



IMPELLA RP®

**Breakthrough Heart Support Technologies:** ABIOMED's portfolio of heart support and recovery technologies offer interventional cardiologists and surgeons multiple options for use across a broad clinical spectrum in the catheterization lab and the surgical suite.



## AUTOMATED IMPELLA® CONTROLLER

The Automated Impella Controller is the primary user control interface for the Impella platform. It controls the Impella catheter performance, monitors for alarms, and displays real time hemodynamic and catheter position information.

## PIPELINE TECHNOLOGY\*



IMPELLA ECP™



IMPELLA 5.5™



IMPELLA BTR™

\* Impella ECP™, Impella 5.5™ and Impella BTR™ devices are currently in development and are not approved for use or sale in the United States. The Impella 5.5 has CE marking approval in Europe. For indications for use and important safety information concerning Impella devices, please visit [www.protectedpci.com/hcp/information/isi](http://www.protectedpci.com/hcp/information/isi).



“There is no way that I would have survived my heart attack without the support of my physicians, nurses, hospital administration and the Impella heart pump. Heart recovery gave me my active life back. I am grateful for the chance to watch my young daughter grow up, be a role model to her and continue my career with the military.” — JAY SANCHEZ



# JOSEPH “JAY” SANCHEZ

S A N T E F E , N M

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## IMPELLA 2.5®

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Jay Sanchez, 52, has always been accustomed to a busy and regimented lifestyle as an officer in the National Guard. In April 2016, Jay went to the gym for an indoor cycling class and after becoming severely ill later that night, he drove himself to the ER at St. Vincent’s Hospital in Santa Fe, New Mexico.

As soon as Jay arrived, he suffered a massive heart attack. Physicians quickly started CPR and shocked Jay four times. Jay was in cardiogenic shock.

Jay was rushed to the cath lab where an intra-aortic balloon pump was placed along with multiple stents. Jay showed little to no improvement, his heart was failing and he was going into organ failure. The hospital had not yet used the Impella device, but the staff

was prepared to do whatever it would take to save Jay’s life. Jay was returned to the cath lab and Dr. Mark Zolnick and Dr. Timothy Vellinga decided to use the Impella 2.5 heart pump to provide hemodynamic support.

After five days of Impella support, Jay’s heart began to recover and the Impella was removed. Two weeks later, Jay was discharged home with his native heart and a normal ejection fraction. Jay has since returned to work, serving his country, and is now back to his favorite job of being a dad.

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“Due to Jay’s heart attack, he was in cardiogenic shock. We chose to use the Impella 2.5 to support his heart and perfuse his organs. Thanks in part to this device, Jay is back to work and being a dad to his daughter.”

— MARK ZOLNICK, MD

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“The day I gave birth to my third child was supposed to be a joyous day, but it quickly turned into a nightmare. I am so thankful that my physicians used the Impella device to allow my heart to rest and recover. I was able to return home and resume my bustling life as a dedicated mother and wife with no limitations. I cherish every milestone and each moment spent with my family. The future is bright and I can’t wait to see my children grow up.” — LAURA HERNANDEZ

# LAURA HERNANDEZ

M I A M I , F L

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IMPELLA CP®

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After delivering her third child at South Miami Hospital in June 2015, Laura Hernandez, 28, experienced pregnancy-related complications that led to cardiogenic shock, an often fatal condition in which the heart cannot pump enough blood to sustain life and support the body's organs.

Dr. Jamie Ghitelman identified Laura's critical condition and implanted the Impella CP to provide hemodynamic support to Laura's weak heart. Once Laura stabilized, she was transferred to Memorial Regional Hospital in Miami, Florida. After three days of Impella support, her heart function improved and Dr. Enrique Gongora weaned and

explanted the Impella device. Laura's heart had a full recovery and she was discharged home to her family and her new baby.

Today, Laura is a school administrator and is back to being a busy mom and wife.

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“Laura’s life was saved, in part due to this exciting Impella technology. I am so pleased to see that she has made a full recovery and returned to her busy life as a mom.” – **ENRIQUE GONGORA, MD**

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“After my long history of cardiac conditions, I was left hopeless and with a diminished quality of life. Everything changed after my Protected PCI procedure with the Impella CP heart pump. Immediately after the procedure, I felt immensely better—I could breathe again! Thanks to my improved quality of life, I am back to traveling with my wife and I am grateful for each moment spent with my two children and five grandchildren.” — **BILL SCHRIMPL**

# WILLIAM “BILL” SCHRIMPL

N A P E R V I L L E , I L

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IMPELLA CP®

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Bill Schrimpl, 66, had a long history of heart complications and suffered a heart attack in 2008. Up until 2016, Bill’s most prominent symptom was trouble breathing with any activity, which left him without energy and unable to work. Multiple physicians told Bill there was no procedure that could relieve his shortness of breath.

In 2016, Bill was fortunate to be referred to Dr. Tony DeMartini, an interventional cardiologist at Edward Hospital in Illinois, who explained the potential benefit of a Protected PCI procedure. With the support of the Impella CP heart pump, Dr. DeMartini was able to perform a complete

revascularization and place multiple stents. Bill now breathes normally, and has regained his quality of life, with an improved ejection fraction. He now rides his bicycle with his wife, can work out on the elliptical and lives an active life with his many grandchildren.

Edward Hospital has an established Heart Recovery Program and a Protected PCI coordinator who educates the community on the benefits of Protected PCI. Bill has become a Heart Recovery Advocate for other patients.

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“Our team at Edward Hospital is proud to offer Protected PCI with Impella to patients like Bill who are suffering from heart failure and believe there are no other options. With Bill, we saw a marked improvement in his ejection fraction after the procedure, which has led to an improved quality of life. It is great to see Bill enjoying life with his wife, children and grandchildren.” – **TONY DEMARTINI, MD**

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“Given the severity of my heart attack, I was fortunate for many reasons: the response of EMS professionals, the incredible work of Dr. Stahlman and his staff and the support of the Impella heart pump, which allowed my heart to rest and recover. I am appreciative that our country has this innovative technology available. Now, I am back to my normal life and appreciate each day.” — GOVERNOR TOM RIDGE

# GOVERNOR TOM RIDGE

A U S T I N , T X

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IMPELLA CP®

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In November 2017, former Pennsylvania Governor Tom Ridge, 72, suffered a massive heart attack while attending a conference in Texas. He flatlined three times and received CPR at the hotel and in the ambulance. Upon arrival at Dell Seton Medical Center at the University of Texas, Governor Ridge was in dire circumstances and rushed directly to the cath lab.

Governor Ridge was in cardiogenic shock. His ejection fraction was 5% and physicians found a 100% blockage in his left anterior descending coronary artery, known as the “widow maker.”

Dr. Matthew Stahlman inserted the Impella CP heart pump for

hemodynamic support and opened the blockage and placed multiple stents.

After four days in the ICU with Impella unloading his heart and supporting his vital organs, the pump was weaned and removed and Governor Ridge was discharged home to his family. Governor Ridge’s ejection fraction has since returned to normal and he has resumed working full-time and enjoying life with his family.

Governor Ridge was kind enough to host ABIOMED CEO, Mike Minogue, and his son, Bo, at his Washington, DC office.

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“Governor Ridge presented with an extremely weak heart and required rapid hemodynamic support. As soon as we placed the Impella, we saw an immediate improvement in his ejection fraction. I am so pleased that Governor Ridge is back to his busy life in DC without restrictions.” – **MATTHEW STAHLMAN, MD**

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# NEW AMERICAN HEART ASSOCIATION STATISTICS PREDICT THAT BY YEAR 2035,

# 45%

OF THE TOTAL U.S. POPULATION, OR APPROXIMATELY 131 MILLION PEOPLE,  
**will have at least one health problem  
related to heart disease.**

24 million will have coronary heart disease and nearly  
9 million will have congestive heart failure.\*

#1 CAUSE OF DEATH IN U.S.	TOP RISK FACTORS FOR HEART FAILURE	#1 CARDIAC MORTALITY RISK IN HOSPITAL	#1 HEALTH EXPENDITURES
(1 IN 3 DEATHS) CORONARY ARTERY DISEASE/HEART FAILURE: 875,000 DEATHS	LOW EJECTION FRACTION & FIRST HEART ATTACK (AMI)	CARDIOGENIC SHOCK	HEART CONDITIONS (\$204B)

\* American Heart Association: Heart Disease and Stroke Statistics—2015 Update

- Halkin A et al. Prediction of mortality after primary percutaneous coronary intervention for acute myocardial infarction, *J Am Coll Cardiol* 2005;45:1397-1405 ; Solomon et al. Influence of Ejection Fraction on Cardiovascular Outcomes in a Broad Spectrum of Heart Failure Patients, *Circulation* 2005; Curtis JP, et al. The association of left ventricular ejection fraction, mortality, and cause of death in stable outpatients with heart failure. *J Am Coll Cardiol* 2003; 42: 736-42
- Historic Survival without Impella Support/Protocols:1990-2006: -50% Mortality ; 2017 CULPRIT SHOCK Study: -50% Mortality, *NEJM*; Jeger, et al. *Ann Intern Med.* 2008
- Heart Disease Could Cost U.S. \$1 Trillion Per Year By 2035: Report. <https://health.usnews.com/health-care/articles/2017-02-14/heart-disease-could-cost-us-1-trillion-per-year-by-2035-report>

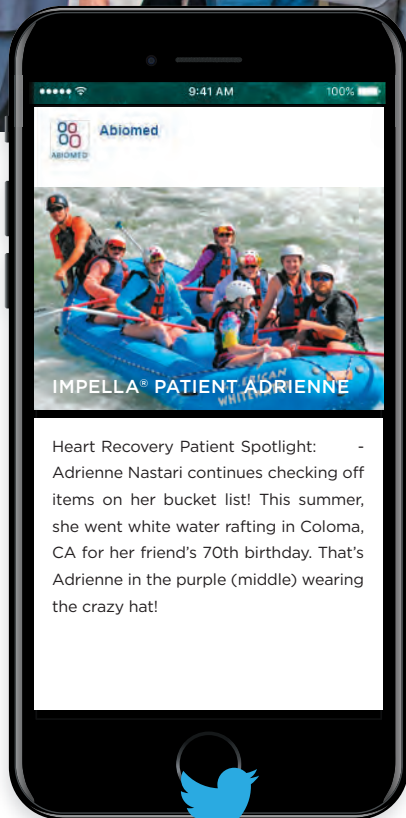


# ABIOMED PATIENT ADVOCACY PROGRAM

Each year, ABIOMED welcomes several patients to our headquarters in Danvers, Massachusetts for a Patient Summit to learn more about Heart Recovery, tour our facility and meet ABIOMED employees. Patient Advocacy continues to emerge as an important initiative, as it highlights the voice of the patient. Our patient-focused culture is a major contributor to the Company's success, as we put Patients First in our day-to-day responsibilities. ABIOMED is fully dedicated to finding ways to bring the most advanced and beneficial technology to patients and physicians.



Heart Recovery Advocates join CEO Mike Minogue, Thorsten Siess and Dr. Jeffrey Moses of Columbia University for the FY 2018 Patient Summit.



**10K+**  
TWEETS ABOUT  
IMPELLA



More than 50 Impella patients and their families gathered at Detroit Medical Center in August to reunite with the cardiovascular clinical teams who helped save their lives with innovative procedures and Impella® technology. This event—the largest Heart Recovery Reunion ever—provided a unique opportunity for patients, families, physicians and ABIOMED's CEO and local team to celebrate heart recovery.

# WOMEN'S INITIATIVE FOR HEART RECOVERY

In conjunction with the Company's expanded FDA approval for cardiogenic shock associated with cardiomyopathy, including peripartum and postpartum cardiomyopathy, ABIOMED has launched a Women's Initiative focused on heart recovery education and awareness. This Women's Initiative includes an advisory board led by Cindy Grines, MD, of Northwell Health, and includes a group of female physicians with the goal of improving outcomes for women suffering from cardiovascular disease.



Impella CP patient Laura, Impella 5.0 patient Iman, and Impella 2.5 patient Jalesia visited ABIOMED headquarters to celebrate the new indication and learn more about the Women's Initiative for Heart Recovery.



Dr. Cindy Grines joined Impella CP patient Laura for a media day in New York City this spring.



Impella CP & Impella 5.0 patient, Jenny, and her sons, Dyllan and Jackson.

# HEART RECOVERY REUNIONS

Heart Recovery Reunions welcome patients treated with the Impella® platform back to their hospital to reunite with physicians, nurses, cath lab staff, EMTs, flight crew and other staff.

Impella CP patient Rick



Impella CP patient Nancy



In addition to Heart Recovery Reunions, ABIOMED invites a patient to speak at each Board of Directors meeting. During the Q4 meeting, Impella CP patient Donna shared her story of cardiomyopathy and heart recovery.



# ABIOMED EMPLOYEES

N. Taylor • C. Whalen • M. DeSoto • K. Bauckman • K. Kasica • D. Frattaroli • G. Ganesalingam • A. Salindrija • C. Pechstein • J. Leurs • L. Holzwart • V. Mayer • M. Stanivukovic • I. Diaz Yelamos • R. Quinn • J. Howard • M. O'Connell • S. Micklus • MJ. Deering • D. Ooten • I. Kabnick • C. Kariores • J. Williams • J. Guarnaccia • T. Aguirre • B. Greenspoon • E. Geary • G. Offenhauser • H. Lewis • R. Olivea • J. Herndon • M. Flores • J. Garcia • C. Nayeri • W. Regenold • M. Pearson • C. McCain • M. Flicker • G. Lord • A. Doney • D. Mann • R. Miller • J. Cutrone • J. Hawryliw • D. France • T. Stewart • S. Bresnahan • K. Hallier • J. Anderson • J. Carlson • D. Horton • L. Cascio-Riley • M. Ledbetter • J. Franks • M. Bunt • I. Goldberg • I. McLeod • R. Hanania • C. Koppel • Z. Tao • C. Hastie • R. Poitras • A. Bird • A. Smith • M. Webb • S. St. Jean • S. Leng • J. Becker • Y. Yanishevsky • B. Rowan • I. Welch • H. Deshpande • C. Dupont • E. Loeup • E. Mora • M. Gonzalez • P. Rose • R. Sellars • M. Tafone • B. Williams • S. Neer • S. Balk • C. Rogers • J. Perrone • C. Yen • E. Robidoux • M. Heinze • R. Lutz • H. Shee • E. Labaco • S. Themo • S. Fenton • A. Richardson • M. Caulfield • J. Colucci • A. Dickson • T. Favini • E. Sperry • I. Ghiu • C. Mindrescu • A. Medjamia • O. Scully • A. Inglis • S. O'Leary • T. Richter • E. MacNeil • C. Sweazy • P. Miah • J. Hale • I. Tabata • A. Grubb • K. Mahoney • C. Harms • E. Yamano • A. Chretien • R. Stewart • M. Hout • K. Wallbrück • C. Cohen • U. Chandrasekaran • S. Hess • M. McNall • J. Raykovicz-Joiner • R. Clark • E. Romano • K. Simmonds • J. Limoli • C. Dos Santos • S. Rana • D. Houde • P. Sawtelle • A. Lim • Y. Diaz • T. Sy • M. Losolfo • M. Berube Mootafian • J. Smart • J. Carter • M. Zarella • F. Silva • T. Blood • J. Wright • G. Melo • R. Sanchez • R. Mateo • N. Pinciario • L. Moreno • E. Sicalo • J. Harbison • M. Surette • R. Deveau • S. Standridge • S. O'Connor • J. Kelso • M. Naso • T. Trapp • M. Visenescu • R. Vittini • S. Vargas • K. Rodriguez • A. Dumke • E. Tacvorian • A. Agnello • P. Lemay • M. Sami • R. Srinivasan • J. Corrado • C. Malzkorn • N. DePiero • R. Swierczek • K. Al Haffar • W. Frisbee • S. Crowley • S. Langevain • W. Gonzalez • D. Dyrnish • B. McCormack • M. Mauricio • S. Reimer • P. Buchwald • E. Drago • T. Moore • J. Killeen • E. Walker • H. Pothier • V. Zilberman • D. Michels • S. Reginali • E. Francis • P. Cooper • V. Rothrock • M. Houde • L. Rossi • C. Macdonald • P. McLean • J. Weddell • F. Natale • S. Pilz • J. Hoynacki • J. Fore • P. Chuinard • J. Blizard • J. Stevens • B. Finley • R. Bordogna • T. Yary • D. Prum • D. Welsh • T. George • N. Diecidue • A. Gentile • E. Jahangir • M. Finnegan • W. Macdonald • C. Loughlin • D. Filipiak • K. Kesterson • T. Ortiz • M. Tjalsma • D. Bastable • L. Ellis • K. Spinale • B. O'Neil • D. Brissette • G. Lim • R. Gandhi • S. Chow • J. Modlish • N. Roberts • M. McCalister • M. Pine • N. Bailey • T. Georges • B. Cunkelman • C. Sheils • A. Berson • D. Krstovski • K. Pham • A. Magichev • G. Angacian • A. Munroe • S. Patterson • J. Dobson • S. Hayward • G. Eichmann • S. Corbett • J. Gardner • S. Caissie • R. D'Ambrosio • V. Barry • L. Tuy • S. Andrews • M. Kortyka • D. Vo • M. Cotter • M. Howley • S. McEvoy • W. Bolt • D. Weber • T. Sieß • S. Bilazarian • K. Boucher • A. Greenfield • P. Gilardi • J. Riegel • C. Yu • J. Burgin • G. Pendergast • PH. Fokom • M. Galvin • C. Liu • Q. Tan • S. Flynn • M. Joyce • L. Day • J. Gage • C. Benson • R. Roccio • R. Barisano • K. Carroll • A. Packard • E. Nishimura • M. Plano • K. Nikola • J. Ryder • L. Palmer • C. Jeon • S. Gebel • D. Raess • N. Josephy • J. Mason • J. Josephs • J. Brodbine • S. Courtemanche • B. Polanco • M. Böhm • A. Smith-Attuquayefio • J. Lefavour • S. Vaughan • J. Spector • R. Pignatone • S. Mohanan • N. Ketteniß • D. Gonzalez • K. Kou • C. Martinez • A. Rodriguez • M. Ventura • R. Villavicencio • Y. Leng • J. Cabrera • J. Mao • R. Kratman • D. Govender • M. Schooley • B. Prince • S. Bunk • A. Ship • A. El Katerji • R. Fishman • E. Elferrri • Z. Qi • J. Murphy • C. Moyer • C. DeLorenzo • K. Lee • P. Chhouk • G. Gronlund • J. Brigham • S. Delibac • D. Mraz • G. Fantuzzi • TA. Nguyen • C. Korkuch • L. Hrdy • B. Horrigan • T. Dohmen • J. Mone • L. Brodbeck • M. Moniz • D. Brousseau • E. Liharski • S. Narayanan • P. Pamidi • M. Pfoser • C. Hussey • S. Russell • N. Hysa • B. Kodarapu • D. Sargent • I. Kishimoto • E. Flaherty • J. Foss • J. St. Agathe • M. Flynn • K. Hanlon • H. Maurer • G. Yuan • T. Zhang • C. Zarins • L. Khammanivong • S. Burns • S. Müller • Y. Körfer • J. Fabig • J. Rekers • J. Hartigan • E. Hosfelt • B. Bonaventura • A. Fothergill • M. Bianchi • J. Hendrick • M. Mason • A. MacGregor • H. Sattler • T. Tan • G. Christanday • M. Ford • J. Kajewski • J. Sweetman • J. Page • J. Richard • M. Generalovich • C. Axberg • W. Stafford • K. Chappell • R. Willis • W. Lowe • A. Fass • T. Flanagan • A. Lee • T. Cooper • L. 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We are proud to support the following organizations:

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ABIOMED is proud to support those who have served our country. ABIOMED CEO, Mike Minogue, is co-founder and chairman of MVPvets (Mentoring Veterans Program), a nationwide initiative dedicated to helping returning military veterans transition to careers in the life science industries.

2018 FORM 10-K





**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 the fiscal year ended March 31, 2018

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: 001-09585



**ABIOMED, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**22 Cherry Hill Drive  
Danvers, Massachusetts**

(Address of Principal Executive Offices)

**04-2743260**

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

**01923**

(Zip Code)

**(978) 646-1400**

(Registrant's Telephone Number, Including Area Code)

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

Common Stock, \$.01 par value

**Name of Each Exchange on Which Registered:**

The NASDAQ Stock Market LLC

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

None

Indicate by check mark if 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 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 whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of the 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, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was \$7,452,252,182. As of May 8, 2018, 44,477,837 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 2018 Annual Meeting of Stockholders, which is scheduled to be filed within 120 days after the end of Abiomed, Inc.'s fiscal year, are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K.

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### NOTE REGARDING TRADEMARKS AND REGISTERED MARKS

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### NOTE REGARDING COMPANY REFERENCES

Throughout this report on Form 10-K (the “Report”), “Abiomed, Inc.,” the “Company,” “we,” “us” and “our” refer to ABIOMED, Inc. and its consolidated subsidiaries.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the documents incorporated by reference in this report, includes forward-looking statements. These forward-looking statements may be accompanied by such words as “anticipate,” “believe,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “potential,” “project,” “target,” “will” and other words and terms of similar meaning. Each forward-looking statement in this report is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Forward-looking statements in these documents include, but are not necessarily limited to, those relating to:

- *the ability of patients, hospitals and other customers using our products to obtain reimbursement of their medical expenses by government healthcare programs and private insurers including potential changes to current government and private insurers’ reimbursements;*
- *other competing therapies that may in the future be available to heart failure patients;*
- *the development and commercialization of new and enhancement of existing products and anticipated costs, including research and development, sales and marketing, manufacturing and training costs associated with product development;*
- *the anticipated launch dates of technological improvements in existing products and studies in pipeline products*
- *our plans to potentially acquire new businesses or technologies;*
- *the potential markets that exist or could develop for our products and products under development;*
- *our business strategy, and commercial plans for our products, including our expansion into new markets such as Japan;*
- *our revenue and revenue growth expectations, our level of operating expenses and our goal of maintaining profitability;*
- *expected capital expenditures for the fiscal year ending March 31, 2019;*
- *plans with and expected enrollment in our clinical studies and registries;*
- *demand for and expected shipments of our products;*
- *our belief that the existing manufacturing facilities give us the necessary physical capacity to produce sufficient quantities of products to meet anticipated demand;*
- *the expectation that we will be able to expand our manufacturing capacity to support expected demand for our Impella® devices;*
- *the expectation that our suppliers will furnish us required components when we need them or be able to provide us inventory materials to support our expected growth in demand for our products;*
- *our ability to protect our intellectual property, including patent, trademark, copyright, trade secret and domain name protection;*
- *our belief that patents will issue pursuant to our pending or future patent applications;*
- *possible shifts in the revenue mix associated with our products; our ability to increase revenues from our Impella line of heart pumps and the sufficiency of revenues, profits and cash flows to fund future operations;*
- *the impact of market factors such as changes in interest rates, currency exchange rates on our operations and the fair value of our financial instruments;*
- *the impact of excess tax benefits and shortfalls associated with stock-based awards on our consolidated financial statements and disclosures;*
- *the impact of the Tax Cuts and Jobs Act, or Tax Reform, on our consolidated financial statements and disclosures;*
- *future actions related to or results of ongoing investigations, and litigation, including product liability claims, and expenditures or costs related thereto;*
- *our expectations concerning additional Pre-Market Approvals or PMA approvals, supplement submissions or other regulatory applications in additional foreign markets for our Impella devices;*
- *our expectations regarding continuing consolidation of medical device customers into larger purchasing groups and any resulting pressure on product pricing;*

- *plans with respect to clinical trials and registries; and*
- *the sufficiency of our liquidity and capital resources.*

Additional factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include our inability to predict the outcome of investigations and litigation and associated expenses; possible delays in our research and development programs; our ability to obtain regulatory approvals and market our products, and uncertainties related to regulatory processes; greater government scrutiny and regulation of the medical device industry and our ability to respond to changing laws and regulations affecting our industry, including any reforms to the regulatory approval process administered by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities, and changing enforcement practices related thereto; the inability to manufacture products in commercial quantities at an acceptable cost; the acceptance by physicians and hospitals of our products; the impact of competitive products and pricing; uncertainties associated with future capital needs and the risks identified under “Risk Factors” section set forth in Item 1A of Part I and elsewhere in this report, as well as other information we file with the Securities and Exchange Commission, or SEC. Readers are cautioned not to place undue reliance on any forward-looking statements contained in this report, which speak only as of the date of this report. We undertake no obligation to update or revise these forward-looking statements whether as a result of new information, future events or otherwise, unless otherwise required by law. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a leading provider of temporary mechanical circulatory support devices, and we offer a continuum of care to heart failure patients. We develop, manufacture and market proprietary products that are designed to enable the heart to rest, heal and recover by improving blood flow to the coronary arteries and end-organs and/or temporarily assisting the pumping function of the heart. Our products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists, the electrophysiology lab, the hybrid lab and in the heart surgery suite by cardiac surgeons. A physician may use our devices for patients who are in need of hemodynamic support prophylactically, urgently or emergently before, during or after angioplasty or heart surgery procedures. We believe that heart recovery is the optimal clinical outcome for a patient experiencing heart failure because it enhances the potential for the patient to go home with their own heart, facilitating the restoration of quality of life. In addition, we believe that, for the care of such patients, heart recovery is often the most cost-effective solution for the healthcare system.

Our strategic focus and the driver of our revenue growth is the market penetration of our family of Impella® heart pumps. The Impella device portfolio, which includes the Impella 2.5®, Impella CP®, Impella RP®, Impella LD® and Impella 5.0® devices, has supported numerous patients worldwide. All of our product and service revenue in the near future will be from our Impella devices.

In March 2015, we received FDA approval of a PMA for use of the Impella 2.5 device during elective and urgent high-risk percutaneous coronary intervention, or PCI, procedures. In December 2016, the FDA expanded this PMA approval in the U.S. to include the Impella CP device. With these approved indications, the Impella 2.5 and Impella CP devices provide the only minimally invasive treatment options indicated for use during high-risk PCI procedures in the U.S. In April 2016, the FDA approved a PMA supplement for our Impella 2.5, Impella CP, Impella 5.0 and Impella LD devices to provide treatment for ongoing cardiogenic shock that occurs following a heart attack or open heart surgery. The intent of our Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

In September 2017, we received FDA approval of a PMA for the Impella RP heart pump. The Impella RP heart pump is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area  $\geq 1.5$  m<sup>2</sup>, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. With this approval, the Impella RP heart pump is the only percutaneous temporary ventricular support device that is FDA-approved as safe and effective for right heart failure as stated in the indication.

In February 2018, we received two expanded PMA approvals from the FDA for our Impella heart pumps. The first expanded approval is for use of Impella 2.5, CP, 5.0 and LD heart pumps on patients with cardiogenic shock associated with cardiomyopathy, including peripartum and postpartum cardiomyopathy. The second expanded PMA approval is for use of the Impella 2.5 and Impella CP heart pumps during elective and high-risk PCI procedures. This expanded PMA approval confirms Impella support as appropriate in patients with severe coronary artery disease, complex anatomy and extensive comorbidities, with or without depressed ejection fraction.

In April 2018, we received FDA approval for Impella CP with SmartAssist and Optical Sensor which is intended to provide enhanced monitoring capability, reduce setup time and improve ease of use for physicians. The optical sensor technology is also approved under CE Mark in the European Union.

In September 2016, we received Pharmaceuticals and Medical Devices Agency, or PMDA, approval from the Japanese Ministry of Health, Labour & Welfare, or MHLW, for our Impella 2.5 and Impella 5.0 heart pumps to provide treatment of drug-resistant acute heart failure in Japan. In July 2017, we received approval from the MHLW for reimbursement for the Impella 2.5 and 5.0 heart pumps. Reimbursement in Japan for the Impella 2.5 and 5.0 is equivalent to our average Impella sales price in the U.S. We commenced commercialization in Japan during the second quarter of fiscal 2018 and have begun a slow commercial launch of Impella in Japan. The first Japanese patient was treated with the Impella device in October 2017.

Our Impella 2.5, Impella 5.0, Impella LD, Impella CP and Impella RP devices also have CE Mark approval and Health Canada approval, which allows us to market these devices in the European Union and Canada.

In April 2018, we announced that we have received CE marking approval in the European Union for the Impella 5.5 heart pump and the first patient was treated at University Heart Center in Hamburg, Germany. The Impella 5.5 heart pump is not approved for use or sale in the U.S.

In May 2017, we announced the enrollment of the first patient in the FDA approved prospective multi-center feasibility study, STEMI Door to Unloading with Impella CP system in acute myocardial infarction. The trial focuses on the feasibility and safety of unloading the left ventricle using the Impella CP heart pump prior to primary PCI in patients presenting with ST segment elevation myocardial infarction, or STEMI, without cardiogenic shock with the hypothesis that this will potentially reduce infarct size. The study, which received FDA approval in October 2016, will enroll up to 50 patients at 10 sites. We expect to complete enrollment in the first half of fiscal 2019.

We expect to continue to make additional PMA supplement submissions for our Impella portfolio of devices for additional indications.

## **Corporate Background**

Our Company was founded in 1981 and we are currently incorporated in Delaware. Our common stock is listed on the NASDAQ Global Select Market under the ticker symbol ABMD.

Our principal executive offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923. Our telephone number is (978) 646-1400. We make available, free of charge on our website located at [www.abiomed.com](http://www.abiomed.com), our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the SEC. We have a Code of Conduct and Compliance Policy that applies to all of our directors, officers, and employees. Our Code of Conduct and Compliance Policy is posted on our website and a paper copy of this document may be obtained free of charge by writing to the Company's Chief Compliance Officer at our principal executive offices located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, or by email at [IR@abiomed.com](mailto:IR@abiomed.com). We intend to disclose any future amendments to, or waivers from, the Code of Conduct and Compliance Policy through a posting on our website. Our audit committee, governance and nominating committee and compensation committee charters are also posted on our website. The contents of our website are not incorporated by reference into this report. In addition, the public may read and copy any materials we file or furnish with the SEC, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Moreover, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with the SEC at [www.sec.gov](http://www.sec.gov).

## **Our Existing Products**

### ***Impella 2.5®***

The Impella 2.5 device is a percutaneous micro heart pump with an integrated motor and sensors. The device is designed primarily for use by interventional cardiologists to support patients in the cath lab who may require assistance to maintain circulation. The Impella 2.5 heart pump can be quickly inserted via the femoral artery to reach the left ventricle of the heart, where it is directly deployed to draw blood out of the ventricle and deliver it to the circulatory system. This function is intended to reduce ventricular work and provide blood flow to vital organs. The Impella 2.5 heart pump is introduced with normal interventional cardiology procedures and can pump up to 2.5 liters of blood per minute.

The Impella 2.5 device received 510(k) clearance from the FDA in June 2008 for partial circulatory support for up to six hours. In March 2015, we received PMA approval from the FDA for the use of the Impella 2.5 device during elective and urgent high-risk PCI procedures. With this PMA approval, the Impella 2.5 device became the first FDA approved hemodynamic support device for use during high-risk PCI procedures. Under this first PMA, the Impella 2.5 is a temporary (up to six hours) ventricular support device indicated for use during high-risk PCI performed in elective or urgent hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 device in these patients may prevent hemodynamic instability that may occur during planned temporary coronary occlusions and may reduce periprocedural and post-procedural adverse events. The product labeling allows for the clinical decision by physicians to leave the Impella 2.5 device in place beyond the intended duration of up to six hours should unforeseen circumstances arise.

In April 2016, the FDA approved a supplement to our March 2015 PMA for the use of our Impella 2.5, Impella CP, Impella 5.0 and Impella LD devices to provide treatment for ongoing cardiogenic shock. This PMA supplement covers a set of indications related to the use of the Impella devices in patients suffering cardiogenic shock following acute myocardial infarction or cardiac surgery and allows for a longer duration of support.

Pursuant to the April 2016 PMA approval, the Impella 2.5, Impella CP, Impella 5.0 and Impella LD catheters, in conjunction with the Automated Impella Controller, or AIC, were approved as temporary ventricular support devices intended for short term use ( $\leq 4$  days for the Impella 2.5 and Impella CP, and  $\leq 6$  days for the Impella 5.0 and LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately ( $< 48$  hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures. The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function. Optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without an intraortic balloon pump, or IABP.

The Impella 2.5 device has CE Mark approval in the European Union for up to five days of use and is approved for use in up to 40 countries. The Impella 2.5 device also has Health Canada approval which allows us to market the device in Canada.

In September 2016, we received PMDA approval from the Japanese MHLW for our Impella 2.5 and Impella 5.0 heart pumps to provide treatment of drug-resistant acute heart failure in Japan. In July 2017, we received approval from the MHLW for reimbursement of the Impella 2.5 and 5.0 heart pumps. Reimbursement in Japan for the Impella 2.5 and 5.0 is equivalent to our average Impella sales price in the U.S. and we commenced commercialization in Japan during the second quarter of fiscal 2018. The first Japanese patient was treated with the Impella device in October 2017.

In February 2018, we received two expanded PMA approvals from the FDA for our Impella heart pumps. The first expanded PMA approval is for use of Impella 2.5, CP, 5.0 and LD heart pumps on patients with cardiogenic shock associated with cardiomyopathy, including peripartum and postpartum cardiomyopathy. The second expanded PMA approval was for use of the Impella 2.5 and Impella CP heart pumps during elective and high-risk PCI procedures. This expanded PMA approval confirms Impella support as appropriate in patients with severe coronary artery disease, complex anatomy and extensive comorbidities, with or without depressed ejection fraction.

### ***Impella CP®***

The Impella CP device provides blood flow of approximately one liter more per minute than the Impella 2.5 device and is primarily used by either interventional cardiologists to support patients in the cath lab or by cardiac surgeons in the heart surgery suite.

In September 2012, we announced that the Impella CP device received 510(k) clearance from the FDA. In April 2016, the FDA approved the PMA supplement for certain of our devices, including our Impella CP device to provide treatment for ongoing cardiogenic shock.

In February 2018, we received two expanded PMA approvals from the FDA for our Impella heart pumps. The first expanded PMA approval is for use of Impella 2.5, CP, 5.0 and LD heart pumps on patients with cardiogenic shock associated with cardiomyopathy, including peripartum and postpartum cardiomyopathy. The second expanded PMA approval is for use of the Impella 2.5 and Impella CP heart pumps during elective and high-risk PCI procedures. This expanded PMA approval confirms Impella support as appropriate in patients with severe coronary artery disease, complex anatomy and extensive comorbidities, with or without depressed ejection fraction.

These PMA approvals allow the Impella CP to be used as a temporary ( $\leq 6$  hours) ventricular support system indicated for use during high risk PCI procedures performed in elective or urgent hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined that high-risk PCI is the appropriate therapeutic option. The product labeling allows for the clinical decision by physicians to leave the Impella CP device in place beyond the intended duration of up to six hours should unforeseen circumstances arise.

The Impella CP device has CE Mark approval in the European Union for up to five days of use and is approved for use in up to 40 countries.

In April 2018, we received FDA approval for Impella CP with SmartAssist and Optical Sensor which is intended to provide enhanced monitoring capability, reduce setup time and improve ease of use for physicians. The optical sensor technology is also approved under CE Mark in the European Union.

In May 2017, we announced the enrollment of the first patient in the FDA approved prospective multi-center feasibility study, STEMI Door to Unloading with Impella CP system in acute myocardial infarction. The trial focuses on the feasibility and safety of unloading the left ventricle using the Impella CP heart pump prior to primary PCI in patients presenting with ST segment elevation myocardial infarction, or STEMI, without cardiogenic shock with the hypothesis that this will potentially reduce infarct size. The study, which received FDA investigational device approval to proceed in October 2016, will enroll up to 50 patients at 10 sites. We expect to complete enrollment in the first half of fiscal 2019.

The primary endpoints of the feasibility study will focus on safety, including major adverse cardiovascular and cerebrovascular events, or MACCE, at 30 days. All patients will undergo cardiac magnetic resonance imaging to assess infarct size as a percent of left ventricular mass at 30 days post-PCI. Patients will be randomized to Impella CP placement with immediate primary PCI, or to Impella CP placement with 30 minutes of unloading prior to primary PCI. The hypothesis of this novel approach to treating STEMI patients, based on extensive mechanistic research, is that unloading the left ventricle prior to PCI reduces myocardial work load, oxygen demand and also initiates a cardio-protective effect at the myocardial cell level, which may alleviate myocardial damage caused by reperfusion injury at the time of revascularization. This feasibility study will help refine the protocol and lay the groundwork for a future pivotal study with more sites and patients and will be designed for statistical significance.

### ***Impella 5.0® and Impella LD®***

The Impella 5.0 and Impella LD devices are percutaneous micro heart pumps with integrated motors and sensors for use primarily in the heart surgery suite. These devices are designed to support patients who require higher levels of circulatory support as compared to the Impella 2.5.

The Impella 5.0 device can be inserted into the left ventricle via femoral cut down or through the axillary artery. The Impella 5.0 device is passed into the ascending aorta, across the valve and into the left ventricle. The Impella LD device is similar to the Impella 5.0 device, but it is implanted directly into the ascending aorta through an aortic graft. Both of these procedures are normally performed with the assistance of cardiac surgeons in the surgery suite. The Impella 5.0 and Impella LD devices can pump up to five liters of blood per minute, potentially providing full circulatory support.

The Impella 5.0 and Impella LD devices originally received 510(k) clearance in April 2009, for circulatory support for up to six hours. In April 2016, the FDA approved the PMA supplement for certain of our devices, including the Impella 5.0 and Impella LD devices to provide treatment for ongoing cardiogenic shock following a heart attack or open heart surgery. In February 2018, we received an expanded FDA PMA approval for use of Impella 2.5, Impella CP, Impella 5.0, and Impella LD heart pumps to provide treatment for heart failure associated with cardiomyopathy leading to cardiogenic shock. This approval expands the previous indication for acute myocardial infarction, or AMI, cardiogenic shock and post-cardiotomy shock, or PCCS, received in April 2016.

The Impella 5.0 and Impella LD devices have CE Mark approval in the European Union for up to ten days' duration and are approved for use in over 40 countries.

In July 2017, we received approval from the Japanese MHLW for reimbursement for the Impella 2.5 and 5.0 heart pumps. Reimbursement in Japan of the Impella 2.5 and 5.0 is equivalent to our average Impella sales price in the U.S. and we commenced commercialization in Japan during the second quarter of fiscal 2018. The first Japanese patient was treated with the Impella device in October 2017.

### ***Impella RP®***

The Impella RP is a percutaneous catheter-based axial flow pump that is designed to allow greater than four liters of blood flow per minute and is intended to provide the flow and pressure needed to compensate for right side heart failure. The Impella RP is the first percutaneous single access heart pump designed for right heart support to receive FDA approval. The Impella RP device is approved to provide support of the right heart during times of acute failure for certain patients who have received a left ventricle assist device or have suffered heart failure due to AMI, a failed heart transplant, or following open heart surgery.

In November 2012, the Impella RP device received U.S. investigational device exemption, or IDE, approval from the FDA for use in RECOVER RIGHT, a pivotal clinical study in the U.S. This was a study of 30 patients who presented signs of right side heart failure, required hemodynamic support, and were capable of being treated in the catheterization lab or cardiac surgery suite. The study was completed in March 2014 and collected safety and effectiveness data on the percutaneous use of the Impella RP device and was submitted to the FDA in support of a Humanitarian Device Exemption, or HDE. An HDE is similar to a PMA application but is intended for patient populations of 8,000 or less per year in the U.S. and is subject to certain profit and use restrictions. In January 2015, we received HDE approval for the Impella RP device from the FDA.



In September 2017, we received FDA approval of a PMA for the Impella RP heart pump. This latest approval follows the prior FDA HDE received in January 2015 and adds the Impella RP heart pump to our platform of PMA approved devices. The Impella RP heart pump is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area  $\geq 1.5$  m<sup>2</sup>, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. With this approval, the Impella RP heart pump is the only percutaneous temporary ventricular support device that is FDA-approved as safe and effective for right heart failure as stated in the indication.

In April 2014, the Impella RP device received CE Mark approval which allows for commercial sales of the Impella RP device in the European Union and other countries that require a CE Mark approval for commercial sales.

## **Our Product Pipeline**

### ***Impella 5.5™***

The Impella 5.5 device is designed to be a percutaneous micro heart pump with integrated motors and sensors. The Impella 5.5 device is designed to be smaller, provide months of hemodynamic support and is expected to allow for greater than five liters of blood flow per minute. In April 2018, we announced that we received CE mark approval in the European Union for the Impella 5.5 heart pump and the first patient was treated at University Heart Center in Hamburg, Germany. We anticipate conducting a first-in-man trial outside of the U.S. in calendar year 2018. The Impella 5.5 pump has not been approved for commercial use or sale in the U.S.

### ***Impella ECP™***

The Impella ECP pump is designed for blood flow of greater than three liters per minute. It is intended to be delivered on a standard sized catheter and will include an expandable inflow in the left ventricle. We anticipate conducting a first-in-human trial outside of the U.S. in fiscal 2019. The Impella ECP pump is still in development and has not been approved for commercial use or sale.

In July 2014, we acquired all of the issued shares of ECP Entwicklungsgesellschaft mbH, or ECP, a German limited liability company based in Berlin, Germany, for \$13.0 million in cash, with additional potential payments up to a maximum of \$15.0 million based on the achievement of certain technical, regulatory and commercial milestones. In connection with our acquisition of ECP, ECP acquired all of the issued shares of AIS GmbH Aachen Innovative Solutions, or AIS, a German limited liability company, for \$2.8 million in cash which was provided by us. AIS, based in Aachen, Germany, holds certain intellectual property useful to ECP's business, and, prior to being acquired by ECP, had licensed such intellectual property to ECP.

### ***Impella BTR™***

The Impella BTR device is designed to be a percutaneous micro heart pump with integrated motors and sensors. The Impella BTR device is designed to be smaller, provide up to one year of hemodynamic support and is expected to allow for greater than five liters of blood flow per minute. The Impella BTR device also includes a wearable driver designed for hospital discharge. The Impella BTR pump is still in development and has not been approved for commercial use or sale.

## **Summary of Recent Financial Performance**

For fiscal 2018, we recognized net income of \$112.2 million, or \$2.54 per basic share and \$2.45 per diluted share, compared to \$52.1 million, or \$1.21 per basic share and \$1.17 per diluted share for the prior fiscal year. For fiscal year 2018, total revenue was \$593.7 million, up 33% compared to revenue of \$445.3 million in fiscal year 2017. The increase in our net income for fiscal 2018 was driven primarily by higher Impella product revenue due to greater utilization of our Impella devices in the U.S. and Germany. We also received regulatory approval in Japan during September 2017 and we began a limited commercial launch in Japan during fiscal 2018. Further, the adoption of ASU 2016-09 (defined below) resulted in an increase of net income of \$31.0 million, or \$0.70 per basic and \$0.68 per diluted share for the year ended March 31, 2018. Additionally, the enactment of the Tax Cuts and Jobs Act, or the Tax Reform Act resulted in a decrease in net income of \$21.4 million, or \$0.48 per basic and \$0.47 per diluted share for the year ended March 31, 2018. Information regarding our total assets are contained within our consolidated financial statements in this Report.

## Our Markets

According to the AHA's Heart Disease and Stroke Statistics 2018 Update Report, coronary heart disease, or CHD, causes approximately one of every seven deaths in the U.S. CHD is a condition of the coronary arteries that causes reduced blood flow and insufficient oxygen delivery to the affected portion of the heart. CHD leads to acute myocardial infarction, or AMI, commonly known as a heart attack, which may lead to heart failure, a condition in which the heart is unable to pump enough blood to the body's major organs.

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

In more severe cases of heart failure, patients are sent directly to the surgery suite for coronary bypass or valve replacement surgery. The most severe acute heart failure patients are in profound cardiogenic shock, including those suffering from myocarditis (a viral attack of the heart), or from those suffering from an impaired ability of the heart to pump blood after a heart attack or heart surgery. These patients typically require treatments involving the use of mechanical circulatory support devices that provide increased blood flow and reduce the stress on the heart. Many less severe patients in the cath lab could also benefit from circulatory support devices or other clinical treatment, which could potentially prevent them from entering into profound shock.

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

An IAB is an inflatable balloon inserted via a catheter into a patient's circulatory system and is inflated and deflated in the aorta. This is used as an initial line of therapy in the cath lab or the surgery suite for patients with diminished heart function. However, IABs typically provide only limited enhancement and depend on the patient's own heart to generate the majority of the patient's blood flow. In addition, IABs are often required to be used in conjunction with inotropes or other drugs to stimulate heart muscle ejection. The use of these drugs, however, increases the risk of mortality. Further, the clinical efficacy of IABs has been challenged due to the conclusions of the randomized, prospective, open-label, multicenter "SHOCK II" Trial. The conclusion of the trial was that the use of IAB counterpulsation did not significantly reduce 30-day mortality in patients with cardiogenic shock complicating acute myocardial infarction for whom an early revascularization strategy was planned. Further, IABs have limited effectiveness in patients that are arrhythmic and/or in cardiogenic shock and published reports have indicated that IABs do not reduce mortality for patients in cardiogenic shock.

Percutaneous assist devices and VADs are mechanical devices that help the failing heart pump blood or take over the pumping function of the failing heart. Historically, VADs have been highly invasive and require implantation in the surgery suite. Percutaneous assist devices allow for less invasive placement and removal, and can be done through a small puncture in the leg in the cath lab, electrophysiology lab, or operating room. The use of surgically placed VADs generally falls into three sub-categories: recovery, bridge-to-transplant and destination therapy.

Recovery VADs are designed to enable the patient's heart to rest and potentially recover so that the patient can return home with his or her own heart. Because recovery is the goal, these devices are designed to minimize damage to heart tissue and are removed once the patient's heart has recovered. If possible, recovery of a patient's heart is generally preferred to transplantation or prolonged device implantation, both of which have significant side effects for the patient and increase the risk of mortality. We believe heart recovery is a preferred clinical outcome for patients, since it generally lowers the overall relative cost to the healthcare system versus alternative therapies and treatment paths that may require multiple surgeries, lengthy or repeated hospital stays, chronic therapeutic and immunosuppressant drugs and other related healthcare costs.

## **Research and Product Development**

Since our founding in 1981, we have gained substantial expertise in circulatory support through the development of many product platforms to support heart patients. This includes our Impella platform that we currently market and other technologies that we have supported, and sold in the past, which we do not actively market currently. We also continue to work on developing new technologies as well, such as the optical sensor technology for the Impella CP device. Our current strategy is to develop a complete portfolio of products across the continuum of care in heart recovery, primarily focused in the area of circulatory care. We intend to continue to use this experience to develop additional circulatory support products as well as making enhancements to our existing products. In addition, we have a number of new products at various stages of development, some of which integrate the Impella technology platform including the Impella 5.5, Impella ECP and Impella BTR devices.

As of March 31, 2018, our research and development staff consisted of 208 full-time employees. We expended \$75.3 million, \$66.4 million and \$49.8 million on research and development in fiscal years 2018, 2017 and 2016, respectively. Our research and development expenditures include costs related to clinical trials and studies for our Impella devices.

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

As of March 31, 2018, our worldwide sales, clinical support, marketing and field service teams included 482 full-time employees, 406 of whom are in the U.S. and Canada and 76 of whom are in Europe and Asia. In recent years, we have significantly increased the number of our direct sales and clinical support personnel in the U.S and Germany.

Our clinical support personnel consist primarily of registered nurses and other personnel with considerable experience in either the surgery suite or the cath lab, and they play a critical role in training physicians in the use of our products.

International sales (sales outside the U.S., primarily in Europe) accounted for 11%, 9% and 8% of total revenue during fiscal years 2018, 2017 and 2016, respectively.

## **Manufacturing**

We manufacture our products in Danvers, Massachusetts and Aachen, Germany. Our Aachen facility performs final assembly and manufactures most of our disposable Impella devices, including the Impella 2.5, Impella 5.0, Impella LD, Impella CP and Impella RP devices. Our Danvers facility also manufactures and performs final assembly for the Impella CP device and certain Impella subsystems and accessories, including our Automated Impella Console, or AIC, our console for our Impella devices. In addition, we rely on third-party suppliers to provide us with components used in our existing products and products under development. For example, we outsource some of the manufacturing for components and circuit cards within our consoles.

We believe our existing manufacturing facilities give us the necessary physical capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months based on our current revenue forecast. We have recently expanded our manufacturing capacity in both our Aachen and Danvers facilities to support the growing demand for our Impella devices. We expect to continue to expand our manufacturing capacity as we support expected growing demand for our Impella devices. Our U.S. and German manufacturing facilities are certified as being in compliance with standards established by the International Organization for Standardization, or ISO, and operate under the FDA's good manufacturing practice requirements for medical devices set forth in the Quality System Regulation, or QSR.

## **Intellectual Property**

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

A substantial portion of our intellectual property rights relating to the Impella devices and other products under development, such as the Impella 5.5<sup>TM</sup>, Impella ECP<sup>TM</sup>, and Impella BTR<sup>TM</sup> devices, are 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.

We own or have rights to numerous U.S. and foreign patents. Our U.S. patents have expiration dates ranging from 2018 to 2035 and our foreign patents have expiration dates ranging from 2018 to 2032. 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 could be required to pay royalties.

Our patents may not provide us with competitive advantages. Our pending or future patent applications may not be issued. Others may hold or obtain patents that cover aspects or uses of our innovations. The patents of others may render our patents obsolete, limit our ability to patent or practice our 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, which may also be costly and time consuming.

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 many companies that have substantially greater or broader financial, product development, sales and marketing resources and experience than we do. Furthermore, new product development and technological change characterize the areas in which we compete. Our present or future products could be rendered obsolete or uneconomical as a result of technological advances by one or more of our present or future competitors or by other therapies, including drug therapies. We must continue to develop and commercialize new products and technologies to remain competitive in the cardiovascular medical technology industry. We believe that we compete primarily on the basis of clinical superiority supported by extensive data, and innovative features that enhance patient benefit, product performance, ease of use and reliability. Customer and clinical support, and data that demonstrate both improvement in a patient's quality of life and a product's cost-effectiveness are additional aspects of competition.

The cardiovascular segment of the medical technology industry is dynamic and subject to significant change due to cost-of-care considerations, regulatory reform, industry and customer consolidation and evolving patient needs. The ability to provide products and technologies that demonstrate value and improve clinical outcomes is becoming increasingly important for medical technology manufacturers.

We are aware of other heart replacement device research efforts in the U.S., Canada, Europe and Japan. In addition, there are a number of companies, including Abbott Laboratories, Medtronic, Edwards Lifesciences, Boston Scientific, CardiacAssist (Tandem Life), Terumo Heart, Teleflex, Getinge (Maquet Cardiovascular), and several early-stage companies, that are developing heart assist products, including implantable left ventricular assist devices and miniaturized rotary ventricular assist devices that directly and indirectly compete with our products.

## **Third-Party Reimbursement**

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

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 in the U.S. and, along with its contractors, establishes coverage and reimbursement policies for the Medicare program. Medicare's coverage and reimbursement policies are particularly significant to our business because a large percentage of the population for which our products are intended includes individuals who are Medicare beneficiaries. In addition, private payers often follow the coverage and reimbursement policies of Medicare. We cannot assure that government or private third-party payers will continue to cover and reimburse the procedures using our products in whole or in part in the future or that payment rates for reimbursement will be adequate.

Medicare payment may be made, in appropriate cases, for procedures performed in the in-patient hospital setting using our technology. Medicare generally reimburses healthcare institutions in which the procedures are performed based upon prospectively determined amounts. For hospital in-patient stays, the prospective payment generally is determined by the patient's condition and other patient data and procedures performed during the in-patient stay, using a classification system known as International Classification of Diseases, or ICD, and medical severity diagnosis-related groups, or MS 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 MS DRG-based payments made to hospitals for the procedures during which our devices are implanted, removed, or replaced. Because prospective payments are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, hospitals have incentives to lower their in-patient operating costs by utilizing products, devices and supplies that will reduce the length of in-patient stays, decrease labor or otherwise lower their costs.

Coverage and reimbursement for procedures to implant, remove or replace our products are generally established in the U.S. market. For instance, Medicare covers the use of LVADs 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 destination therapy for patients who require permanent mechanical cardiac support, when the use is consistent with FDA approval and FDA-approved labeling instructions, as applicable. Coverage and reimbursement for procedures to implant the Impella 2.5, Impella CP, Impella 5.0, Impella LD and Impella RP devices are also established for in-hospital use by Medicare including ICD-10 for procedures and MS DRG coding. Actual coverage and payment may vary by local Medicare fiscal intermediary or third-party insurer. Our Impella devices are also covered by commercial and/or Medicare plans of many third-party insurers including Aetna, Humana, Cigna, Blue Cross Blue Shield, and United Healthcare.

In October 2017, the American Hospital Association, or AHA Coding Clinic publication confirmed an insertion code for all Impella cases thereby billing out to MS-DRG 215, Heart Assist System Implant, for all percutaneous uni-ventricular Impella insertions. The Company's Impella heart pumps are now most commonly reimbursed under three MS-DRG categories including: (1) percutaneous, uni-ventricular insertions in MS-DRG 215; (2) right and left side heart support known as bi-ventricular and removal in MS-DRG 1-2; and (3) hospitals receiving transferred patients with removal of the device in MS-DRG 268-269. The AHA and the CMS have facilitated a system of care around the utilization of percutaneous heart pumps, and transfer of patients to specialized centers. This progress also represents the expansion of Impella FDA indications for High Risk PCI, AMI Cardiogenic Shock, and bi-ventricular support.

In April 2018, CMS released a proposed set of hospital payment levels for patient discharges after October 1, 2018. The April 2018 Proposed Rule for the Inpatient Prospective Payment System, or IPPS, update includes ICD-10 coding and assignment of percutaneous Impella implantation to MS-DRG 215 for Other Heart Assist System Implant. The Proposed Rule also maintained bi-ventricular Impella support in MS-DRG 1-2 assignments, and Impella hospital transfer and support in MS-DRG 268-269 for the receiving hospital. Impella related procedures were previously assigned to MS-DRG 216-221 for assistance in the catheterization lab only, and were reimbursed at a lower rate than MS-DRG 215 and MS-DRGs 1-2. A designated DRG 215 code will simplify coding and enable hospitals to receive payment in multiple settings and indications. The MS-DRG 215 proposed rate is lower than the previous year based on the CMS process to evaluate hospital charges, length of stay, patient comorbidities, taking into account hospital efficiencies over the prior year. The proposed rule for IPPS is open for public comment until June 2018. The final rulemaking may differ substantially from this proposal and will take effect October 1, 2018.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services when they perform surgeries to implant, remove, replace or repair our devices or when they perform percutaneous insertion and removal of Impella 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 or repositioning of our approved products are billed using a variety of CPT codes. Generally, Medicare payment levels for physician services are based on the Medicare Physician Fee Schedule and are revised annually by CMS.

In general, third-party reimbursement programs in the U.S. and abroad, whether government-funded or commercially insured, are developing a variety of increasingly sophisticated methods of controlling healthcare costs, including prospective reimbursement and capitation programs, group purchasing, reducing benefit coverage, requiring second opinions prior to major surgery, negotiating reductions to charges on patient bills, promoting healthier lifestyle initiatives and exploring more cost-effective methods of delivering healthcare. These types of cost containment programs, as well as legislative or regulatory changes to reimbursement policies, could limit the amount which healthcare providers may be willing to pay for our medical devices.

In September 2016, we received PMDA approval from the MHLW for our Impella 2.5 and Impella 5.0 heart pumps to provide treatment of drug-resistant acute heart failure in Japan. In July 2017, we received approval from the MHLW for reimbursement of the Impella 2.5 and 5.0 heart pumps. Reimbursement in Japan for the Impella 2.5 and 5.0 is equivalent to our average Impella sales price in the U.S. and we commenced commercialization in Japan during the fiscal year ended March 31, 2018.

## **Government Regulation and Other Matters**

Our products and facilities are subject to regulation by numerous government agencies, including the FDA, European Community Notified Bodies, and the Japanese Pharmaceuticals and Medical Devices Agency, to confirm compliance with the various laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. We are also governed by federal, state, local, and international laws of general applicability, such as those regulating employee health and safety, and the protection of the environment. Overall, the amount and scope of domestic and foreign laws and regulations applicable to our business has increased over time.

### ***United States Regulation***

In the U.S., the FDA has responsibility for regulating medical devices under the authority of the Federal Food, Drug and Cosmetic Act, or FDCA. The FDA regulates design, development, testing, clinical studies, manufacturing, labeling, distribution, import, export, sale promotion, and record keeping for medical devices, and reporting of adverse events, recalls, or other field actions by manufacturers and users to identify potential problems with marketed medical devices. Many of the devices that we develop, manufacture and market are in a category for which the FDA has implemented stringent clinical investigation and pre-market clearance or approval requirements. The process of obtaining FDA clearance or approval to market a product is resource intensive, lengthy, and costly. FDA review may involve substantial delays that adversely affect the marketing and sale of our products. A number of our products are pending regulatory clearance or approval to begin commercial sales in various markets. Ultimately, the FDA may not authorize the commercial release of a medical device if it determines the device is not safe and effective or does not meet other standards for clearance or approval. Additionally, even if a product is cleared or approved, the FDA may require postmarket testing and surveillance programs to monitor the effects of these products once commercialized.

The FDA has the authority to halt the distribution of certain medical devices, detain or seize adulterated or misbranded medical devices, order the repair, replacement, or refund of the costs of such devices, or preclude the importation of devices that are or appear to be violative. The FDA also conducts inspections to determine compliance with the QSR concerning the manufacturing and design of devices and medical device reporting regulations, recall regulations, clinical testing regulations, and other requirements. The FDA may withdraw product clearances or approvals due to failure to comply with regulatory standards, or the occurrence of unforeseen problems following initial approval, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. Additionally, the failure to comply with FDA or comparable regulatory standards or the discovery of previously unknown product problems could result in fines, delays, or suspensions of regulatory clearances or approvals, seizures, injunctions, recalls, refunds, civil money penalties, or criminal prosecution. Our compliance with applicable regulatory requirements is subject to continual review. Moreover, the FDA and several other U.S. agencies administer controls over the export of medical devices from the U.S. and the import of devices into the U.S., which could also subject us to sanctions for noncompliance.

### ***Premarket Regulation***

The FDA classifies medical devices into one of three classes (Class I, II or III) based on the statutory framework described in the FDCA. Our Impella products are categorized as Class III devices. Class III devices are typically life-sustaining, life-supporting or implantable devices, or new devices that have not been found to be substantially equivalent to legally marketed devices. Class III devices must generally receive PMA approval from the FDA before they can be marketed.

The PMA approval pathway requires that the applicant demonstrate to the FDA's satisfaction, based on valid scientific evidence, that there is a reasonable assurance of the safety and effectiveness of the device for its intended use. During the PMA process, the FDA examines detailed data to assess the safety and effectiveness of the device. This information includes design, development, manufacture, labeling, advertising, preclinical testing and clinical study data. Prior to approving a PMA, the FDA may conduct an inspection of the manufacturing facilities and the clinical sites where supporting studies were conducted. The facility inspection evaluates the company's compliance with QSR. An inspection of clinical sites evaluates compliance with good clinical practice standards, including, for studies conducted under an IDE that the studies meet the requirements of FDA's IDE regulations. Typically, the FDA will convene an advisory panel meeting to review the data presented in the PMA. The panel's recommendation is given substantial weight, but is not binding on the FDA. Under a set of performance measures that the FDA has committed to achieving in return for the receipt of user fees from manufacturers, FDA attempts to review all PMAs not requiring an advisory panel meeting within 180 "FDA days" and review of a PMA application that does require an advisory panel meeting within 320 "FDA days." The term "FDA days" excludes the time the applicant spends responding to FDA requests for additional information. While the FDA has approved PMA applications within the allotted time period, reviews can occur over a significantly longer period.

Upon completion of its review, the FDA will either approve or deny the PMA. If the FDA's evaluation is favorable, the PMA is approved and the device may be marketed in the U.S. The FDA may approve a PMA with post-approval conditions such as post-market collection of clinical data. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the PMA approval. A PMA approval may include significant limitations on the indicated uses for which a device may be marketed. The FDA interprets the FDCA as prohibiting the promotion of approved medical devices for unapproved uses. After approval of a PMA, a new PMA or PMA supplement is required in the event of a significant modification to the device, the device labeling, or the manufacturing process. The FDA can initiate proceedings to withdraw a PMA approval for failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial marketing.

In March 2015, we received a PMA approval from the FDA for use of the Impella 2.5 device in the U.S. during elective and urgent high-risk percutaneous coronary intervention, or PCI, procedures. In December 2016, the FDA expanded this PMA approval in the U.S. to include the Impella CP device. In April 2016, the FDA approved a PMA supplement for our Impella 2.5, Impella CP, Impella 5.0 and Impella LD devices to provide treatment for ongoing cardiogenic shock, which occurs following heart attack or open heart surgery. In September 2017, we received a PMA approval from the FDA for the Impella RP heart pump. In February 2018, we received an expanded FDA PMA approval for the Impella 2.5, Impella CP, Impella 5.0, and Impella LD heart pumps to provide treatment for heart failure associated with cardiomyopathy leading to cardiogenic shock. This approval expands the previous indication for AMI cardiogenic shock and post-cardiotomy shock, or PCCS, received in April 2016. Additionally, in February 2018, we received an expanded FDA PMA approval for the Impella 2.5 and Impella CP heart pumps during elective and urgent high-risk PCI procedures. This expanded indication confirms Impella support as appropriate in patients with severe coronary artery disease, complex anatomy and extensive comorbidities, with or without depressed ejection fraction.

The intent of the treatment is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function. We expect to make additional PMA supplement submissions for additional indications for use for our Impella devices in the future.

When clinical trials of a device are required in order to obtain FDA approval, the sponsor of the trial is generally required to file an IDE application before commencing the trials. The FDA reviews and must approve an IDE before a clinical study may begin in the U.S. In addition, the clinical study must be approved by an Institutional Review Board, or IRB, at each clinical site. The FDA, the IRB, or we may suspend a clinical trial at any time for various reasons, including if information emerges suggesting that the subjects are being exposed to an unacceptable health risk. All clinical studies of investigational devices must be conducted in compliance with FDA requirements. Following the completion of a study, the data from the study must be collected, analyzed and presented in an appropriate submission to the FDA, either as a report submitted to the IDE file or in a marketing application such as a PMA.

In addition, certain medical devices can be approved by the FDA in the U.S. under an HDE rather than a PMA. In order for a device to be eligible for an HDE, there must be a qualifying target patient population of less than 8,000 patients per year for which there is no other comparable device available to treat the condition. The FDA must agree that a device meets these criteria before it can be approved under an HDE. FDA approval of an HDE also 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. If another device receives approval through the PMA process that addresses the same patient population as the HDE device, the HDE device may need to be withdrawn from the U.S. market. An approved HDE authorizes sales of the device to any hospital after review and approval by the hospital's IRB. Proposed modifications to approved HDE devices, like modifications to approved PMA devices, require FDA approval through a new HDE application or an HDE supplement.

## *Postmarket Regulation*

The medical devices that we manufacture and distribute pursuant to regulatory clearances or approvals by the FDA and other countries' regulatory authorities are subject to continuing regulation by those agencies. The FDA reviews design, manufacturing, and distribution practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. Among other FDA requirements, we must comply with the FDA's good manufacturing practice regulations for medical devices, known as the QSR. These regulations govern the methods used in, and the facilities and controls used for, the design, testing, manufacture, packaging, labeling, storage, installation, and servicing of all finished medical devices intended for human use. We must also comply with Medical Device Reporting, or MDR requirements, which require us to report to the FDA any incident in any of our products that may have caused or contributed to a death or serious injury, including medical intervention to prevent a death or serious injury, or in which any of our products malfunctioned and, if such malfunction were to recur, would be likely to cause or contribute to a death or serious injury. Labeling, advertising, and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. The FDA's enforcement policy prohibits the marketing of approved medical devices for unapproved uses. We are subject to routine inspection by the FDA for compliance with the 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 seek a judicial injunction enjoining certain violations of the FFDCA and imposing operating restrictions and assess civil or criminal fines and penalties against our officers, employees, or us. The FDA may also recommend criminal prosecution to the U.S. Department of Justice. Conduct giving rise to civil or criminal penalties may also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by our conduct. Regulatory authorities outside the U.S. enforce similar laws and regulations within their respective jurisdictions.

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.

The FDA can require post-market surveillance, or PMS, for significant risk devices, such as our medical devices, that require ongoing collection, analysis, and periodic submission to the FDA of clinical data during commercialization over a period of up to several years. The PMS data collection requirements are often burdensome and expensive. The failure to comply with the FDA's regulations can result in enforcement action, including seizure of products, injunction, prosecution, civil fines and penalties, recall and/or suspension of FDA approval.

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

We are also subject to additional laws and regulations that govern our business operations, products, and technologies, including:

- federal, state, and foreign anti-kickback laws and regulations, which generally prohibit payments and other financial benefits to physicians or other purchasers of medical products as an inducement to purchase a product;
- the Stark law, which prohibits physicians from referring Medicare patients to a provider that bills this program for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that provider, subject to numerous specific exemptions;
- federal and state laws and regulations that protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of such information, in particular, the Health Insurance Portability and Accountability Act of 1996, or HIPAA;
- the Physician Payments Sunshine Act, or PPSA, which requires public disclosure of the financial relationships of United States physicians and teaching hospitals with applicable manufacturers, including medical device, pharmaceutical, and biologics companies;



- the False Claims Act, or FCA, which prohibits the submission of false or otherwise improper claims for payment to a federally funded health care program, and health care fraud statutes that prohibit false statements and improper claims to any third-party payer, and may be enforced through whistleblower or 'qui tam' lawsuits filed by private individuals; and
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, which can be used to prosecute companies in the U.S. for arrangements with foreign government officials or other parties outside the U.S.

Failure to comply with these laws and regulations could result in criminal liability, significant fines or penalties, negative publicity, and substantial costs and expenses associated with investigation enforcement activities, and individual settlement agreements that impose a government monitor for a period of several years. To assist in our compliance efforts, we adhere to many codes of ethics and conduct regarding our sales and marketing activities in the U.S. and other countries in which we operate, including the ABIOMED Code of Conduct and Compliance Policy.

### ***International Regulation***

Internationally, the approval and regulation of medical devices is subject to a variety of laws and regulation. In Europe, our products are subject to extensive regulatory requirements. Our Impella 2.5, Impella 5.0, Impella LD, Impella CP, Impella RP and AIC are all approved under CE Mark and are available for sale in the European Union and other markets that recognize CE Mark approval. The European Union requires that medical devices may only be placed on the market if they do not compromise safety and health when properly installed, maintained, and used in accordance with their intended purpose. National laws conforming to the European Union's legislation regulate our products under the medical devices regulatory system. Although the more variable national requirements under which medical devices were formerly regulated have been substantially replaced by the European Union Medical Devices Directive, individual nations can still impose unique requirements that may require supplemental submissions. The European Union medical device laws require manufacturers to declare that their products conform to the essential regulatory requirements after which the products may be placed on the market bearing the CE Mark. Manufacturers' quality systems for products in all but the lowest risk classification are also subject to certification and audit by an independent notified body. In Europe, particular emphasis is being placed on more sophisticated and faster procedures for the reporting of adverse events to the competent authorities.

In May 2017, the European Union implemented a new regulatory requirement for medical devices under the MDR. The MDR becomes fully effective in 2020 and will bring significant new requirements for many medical devices, including enhanced requirements for clinical evidence and documentation, increased focus on device identification and traceability, and additional postmarket surveillance and vigilance. Compliance with the MDR will require re-certification of many of our products to the enhanced standards.

In Japan, pre-market approval and clinical studies are required as is governmental pricing approval for medical devices. Clinical studies are subject to a stringent "Good Clinical Practices" standard. Approval time frames from the Japanese MHLW vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation of medical devices into Japan is subject to the "Good Import Practices" regulations. As with any highly regulated market, significant changes in the regulatory environment could adversely affect future sales.

In many of the other foreign countries in which we market our products, we may be subject to regulations affecting, among other things:

- product standards and specifications;
- packaging requirements;
- labeling requirements;
- marketing restrictions;
- product collection and disposal requirements;
- quality system requirements;
- import restrictions;
- tariffs;
- duties; and
- tax requirements.

Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA. In some countries, the level of government regulation of medical devices is increasing, which can lengthen time to market and increase registration and approval costs. In many countries, the national health or social security organizations require our products to be qualified before they can be marketed and considered eligible for reimbursement.

### ***Health Care Initiatives***

Government and private sector initiatives to limit the growth of health care costs, including price regulation and competitive pricing, coverage and payment policies, comparative effectiveness reviews, technology assessments, and managed-care arrangements, are continuing in many countries where we do business, including the U.S., Canada, Europe, and Asia. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies. For example, government programs, private health care insurance, and managed-care plans have attempted to control costs by restricting coverage and limiting the level of reimbursement for procedures or treatments, and some third-party payers require their pre-approval before new or innovative devices or therapies are utilized by patients. These various initiatives have created increased price sensitivity over medical products generally and may impact demand for our products and technologies.

The delivery of our products is subject to regulation by the department of Health and Human Services in the U.S. and comparable state and foreign agencies responsible for reimbursement and regulation of health care items and services. Foreign governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services. Reimbursement schedules regulate the amount the U.S. government will reimburse hospitals and doctors for the inpatient care of persons covered by Medicare. CMS may also review whether and/or under what circumstances a procedure or technology is reimbursable for Medicare beneficiaries. Changes in current reimbursement levels could have an adverse effect on market demand and our pricing flexibility.

Health care cost containment efforts have also prompted domestic hospitals and other customers of medical device manufacturers to consolidate into larger purchasing groups to enhance purchasing power and this trend is expected to continue. The medical device industry has also experienced some consolidation, partly in order to offer a broader range of products to large purchasers. As a result, transactions with customers are larger, more complex, and could likely involve more long-term contracts than in the past. These larger customers, due to their enhanced purchasing power, may attempt to increase pressure on product pricing.

### ***Health Care Reform***

In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or together, the Affordable Care Act, or ACA. The law includes provisions that, among other things, reduce or limit Medicare reimbursement, mandate that all individuals have health insurance (with limited exceptions) and impose increased taxes. In December 2015, the former U.S. President signed into law the Consolidated Appropriations Act, 2016, which included a two-year moratorium on the medical device excise tax such that medical device sales in 2016 and 2017 are exempt from the medical device excise tax. As part of continuing legislation signed by the U.S. President and passed by the U.S. Congress in January 2018, the medical device excise tax moratorium was further extended until January 1, 2020.

Initiatives to repeal the ACA, in whole or in part, to delay implementation or funding, and to offer amendments or supplements to modify its provisions have been persistent and have increased as a result of the 2016 election. Efforts to pass comprehensive repeal legislation have failed, but the outlook for ACA-compliant insurance plans is still uncertain. The current U.S. executive administration has recently begun to encourage certain alternative health plans that are not required to comply with ACA coverage standards, including short-term and association health plans. If these plans become more widespread, premiums for the more comprehensive plans required by the ACA may increase, which could result in a decrease in the number of Americans with comprehensive health care insurance.

## ***Other Regulations***

Our business requires us to use and store personally identifiable information of our customers, vendors, employees and business partners and, in certain instances patients treated with our products in the clinical setting. We are subject to various domestic and international privacy and security regulations, including but not limited to HIPAA and the General Data Protection Regulation, or the GDPR. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. The GDPR is a comprehensive update to the data protection regime in the European Economic Area that is effective in fiscal 2019. The GDPR imposes new requirements relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third party processors. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including fines and penalties for noncompliance with the GDPR.

We are also subject to various international, federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development and manufacturing activities. Specifically, the manufacture of our biomaterials is subject to compliance with federal environmental regulations and by various state and local agencies. Although we believe we are in compliance with these laws and regulations in all material respects, we cannot provide assurance that we will not be required to incur significant costs to comply with these and other laws or regulations in the future.

## **Seasonality**

Our quarterly net sales are influenced by many factors, including new product introductions, acquisitions, regulatory approvals, patient and physician holiday schedules, and other factors. Net sales in the first half of our fiscal year were 45%, 46%, and 45% of total fiscal year net sales for fiscal 2018, 2017 and 2016, respectively. Revenues are typically lower in the first half of our fiscal year due to the seasonality of the U.S. and European markets, where summer vacation schedules normally result in fewer medical procedures.

## **Employees**

As of March 31, 2018, we had 1,143 full-time employees, including:

- 208 in product engineering, research and development, clinical development and regulatory;
- 482 in sales, clinical support, marketing, field service and related support;
- 344 in manufacturing; and
- 109 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.

## ITEM 1A. RISK FACTORS

*Investing 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. If any of these risks materialize, the trading price of our common stock could fall and you could 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 of such forward-looking statements discussed at the beginning of the report.*

### Risks Related to Our Business

#### ***We depend on Impella® products for a significant portion of our revenues.***

We derive, and expect to continue to derive in the near future, all of our revenues from sales of our Impella devices. While we cannot fully predict what level of revenues our Impella devices will generate, we anticipate that Impella revenues will continue to account for all of our revenues in the near future. Implementation of our business strategy depends on continued revenues from our Impella devices. Our ability to generate revenues from our Impella devices may be impaired by the factors described below:

- our failure to obtain approvals from the FDA and foreign regulatory authorities or to comply with government regulations, or the withdrawal of market clearance or the taking of other enforcement actions that could limit or impair our ability to sell our products;
- lack of acceptance or continued acceptance by physicians;
- our reliance on specialized suppliers for certain components and materials;
- manufacturing or quality control problems;
- our inability to protect our proprietary technologies or an infringement of others' patents;
- the loss of a distributor or a distributor's failure to perform its obligations;
- our failure to compete successfully against our existing or potential competitors;
- additional risks associated with selling in international markets;
- long and variable sales and deployment cycles;
- failure by third-party payers to provide appropriate levels of reimbursement for hospitals and physicians using our products;
- our failure to comply with federal and state regulations; and
- product liability claims.

#### ***If we fail to compete successfully against our existing or potential competitors, our revenues 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. Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products. Factors affecting our competitive position include:

- the availability of other products and procedures that are technically equivalent or superior to our products, and which may be sold at lower prices;
- product performance and design;
- product safety;
- sales, marketing and distribution capabilities;
- comparable clinical outcomes;
- success and timing of new product development and introductions;
- physician and hospital acceptance of our products;

- penetration into existing and new geographic markets; and
- intellectual property protection.

Our customers are primarily hospitals that 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 for our products. We believe that important competitive factors with respect to the development and commercialization of our products include the relative speed with which we can develop products, establish clinical utility, complete clinical trials and regulatory approval processes, obtain and protect reimbursement, maintain cost effectiveness for our products, and supply commercial quantities of our products to our customers.

Advances in medical technology, biotechnology and pharmaceuticals may reduce the size of the potential markets for our products or render our products obsolete. We are aware of other heart replacement device research efforts in the U.S., Canada, Europe and Japan. In addition, there are a number of companies, including Abbott Laboratories, Medtronic, Edwards Lifesciences, CardiacAssist, Terumo Heart, Teleflex, Getinge (Maquet Cardiovascular), and several early-stage companies, that are developing heart assist products, including implantable left ventricular assist devices and miniaturized rotary ventricular assist devices that directly and indirectly compete with our products.

***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. We have experienced significant growth in recent years in which we have expanded our operations and we have increased our employee headcount. 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, marketing and administrative infrastructure and capabilities;
- expanding manufacturing capacity, maintaining quality and increasing production;
- increasing our foreign and domestic regulatory compliance capabilities;
- implementing appropriate operational, financial and IT systems and internal controls;
- identifying, attracting and retaining qualified personnel, particularly experienced clinical staff; and
- hiring, 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 demand for our products and products under development is unproven, and we may be unable to successfully commercialize our products.***

Our products and products under development may not enjoy commercial acceptance or success, which could adversely affect our business and operational results. We need to create new indication and geographic markets for our Impella devices and other existing products, as well as other new or future products, including achieving market acceptance among physicians, hospitals, patients and third-party payers. In particular, we need to gain acceptance of our Impella devices among interventional cardiologists and cardiac surgeons. The obstacles we will face in trying to create successful commercial markets for our products include:

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

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

Medical devices such as ours are extensively regulated by the FDA in the U.S. and by other federal, state, local and foreign authorities. Governmental regulations relate to the testing, development, manufacturing, labeling, design, sale, promotion, distribution, importing, exporting and shipping of our products. In the U.S., before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we must generally first receive PMA from the FDA. This process can be expensive and lengthy, and can entail significant expenses, primarily related to clinical trials. It generally takes between one to three years to receive approval, or even longer, from the time the PMA application is submitted to the FDA. Regulatory clearances or approvals, either foreign or domestic, may not 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. Any significant modifications to the design, materials, or intended use of those devices require FDA approval through PMA or HDE supplemental applications.

If we do not receive FDA approval 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 also market or are beginning to market our products in international markets, including the European Union, Canada, and Japan. Regulatory approval processes differ among those jurisdictions and approval in the U.S. or any other single jurisdiction does not guarantee approval in any other jurisdiction. Obtaining foreign approvals could involve significant delays, difficulties and costs for us and could require additional clinical trials.

***If the FDA or another regulatory or enforcement agency determines that we have promoted our products for one or more off-label uses, we may be subject to various penalties, including civil or criminal penalties.***

The FDA, the U.S. Department of Justice, the Office of the Inspector General of Department of Health and Human Services, and other regulatory or enforcement agencies actively enforce regulations prohibiting the promotion of unapproved medical devices and the promotion of otherwise approved or cleared medical devices for unapproved uses. If any such 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, such agencies could disagree and conclude that we have engaged in off-label promotion.

To the extent a regulatory agency commences such an investigation in the future, we may not be able to resolve that matter, without incurring penalties or facing significant consequences. Even if we are successful in resolving such a matter without incurring penalties, responding to a subpoena or other government inquiry could result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations.

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

***Unsuccessful clinical trials or procedures relating to products under development could have a material adverse effect on our prospects.***

The regulatory approval process for new products and new indications for existing products often requires extensive clinical trials and procedures, including early clinical feasibility studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding such clinical data, could adversely affect both our ability to obtain necessary approvals and the market's view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these clinical trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. Failure to successfully complete these clinical trials or procedures in a timely and cost-effective manner could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures may be contradicted by subsequent clinical analysis. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be delayed, suspended, or terminated by us, the FDA, or other regulatory authorities at any time, if it is believed that the trial participants face unacceptable health risks or for numerous other reasons. 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 safety and effectiveness of the product candidate. The FDA may also require additional pre-clinical studies or clinical trials which could further delay approval of 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, post-approval clinical studies, 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 approved device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a supplemental PMA or HDE approval. The FDA requires each manufacturer to determine in the first instance whether a modification requires approval, but the FDA may review and potentially disagree with any such decision. Modifications of this type are common with new products. We anticipate that the first generation of each of our products will undergo a number of changes, refinements, enhancements and improvements over time. If the FDA requires us to seek approval for modification of a previously approved 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 our regulatory other requirements, the interpretation of which can change. Compliance with QSR and similar legal requirements can be difficult and expensive. Enforcement actions resulting from failure to comply with government requirements could result in fines, suspensions of approvals or clearances, recalls or seizure of products, operating restrictions or shutdown, and criminal prosecutions that could adversely affect the manufacture and marketing of our products. The FDA or another regulatory agency could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements, the occurrence of unanticipated safety problems or other defects in 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 could 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 government 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 by us or our suppliers or design defects, including labeling defects, or unanticipated safety problems. We have in the past initiated voluntary recalls for 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.

***We depend on third-party reimbursement to our customers for market acceptance of our products. If third-party payers fail to provide coverage and appropriate levels of reimbursement for the medical procedures in which our products are used, our sales and profitability would be adversely affected.***

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

In October 2017, the American Hospital Association, or AHA, Coding Clinic publication confirmed an insertion code for all Impella cases thereby billing out to MS-DRG 215, Heart Assist System Implant, for all percutaneous uni-ventricular Impella insertions. The Company's Impella heart pumps are now most commonly reimbursed under three MS-DRG categories including: (1) percutaneous, uni-ventricular insertions in MS-DRG 215; (2) right and left side heart support known as bi-ventricular and removal in MS-DRG 1-2; and (3) hospitals receiving transferred patients with removal of the device in MS-DRG 268-269. The AHA and the CMS have facilitated a system of care around the utilization of percutaneous heart pumps, and transfer of patients to specialized centers. This progress also represents the expansion of Impella FDA indications for High Risk PCI, AMI Cardiogenic Shock, and bi-ventricular support.

In April 2018, CMS released a proposed set of hospital payment levels for patient discharges after October 1, 2018. The April 2018 Proposed Rule for the Inpatient Prospective Payment System, or IPPS, update includes ICD-10 coding and assignment of percutaneous Impella implantation to MS-DRG 215 for Other Heart Assist System Implant. The Proposed Rule also maintained bi-ventricular Impella support in MS-DRG 1-2 assignments, and Impella hospital transfer and support in MS-DRG 268-269 for the receiving hospital. Impella related procedures were previously assigned to MS-DRG 216-221 for assistance in the catheterization lab only, and were reimbursed at a lower rate than MS-DRG 215 and MS-DRGs 1-2. A designated DRG 215 code will simplify coding and enable hospitals to receive payment in multiple settings and indications. The MS-DRG 215 proposed rate is lower than the previous year based on the CMS process to evaluate hospital charges, length of stay, patient comorbidities, taking into account hospital efficiencies over the prior year. The proposed rule for IPPS is open for public comment until June 2018. The final rulemaking may differ substantially from this proposal and will take effect October 1, 2018.

In addition, third-party payers increasingly are requiring evidence that medical devices are cost-effective and if we are unable to meet this requirement, the third-party payer may not reimburse the use of our products, which could reduce sales of our products to healthcare providers who depend upon reimbursement for payment. We also cannot be sure that third-party payers will continue the current levels of reimbursement to physicians and medical centers for use of our products. Any reduction in the amount of this reimbursement could harm our business. Increasing awareness of healthcare costs, public interest in healthcare reform and continuing pressure from Medicare, Medicaid, group purchasing organizations and other payers to reduce costs in the healthcare industry, as well as increasing competition from other protective products, could make it more difficult for us to sell our products at current prices.

***Changes in healthcare reimbursement systems in the U.S. and abroad could reduce our revenues and profitability.***

In March 2010, the U.S. federal government enacted the Affordable Care Act, or ACA, which made changes to the manner in which many healthcare services are provided and paid for in the U.S. The ACA includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes on certain companies and individuals. Results of the recent U.S. elections in 2016 have created a political environment in which substantial portions of the ACA could be repealed or revised. Recent tax reform legislation removes the financial penalty for individuals who do not have health insurance effective in 2019. In addition, proposed changes in regulations would allow wider availability of health insurance that does not provide coverage for all of the essential health benefits required under the ACA. It remains unclear what other portions of the ACA may remain, or what any replacement or alternative programs may be created by any future legislation or regulation. Any such future actions may have significant impact on the reimbursement for healthcare services generally, including reducing significantly the number of Americans who have health insurance, which could lead our health care provider customers to be more cost conscious. Accordingly, our business and results of operations could therefore be adversely affected by any future federal or state healthcare reform legislation or regulation.

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 in certain countries.



***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.***

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights may be applicable to our business. We may be subject to healthcare fraud and abuse regulation and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws and regulations that govern our business operations, products, and technologies, and may affect our ability to operate, include:

- federal, state, and foreign anti-kickback laws and regulations, which generally prohibit payments to physicians or other purchasers of medical products as an inducement to purchase a product;
- the Stark law, which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician’s immediate family) has a financial relationship with that provider;
- federal and state laws and regulations that protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of such information, in particular, the Health Insurance Portability and Accountability Act of 1996, or HIPAA;
- the Physician Payments Sunshine Act, or PPSA, which requires public disclosure of the financial relationships of U.S. physicians and teaching hospitals with applicable manufacturers, including medical device, pharmaceutical, and biologics companies;
- the FCA which prohibits the submission of false or otherwise improper claims for payment to a federally funded health care program, and health care fraud statutes that prohibit false statements and improper claims to any third-party payer; and
- the FCPA which can be used to prosecute companies in the U.S. for arrangements with foreign government officials or other parties outside the U.S.

Failure to comply with these laws and regulations could result in criminal liability, significant fines or penalties, negative publicity, and substantial costs and expenses associated with investigation, enforcement activities, and individual settlement agreements that impose a government monitor for a period of several years. To assist in our compliance efforts, we adhere to many codes of ethics and conduct regarding our sales and marketing activities in the United States and other countries in which we operate.

On April 25, 2014, we received an administrative subpoena from the Boston regional office of the United States Department of Health and Human Services Office of Inspector General, or HHS-OIG, requesting materials relating to our reimbursement of employee expenses and remuneration to healthcare providers from July 2012 through December 2012, in connection with a civil investigation under the False Claims Act. Subsequently, we received Civil Investigative Demands from the U.S. Attorney’s Office for the District of Massachusetts, or the DOJ, that collectively sought additional information relating to this matter for the time period of January 1, 2011 through September 14, 2016. DOJ’s investigation derived from a civil qui tam action, United States ex rel. Max Bennett v. Abiomed, 13-cv-12277, filed on behalf of the United States and certain individual states in the District of Massachusetts by a former employee. The complaint alleged violations of the Federal False Claims Act and analogous state false claims acts, as well as claims that we retaliated against Bennett in violation of federal and state law.

On March 6, 2018, we entered into a Settlement Agreement, or the Settlement Agreement, with the DOJ, on behalf of HHS-OIG, and Bennett to resolve the claims relating to the our reimbursement of employee expenses for meals with healthcare providers. Under the terms of the Settlement Agreement, we agreed to pay \$3.1 million, plus approximately \$30,000 of accrued interest, to the U.S. government. We also agreed to pay \$150,000 to the former Company employee in settlement of his claims for reasonable expenses, costs and attorneys’ fees. The Settlement Agreement contained no admission of liability on the part of the Company and did not require us to enter into a corporate integrity agreement. Pursuant to the Settlement Agreement, the U.S. government and the former Company employee agreed to release the Company from civil monetary liability arising from allegations that the Company caused third parties to submit false claims for payment to Medicare. In connection with the resolution, the various state claims were dismissed without prejudice.

The Settlement Agreement did not resolve the former Company employee’s individual claims of employment retaliation, against which we intend to defend vigorously. We are not able to predict how the former Company employee’s remaining claims might be resolved, or their potential impact on our financial position.

***We are subject to the U.S. Foreign Corrupt Practices Act and other anticorruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.***

Our operations are subject to anti-corruption laws, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage.

We and those acting on our behalf operate in a number of jurisdictions where companies in the medical device and life science industries are exposed to a high risk of potential FCPA violations associated with sales to healthcare professionals and institutions. We participate in transactions with third parties whose corrupt or illegal activities could potentially subject us to liability under the FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. Compliance with the FCPA and these other laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, anti-corruption laws present particular challenges in the medical device industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to enforcement actions. We are also subject to other laws and regulations governing our international operations.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements. If we are not in compliance with the FCPA and other anticorruption laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA and other anti-corruption laws could also have an adverse impact on our reputation, our business, results of operations and financial condition. Further, the failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting.

***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 most of our research and development and regulatory efforts, and significant financial resources, to the development of our Impella devices 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, 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 and limit our ability to bring new products to market.

***The commercial success of our products will require acceptance by cardiac 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 cardiac surgeons and interventional cardiologists, whose decisions are likely to be based on a determination that our products are safe and effective and represent acceptable, cost-effective methods of treatment. Although we have developed relationships with leading cardiac surgeons, the commercial success of Impella devices and our other products will require that we also develop relationships with leading interventional cardiologists in cath labs. 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 cardiac 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.

***Expansion into hospital cardiac centers that have not historically used our products may incur long sales and training cycles that may cause our revenues and operating results to vary significantly from quarter-to-quarter.***

Our products have lengthy sales cycles and we may incur substantial sales and marketing expenses and expend significant effort without making a sale. We sell primarily to hospitals that often have administrative requirements to introduce and expand a new technology, such as Impella devices, at their sites. Even after making the decision to purchase our Impella devices, our customers often deploy our products slowly or infrequently. In addition, cardiac centers of hospitals that buy the majority of our products are usually led by cardiac surgeons who are heavily recruited by competing hospitals. When one of these cardiac surgeons moves to a new hospital, we sometimes experience a significant reduction in purchases by the hospital from which the physician has departed while it replaces the lead physician supporting our Impella devices. As a result, our revenues and operating results may vary significantly from quarter to quarter. In addition, product purchases often lag behind initial expressions of interest in our product by new centers as training and education regarding the use of the products and as well there are internal hospital administrative requirements prior to the initial implant procedures.

***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 business 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 affect future product sales. Furthermore, our inability to educate and train clinicians to use our products may lead to lower demand for our products.

***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 will need to increase our manufacturing capacity to support continued demand for our products. 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, dependable sources of supply, adequacy of internal control policies and procedures and lack of skilled personnel. If we cannot hire, train and retain enough experienced and capable scientific, technical, and manufacturing employees, we may not be able to manufacture sufficient quantities of our existing or future products on time and at an acceptable cost, which could limit market acceptance of our products or otherwise damage our business. In order to meet the expected demand for our Impella devices, we have been implementing process improvements on the Impella production line at our manufacturing facilities in Aachen, Germany and Danvers, Massachusetts to increase the output that we can produce at the facility. In addition to programs designed to further increase yield and capacity levels, we have expanded manufacturing employment and increased manufacturing floor space in Danvers and Aachen. We have relocated selected Impella sub-assembly production to our manufacturing facility in Danvers, Massachusetts and with third party-suppliers and established additional production of the Impella CP device in Danvers to support manufacturing at our Impella production facility in Aachen. We continue to work on initiatives to expand our Impella manufacturing capacity in both Aachen and Danvers. We are also working with our existing suppliers and new suppliers to ensure we are able to have sufficient inventory as we increase our manufacturing capability to support growing demand. We are and will continue to outsource certain sub assembly production to third-party suppliers. We are also working on process improvements, such as certain automation techniques, to allow us to manufacture our products more efficiently. If we are unable to implement these process improvements on a timely basis in order to meet customer demand, it could inhibit our revenue growth.

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

Our products require precise, high-quality manufacturing. Achieving precision and quality control requires skill and diligence by our personnel as well as our vendors. Any 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. Despite our very high manufacturing standards, we cannot completely eliminate the risk of errors, defects or failures. If we or our vendors are unable to manufacture our products 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.

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

We depend heavily on the contributions of the principal members of our business, such as financial, technical, sales and support, regulatory and clinical, operating, manufacturing and administrative management and staff, many of whom would be difficult to replace. Our key personnel include our senior officers, many of whom have very specialized scientific, medical or operational knowledge. The loss of the service of any of the key members of our senior management team may significantly delay or prevent our achievement of our business objectives. Our ability to attract and retain qualified personnel, consultants and advisors is critical to our success. For example, many of the members of our clinical staff are registered nurses with experience in the surgery suite or cath lab, of which only a limited number of whom seek employment with a company like ours. Competition for skilled and experienced personnel in the medical device industry is intense. We face competition for skilled and experienced management, scientific, clinical, engineering and sales personnel from numerous medical device and life sciences companies, universities, governmental entities and other research institutions. If we lose the services of any of the principal members of our management and staff, or if we are unable to attract and retain qualified personnel in the future, especially scientific, clinical 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 many of the components used in our existing products and products in development. For example, we outsource the manufacturing of most of our consoles other than final assembly and testing and the sterilization process for our products. Relying on third-party suppliers makes us vulnerable to component part failures or obsolescence and interruptions in supply, either of which could impair our ability to conduct clinical tests or to ship our products to our customers on a timely basis. Using third-party vendors makes it difficult and sometimes impossible for us to test fully certain components, such as components on circuit boards, maintain quality control, manage inventory and production schedules and control production costs. Manufacturers of our product components may be required to comply with the FDA or other regulatory manufacturing regulations and to satisfy regulatory inspections in connection with the manufacture of the components. Any failure by a supplier to comply with applicable requirements could lead to a disruption in supply. Vendor lead times to supply us with ordered components vary significantly and often can exceed six months or more. Both now, and as we expand our manufacturing capacity, we cannot be sure that our suppliers will furnish us required components when we need them or be able to provide us with sufficient inventory to support our expected growth in demand for our products. These factors could make it more difficult for us to manufacture our products effectively and efficiently 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 or shortage of supply. We have many foreign suppliers for some of our parts in which we are subject to currency exchange rate volatility. Some of our vendors are small in size and may have difficulty supplying the quantity and quality of materials required for our products as our business grows. Vendors that are the sole source of certain products may decide to limit or eliminate sales of certain components 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 are able to 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 our products by recruiting direct sales and support teams outside the U.S. Our international operations in Germany, Japan, France, Canada, the United Kingdom and Singapore are or 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.;
- the requirement to work with distributors or other partners to sell our products;
- longer sales cycles;
- limited protection of intellectual property rights;
- difficulty and delays in collecting accounts receivable;
- different income tax and sales tax environments;

- difficulty in supporting patients using our products;
- difficulty in attracting employees in foreign countries who want to work for a smaller U.S. based company;
- different payroll, employee benefits and statutory requirements;
- 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 rely on distributors to sell our products 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 certain parts of Europe, Asia, South America and the Middle East. 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 in the future. 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 effectively and maintain a continued focus on the sale, distribution and support of our products up to our standards, we could lose sales and impair our ability to compete and introduce our technology in that market. We are also subject to credit risk and foreign currency risk associated with shipments to our distributors and this could negatively impact our financial condition and liquidity in the future.

***The profitability we have achieved in recent years may not be indicative of our ability to sustain profitability and it is possible that we may incur losses from operations in future periods.***

We have recognized net income of \$112.2 million, \$52.1 million and \$38.1 million for the fiscal years ended March 31, 2018, 2017 and 2016, respectively. The profitability we achieved in recent years may not be indicative of our ability to sustain future profitability and it is possible that we may incur losses from operations or net losses in future periods. Any losses incurred in the future may result primarily from, among other things:

- the expansion of our global distribution network;
- investments in new markets such as Japan;
- ongoing product and clinical development;
- costs related to new business development initiatives, such as potential acquisitions of businesses;
- legal expenses related to patent and other matters, such as the Maquet dispute;
- costs associated with hiring additional personnel, performing clinical trials, continuing our research and development relating to our products under development, seeking regulatory approvals and, if we receive these approvals, commencing commercial manufacturing and marketing activities;
- expanded marketing initiatives, particularly with recent PMA approvals in the U.S.;
- income and other related taxes;
- increase in stock-based compensation as we hire new employees and our stock prices has continued or could expect to continue to increase in the future;
- significant expenditures necessary to market and manufacture in commercial quantities our approved circulatory care products; and
- the amount of these expenditures is difficult to forecast accurately and cost overruns may occur.

***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:

- timing of customer orders and deliveries;
- seasonality of sales in the U.S. and European markets, where summer vacation schedules normally result in fewer medical procedures during the first half of our fiscal year;
- competitive changes, such as price changes or new product introductions that we or our competitors may make;
- the impact of additional investments to expand manufacturing capacity on cost of product sales;
- the timing of regulatory actions, such as product approvals or recalls;
- costs we incur developing and testing our Impella heart pumps and other products;
- costs we incur in anticipation of future sales, such as inventory purchases, expansion of manufacturing facilities, or establishment of international sales offices;
- additional taxes;
- impact and timing of equity awards on stock-based compensation;
- timing of certain marketing programs and events;
- availability of physicians to use our products, as there are seasonal impacts, due to physician vacations or training events that limit their ability to be in the hospital to perform procedures that involve our products;
- impact of any businesses or technologies we may acquire in the future;
- economic conditions in the healthcare industry;
- efforts by governments, insurance companies and others to contain healthcare costs, including changes to reimbursement policies; and
- impact of adoption of certain accounting standards.

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 undergo an “ownership change” for U.S. federal income tax purposes, which would limit our ability to utilize net operating losses from prior tax years.***

If we undergo an “ownership change” for U.S. federal income tax purposes, our ability to utilize net operating loss carry-forwards from prior years to reduce taxable income in future tax years might be limited by the Internal Revenue Code, either by limiting the amount of net operating losses that can be utilized to offset taxable income in a given year, or in total over the entire carry-forward period. Certain changes in the ownership of our common stock may result in an ownership change sufficient to limit the availability of our net operating losses. Net operating losses, foreign tax credits and research and development credits have expiry dates in the U.S. and the ability to fully utilize them will be dependent upon generating taxable income in the future. We also have net operating loss carry-forwards in other countries outside of the U.S. and our ability to use those losses in the future to offset taxable income could be limited by tax regulations in those countries.

***Compliance with and changes in tax laws, including recently enacted U.S. Tax Reform legislation, could materially and adversely impact our financial condition, results of operations and cash flows.***

On December 22, 2017, the Tax Cuts and Jobs Act, or Tax Reform, was signed into law that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a rate of 21%, effective January 1, 2018, limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after fiscal 2018 and elimination of net operating loss carrybacks, revisions to the treatment for U.S. federal income tax purposes of foreign earnings, immediate deductions for certain new investments instead of deductions for depreciation

expense over time, and modifying or repealing many business deductions and credits. We have made a provisional estimate of the effects of Tax Reform on our existing deferred tax balances; however, many aspects of the new tax law are uncertain. The law will require significant judgments to be made in the interpretation of various provisions, and the U.S. Treasury Department or Internal Revenue Service could interpret or issue guidance that is different from our interpretation. As a result of Tax Reform, we are currently evaluating the realizability of our tax attributes such as net operating losses, foreign tax credits, and research credits with potential tax planning strategies. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law and this could also impact our tax obligations. Notwithstanding the fact that Tax Reform reduces the U.S. federal income tax rate for corporations, it could adversely affect our business and financial condition.

***We may not have sufficient funds to develop and commercialize our new products or make acquisitions of desirable companies, products or technologies.***

The development, manufacture and sale of any medical device is very expensive and we may require additional funds to make acquisitions of desirable companies, products or technologies. We cannot be sure that we will have the necessary funds to develop and commercialize our new products or acquire companies, products or technologies, or that additional funds will be available on commercially acceptable terms, if at all. If we are unable to obtain the necessary funding to support these efforts, our business may be adversely affected. We believe we have sufficient liquidity to finance our operations for at least the next fiscal year. We also may evaluate from time to time other financing alternatives as necessary to fund operations, and any equity or convertible debt financing may involve substantial dilution to our existing stockholders.

***We own patents, trademarks, trade secrets, copyrights and other intellectual property and know-how that we believe give 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. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, copyright, trade secret and domain name protection laws, as well as confidentiality agreements with our employees and others, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from using our proprietary technologies or from marketing products that are very similar or identical to ours.

A substantial portion of our intellectual property rights relating to the Impella devices 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 or marketing competing products. In addition, some of our former employees who were aware of 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 be assured that consultants, employees and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge, that we will have adequate remedies for any such breach, or that our trade secrets will not become known to or be independently developed by our competitors. The loss of trade secret protection for technologies or know-how relating to our product portfolio and products under development could adversely affect our business and our prospects.

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 result in issued patents or be granted on a timely basis. In addition, issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. The scope of our patent claims also may vary between countries, as individual countries have distinctive patent laws. We may be subject to challenges by third parties regarding our intellectual property, including, among others, claims regarding validity, enforceability, scope and effective term. 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. Our competition may also hold or obtain intellectual property rights that would threaten our ability to develop or commercialize our product offerings. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect our business and our prospects.

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

For a discussion of our material legal proceedings, including those related to patent matters, as of March 31, 2018, please see Note 11 to our consolidated financial statements entitled “Commitments and Contingencies,” which is incorporated by reference into this item.

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

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

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

The risk of product liability claims is heightened when we sell 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. If we have to pay product liability claims in excess of our insurance coverage, our financial condition will be adversely affected.

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

Government regulations require us to track materials used in the manufacture of our products, so that if a problem is identified in one product it can be traced to other products that may have the same problem. An identified quality problem may require reworking or scrapping related inventory and/or recalling previous shipments. Because a malfunction in our products can possibly 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.

***Disruptions of critical information systems or material breaches in the security of our systems could harm our business, customer relations and financial condition.***

We rely in part on information technology to store information, interface with customers, maintain financial accuracy, secure our data and accurately produce our financial statements. If our information technology systems do not effectively and securely collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations would be materially impaired. Any such impairment could have a material adverse effect on our results of operations, financial condition and the timeliness with which we report our operating results.

Our business requires us to use and store personally identifiable information of our customers, vendors, employees and business partners and, in certain instances patients treated with our products in the clinical setting. We are subject to various domestic and international privacy and security regulations, including but not limited to HIPAA and the General Data Protection Regulation, or the GDPR. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. The GDPR is a comprehensive update to the data protection regime in the European Economic Area that is effective in fiscal 2019. The GDPR imposes new requirements relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, and notifications in the event of data breaches and use of third party processors. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including fines and penalties for noncompliance with the GDPR.



Cyber-attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm. While we devote significant resources to network security, data encryption and other security measures to protect our systems and data, including our own proprietary information and the confidential and personally identifiable information of our customers, employees, business partners and patients, these measures cannot provide absolute security. The costs to eliminate or alleviate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and our efforts to address these problems may not be successful, resulting potentially in the theft, loss, destruction or corruption of information we store electronically, as well as unexpected interruptions, delays or cessation of service, any of which could cause harm to our business operations. Moreover, if a computer security breach or cyber-attack affects our systems or results in the unauthorized release of proprietary or personally identifiable information, our reputation could be materially damaged and our operations could be impaired. We would also be exposed to a risk of loss or litigation and potential liability, which could have a material adverse effect on our business, results of operations and financial condition.

***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. 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 its legacy employees, vendors and customers. Additionally, we may acquire development-stage companies that are not yet profitable and which require continued investment, which could decrease our future earnings. We may assume significant liabilities in such a transaction.

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 stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced.

If we include future milestones as part of the potential purchase price of an acquisition, as we did in connection with our acquisition of ECP in July 2014, then we will have to estimate the value of these milestones each reporting period and any changes underlying these estimates with respect to expected timing or valuation of these milestones could have a volatile impact on our earnings.

We periodically make investments in private medical device companies that focus on heart failure, heart pump and other medical device technologies. The aggregate carrying amount of our portfolio of other investments was \$12.6 million and \$7.2 million at March 31, 2018 and 2017, respectively, and is classified within other assets in our consolidated balance sheets. During the years ended March 31, 2018 and 2017, respectively, we made investments of \$6.4 million and \$2.9 million in private medical device companies. These investments are accounted for using the cost method and are evaluated for impairment and measured at fair value only if there are identified events or changes in circumstances that may have a significant adverse effect on the fair value of these investments.

***Revisions to accounting standards and financial reporting and corporate governance requirements could result in changes to our standard practices and could require a significant expenditure of time, attention and resources, especially by senior management.***

We must follow accounting standards and financial reporting and corporate governance requirements and tax laws set by the governing bodies and lawmakers in the U.S. and in other jurisdictions where we do business, as well as NASDAQ. From time to time, these governing bodies and lawmakers implement new and revised rules and laws. These new and revised accounting standards and financial reporting and corporate governance requirements may require changes to our financial statements, financial and governance reporting requirements, the composition of our Board of Directors, the responsibility and manner of operation of various board level committees and the information filed by us with governing bodies. On April, 1, 2017, we adopted the Financial Accounting Standards Board, or the FASB, standard update ASU 2016-09, “*Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*,” or ASU 2016-09, which simplifies several aspects of the accounting for share based payment transactions, including income tax consequences, recognition of stock compensation award forfeitures, classification of awards as either equity or liabilities, the calculation of diluted shares outstanding and classification on the statement of cash flows. For a discussion on the impact of this accounting adoption, including the impact on excess tax benefits recognized us, please see Note 2 to our consolidated financial statements entitled “Summary of Significant Accounting Principles,” which is incorporated by reference into this item. Our main accounting practices that may be affected by changes in the accounting principles are as follows:

- accounting for revenue recognition;
- accounting for intangibles—goodwill and other;
- accounting for fair value measurement of financial assets and financial liabilities;
- accounting for income taxes;
- accounting for stock-based compensation;
- accounting for leases; and
- accounting for business combinations.

Implementing changes required by new standards, requirements or laws likely will require a significant expenditure of time, attention and resources. It is impossible to completely predict the impact, if any, on us of future changes to accounting standards and financial reporting and corporate governance requirements.

In May 2014, the FASB, issued ASU 2014-09, *Revenue from Contracts with Customers* to provide updated guidance on revenue recognition. This new standard will replace most of the existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under the current accounting guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. We will adopt ASU 2014-09 in the first quarter of fiscal 2019, and compliance with this new standard may require a significant expenditure of time, attention and other resources.

***We use estimates, make judgments and apply certain methods in measuring the progress of our business in determining our financial results and in applying our accounting policies. As these estimates, judgments and methods change, our assessment of the progress of our business and our results of operations could vary.***

The methods, estimates and judgments we use in applying our accounting policies have a significant impact on our results of operations. Such methods, estimates and judgments are, by their nature, subject to substantial risks, complexities, uncertainties and assumptions, and factors may arise over time that may lead us to change our methods, estimates and judgments. Changes in any of our assumptions may cause variation in our financial reporting and may adversely affect our reported financial results.

***Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.***

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our financial condition. We maintain insurance for certain environmental risks, subject to substantial deductibles; however, we cannot assure you we can continue to maintain this insurance in the future at an acceptable cost or at all. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations.

***Fluctuations in foreign currency exchange rates could result in declines in our reported sales and results of operations.***

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. At present, we do not hedge our exposure to foreign currency fluctuations. As a result, revenues and expenses 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 April 1, 2017 to March 31, 2018, the price of our stock ranged from a low of \$117.37 per share to a high of \$304.28 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;
- status of regulatory approvals for our products;
- introduction of new products by us or our competitors;
- acquisitions or strategic alliances involving us or our competitors;
- changes in healthcare policy or third-party reimbursement practices;
- changes in estimates of our performance or recommendations by securities analysts;
- the hiring or departure of key personnel;
- results of clinical trials of our products;
- notice of a recall or other safety issue that impacts the ability for customers to use our products;
- future sales of shares of common stock in the public market;
- the outcome of currently pending litigation and governmental investigations, or the initiation of additional litigation or government investigations against the company; and
- market conditions in the industry, particularly around reimbursement for our products 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, the issuance of restricted stock units or the exercise of outstanding options to purchase our common stock, would dilute our stockholders' ownership interest.***

We have historically issued restricted stock units and stock options to acquire our common stock and we expect to continue to issue restricted stock units and stock options to our employees and others in the future. If all outstanding stock options were exercised and all outstanding restricted stock units vested, our stockholders would suffer dilution of their ownership interest. In addition, we have issued from time to time, additional shares of our common stock in connection with acquisitions, public offerings, and other activities. Future issuances of our common stock would also result in a dilution of our stockholders' ownership interest.

***Our 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.***

Provisions of our certificate of incorporation and 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. 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 product 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 gains realized based on 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 corporate offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923. The locations and uses of our major properties as of March 31, 2018, are listed below:

<b><u>Location</u></b>	<b><u>Function</u></b>
Danvers, Massachusetts (22 Cherry Hill Drive)	(1) Corporate Headquarters, Research and Development, Regulatory and Clinical Affairs, Manufacturing, Administration, Marketing, Distribution
Danvers, Massachusetts (24 - 42 Cherry Hill Drive)	(2) Research and Development and Administration
Aachen, Germany	(1) Research and Development, Regulatory and Clinical Affairs, Manufacturing, Administration, Marketing, Distribution
Berlin, Germany	(2) Research and Development
Tokyo, Japan	(2) Administration, Regulatory and Clinical Affairs, Marketing, Distribution

(1) Owned properties

In October 2017, we acquired our corporate headquarters in Danvers, Massachusetts, consisting of 163,560 square feet of space. The total acquisition cost for the land and building was approximately \$16.5 million, with \$3.0 million being recorded to land and \$13.0 million being recorded to building and building improvements.

In February 2017, we acquired our existing European headquarters in Aachen, Germany, consisting of 33,000 square feet of space.

(2) Leased properties

In February 2017, we entered into a lease agreement for an additional 21,603 square feet of office space in Danvers, Massachusetts, which expires on July 31, 2022. In December 2017, we entered into an amendment to this lease to extend the lease term through August 31, 2025 and to add an additional 6,607 square feet of space for which rent will begin on or around June 1, 2018. The amendment also includes a right of first offer to purchase the property effective from January 1, 2018 through August 31, 2035, if the lessor decides to sell the building or receives an offer to purchase the building from a third-party buyer. In March 2018, we entered into an amendment to the lease to add an additional 11,269 square feet of space for which rent will begin on or around June 1, 2018 through August 31, 2025.

In September 2016, we entered into a lease agreement in Berlin, Germany. The term of the lease began May 2017 and expires in May 2024.

In October 2016, we entered into a lease agreement for an office in Tokyo, Japan and expires in September 2021.

We believe our properties have been well maintained, are in good operating condition, and provide adequate productive capacity.

**ITEM 3.    *LEGAL PROCEEDINGS***

We are from time to time involved in various legal actions, the outcomes of which are not within our complete control and may not be known for prolonged periods of time. For a discussion of our material legal proceedings as of March 31, 2018, please see Note 11 to our consolidated financial statements entitled “Commitments and Contingencies,” which is incorporated by reference into this item.

**ITEM 4.    *MINE SAFETY DISCLOSURES***

Not applicable.

## 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:

	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended March 31, 2018</b>		
First Quarter	\$ 147.45	\$ 117.37
Second Quarter	171.00	139.55
Third Quarter	200.28	164.80
Fourth Quarter	304.28	188.05
	<u>High</u>	<u>Low</u>
<b>Fiscal Year Ended March 31, 2017</b>		
First Quarter	\$ 109.66	\$ 92.03
Second Quarter	131.16	108.77
Third Quarter	132.95	95.14
Fourth Quarter	126.04	103.53

#### Number of Stockholders

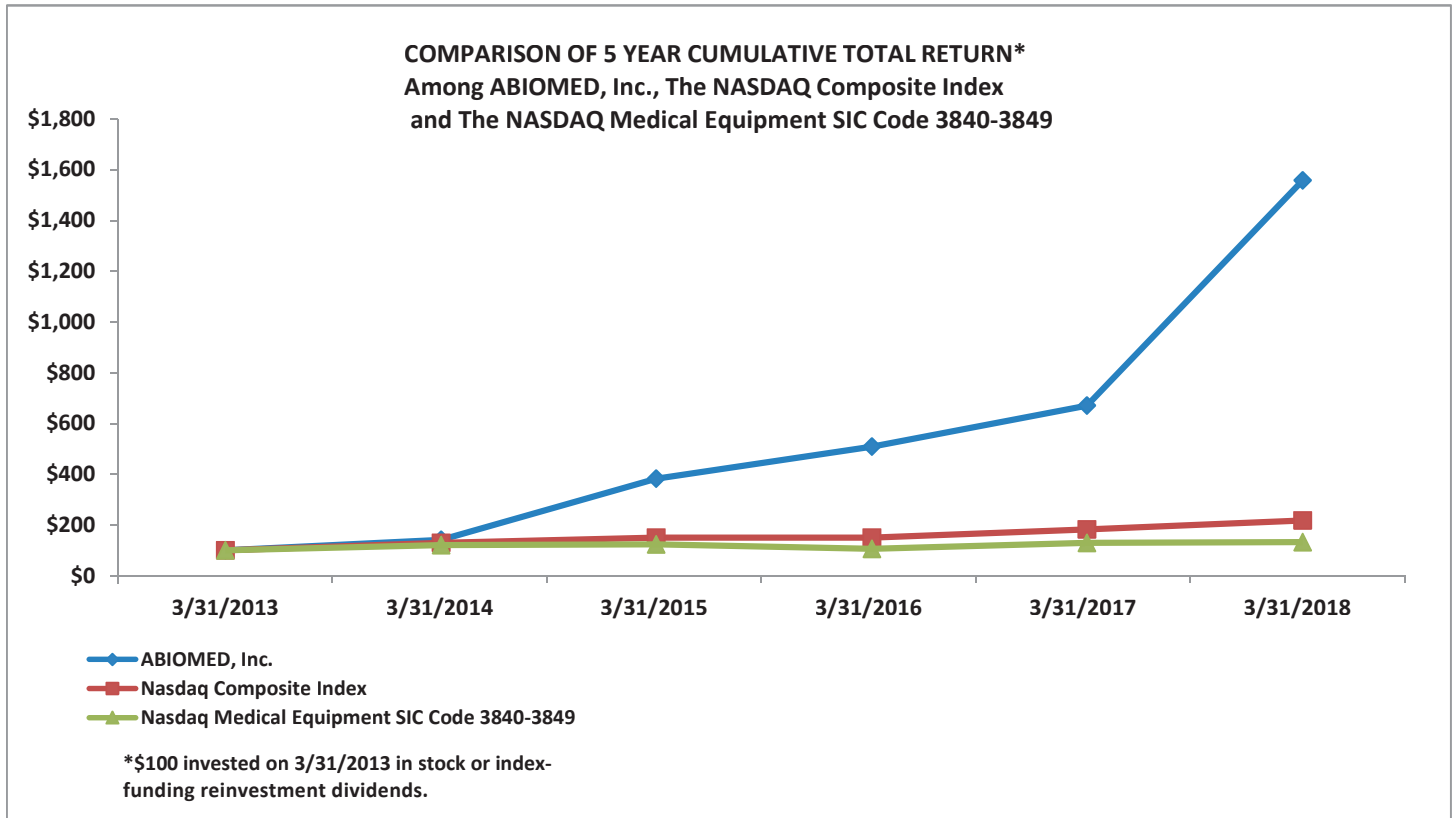
As of May 8, 2018, we had approximately 471 holders of record of our common stock and there were approximately 74,029 beneficial holders of our common stock. Many beneficial holders hold their stock through depositories, banks and brokers included as a single holder in the single "street" name of each 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, 2013 in our Common Stock, the NASDAQ Composite Index (U.S. Companies) and the peer group index, and the reinvestment of any and all dividends.



	Cumulative Total Return (\$)					
	3/31/2013	3/31/2014	3/31/2015	3/31/2016	3/31/2017	3/31/2018
ABIOMED, Inc	100	139	383	508	671	1,559
Nasdaq Composite Index	100	129	150	149	181	216
Nasdaq Medical Equipment SIC Code 3840-3849	100	120	124	105	130	133

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.

## Transfer Agent

American Stock Transfer & Trust Company, 6201 15<sup>th</sup> Avenue, Brooklyn, NY 11219, is our stock transfer agent.

## ITEM 6. SELECTED FINANCIAL DATA

The financial data included within the tables below should be read in conjunction with our consolidated financial statements and related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this report and our previously filed Form 10-Ks.

### SELECTED CONSOLIDATED FINANCIAL DATA

(In thousands, except per share data)

	Fiscal Years Ended March 31,				
	2018	2017	2016	2015	2014
<b>Statement of Operations Data:</b>					
Revenue	\$ 593,749	\$ 445,304	\$ 329,543	\$ 230,311	\$ 183,643
Costs and expenses:					
Cost of revenue	98,581	70,627	50,419	39,945	37,322
Research and development	75,297	66,386	49,759	35,973	30,707
Selling, general and administrative	262,734	218,153	164,261	125,727	107,251
	436,612	355,166	264,439	201,645	175,280
Income from operations	157,137	90,138	65,104	28,666	8,363
Other income (expense):					
Investment income, net	3,688	1,554	395	196	118
Other (expense) income, net	(388)	(349)	339	(97)	49
	3,300	1,205	734	99	167
Income before income taxes	160,437	91,343	65,838	28,765	8,530
Income tax provision (benefit) (1)(2)(3)	48,267	39,227	27,691	(84,923)	1,179
Net income	<u>\$ 112,170</u>	<u>\$ 52,116</u>	<u>\$ 38,147</u>	<u>\$ 113,688</u>	<u>\$ 7,351</u>
Basic net income per share	\$ 2.54	\$ 1.21	\$ 0.90	\$ 2.80	\$ 0.19
Basic weighted average shares outstanding	44,153	43,238	42,204	40,632	39,334
Diluted net income per share	\$ 2.45	\$ 1.17	\$ 0.85	\$ 2.65	\$ 0.18
Diluted weighted average shares outstanding	45,849	44,658	44,895	42,858	41,606
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, and short and long term marketable securities	\$ 399,751	\$ 277,091	\$ 213,053	\$ 145,954	\$ 118,340
Working capital (4)	409,589	257,341	241,851	145,720	87,555
Total assets	786,375	550,414	423,931	338,367	205,407
Stockholders' equity	689,524	452,071	368,775	291,560	168,353

- (1) The Tax Reform Act, among other items, reduces the U.S. federal statutory corporate income tax rate from 35% to 21% effective January 1, 2018. During the year ended March 31, 2018, the Company recorded tax expense adjustments for \$21.4 million related to the revaluation of its deferred taxes due to a reduction of the U.S. federal statutory corporate income tax rate.
- (2) In the first quarter of fiscal 2018, the Company adopted ASU 2016-09 which requires that all excess tax benefits and tax deficiencies related share-based compensation arrangements be recognized as income tax benefit or expense, instead of in stockholders’ equity as previous guidance required. The income tax benefit for the year ended March 31, 2018 included excess tax benefits of \$31.0 million. These recognized excess tax benefits resulted from restricted stock units that vested or stock options that were exercised during the year ended March 31, 2018.
- (3) Income tax benefit for the quarter and year ended March 31, 2015 were impacted by the release of the \$101.5 million valuation allowance on certain deferred tax assets.
- (4) This reflects a \$35.1 million reclassification of current deferred tax assets to long-term deferred tax assets on the March 31, 2015 consolidated balance sheet due to the adoption of ASU No. 2015-17, *Income Taxes (Topic 740)—Balance Sheet Classification of Deferred Taxes*. This reclassification did not impact working capital at March 31, 2014 due to the full valuation allowance on deferred tax assets for those years.



## **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 revenue, gross margin 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 temporary mechanical circulatory support devices, and we offer a continuum of care to heart failure patients. We develop, manufacture and market proprietary products that are designed to enable the heart to rest, heal and recover by improving blood flow to the coronary arteries and end-organs and/or temporarily assisting the pumping function of the heart. Our products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists, the electrophysiology lab, the hybrid lab and in the heart surgery suite by cardiac surgeons. A physician may use our devices for patients who are in need of hemodynamic support prophylactically, urgently or emergently before, during or after angioplasty or heart surgery procedures. We believe that heart recovery is the optimal clinical outcome for a patient experiencing heart failure because it enhances the potential for the patient to go home with their own heart, facilitating the restoration of quality of life. In addition, we believe that, for the care of such patients, heart recovery is often the most cost-effective solution for the healthcare system.

Our strategic focus and the driver of our revenue growth is the market penetration of our family of Impella® heart pumps. The Impella device portfolio, which includes the Impella 2.5® Impella CP®, Impella RP®, Impella LD® and Impella 5.0® devices, has supported numerous patients worldwide. All of our product and service revenue in the near future will be from our Impella devices.

In March 2015, we received FDA approval of a PMA for use of the Impella 2.5 device during elective and urgent high-risk percutaneous coronary intervention, or PCI, procedures. In December 2016, the FDA expanded this PMA approval in the U.S. to include the Impella CP device. With these approved indications, the Impella 2.5 and Impella CP devices provide the only minimally invasive treatment options indicated for use during high-risk PCI procedures in the U.S. In April 2016, the FDA approved a PMA supplement for our Impella 2.5, Impella CP, Impella 5.0 and Impella LD devices to provide treatment for ongoing cardiogenic shock that occurs following a heart attack or open heart surgery. The intent of our Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

In September 2017, we received FDA approval of a PMA for the Impella RP heart pump. The Impella RP heart pump is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area  $\geq 1.5$  m<sup>2</sup>, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. With this approval, the Impella RP heart pump is the only percutaneous temporary ventricular support device that is FDA-approved as safe and effective for right heart failure as stated in the indication.

In February 2018, we received two expanded PMA approvals from the FDA for our Impella heart pumps. The first expanded approval is for use of Impella 2.5, CP, 5.0 and LD heart pumps on patients with cardiogenic shock associated with cardiomyopathy, including peripartum and postpartum cardiomyopathy. The second expanded PMA approval is for use of the Impella 2.5 and Impella CP heart pumps during elective and high-risk PCI procedures. This expanded PMA approval confirms Impella support as appropriate in patients with severe coronary artery disease, complex anatomy and extensive comorbidities, with or without depressed ejection fraction.

In April 2018, we received FDA approval for Impella CP with SmartAssist and Optical Sensor which is intended to provide enhanced monitoring capability, reduce setup time and improve ease of use for physicians. The optical sensor technology is also approved under CE Mark in the European Union.

In September 2016, we received PMDA approval from the Japanese MHLW for our Impella 2.5 and Impella 5.0 heart pumps to provide treatment of drug-resistant acute heart failure in Japan. In July 2017, we received approval from the MHLW for reimbursement for the Impella 2.5 and 5.0 heart pumps. Reimbursement in Japan for the Impella 2.5 and 5.0 is equivalent to our average Impella sales price in the U.S. We commenced commercialization in Japan during the second quarter of fiscal 2018 and have begun a slow commercial launch of Impella in Japan. The first Japanese patient was treated with the Impella device in October 2017.

Our Impella 2.5, Impella 5.0, Impella LD, Impella CP and Impella RP devices also have CE Mark approval and Health Canada approval, which allows us to market these devices in the European Union and Canada.

In April 2018, we announced that we have received CE mark approval in the European Union for the Impella 5.5 heart pump and the first patient was treated at University Heart Center in Hamburg, Germany. The Impella 5.5 heart pump is not approved for use or sale in the U.S.

In May 2017, we announced the enrollment of the first patient in the FDA approved prospective multi-center feasibility study, STEMI Door to Unloading with Impella CP system in acute myocardial infarction. The trial focuses on the feasibility and safety of unloading the left ventricle using the Impella CP heart pump prior to primary PCI in patients presenting with ST segment elevation myocardial infarction, or STEMI, without cardiogenic shock with the hypothesis that this will potentially reduce infarct size. The study, which received FDA approval in October 2016, will enroll up to 50 patients at 10 sites. We expect to complete enrollment in the first half of fiscal 2019.

We expect to continue to make additional PMA supplement submissions for our Impella portfolio of devices for additional indications.

### **Summary of Recent Financial Performance**

For fiscal 2018, we recognized net income of \$112.2 million, or \$2.54 per basic share and \$2.45 per diluted share, compared to \$52.1 million, or \$1.21 per basic share and \$1.17 per diluted share for the prior fiscal year. The increase in our net income for fiscal 2018 was driven primarily by higher Impella product revenue due to greater utilization of our Impella devices in the U.S. and Germany. Further, the adoption of ASU 2016-09 resulted in an increase of net income of \$31.0 million, or \$0.70 per basic and \$0.68 per diluted share for the year ended March 31, 2018. Additionally, the enactment of the Tax Reform Act resulted in a decrease in net income of \$21.4 million, or \$0.48 per basic and \$0.47 per diluted share for the year ended March 31, 2018.

### **Critical Accounting Policies and Estimates**

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States. Preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported amounts of revenue and expenses during the reporting period. Actual results could differ from these estimates. The accounting policies we believe are critical in the preparation of our consolidated financial statements relate to revenue recognition and income taxes. Our significant accounting policies are more fully described under the heading “Summary of Significant Accounting Policies” in Note 2 to our consolidated financial statements contained elsewhere herein.

### ***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 collectability is reasonably assured.

Revenue from product sales to customers is recognized when delivery has occurred. All costs related to product sales are recognized at time of delivery. We do not provide for rights of return to customers on our sales transactions and therefore we do not record a provision for returns.

Maintenance and service support contract revenues are included in revenue and are recognized ratably over the service contract term. Revenue is recognized as it is earned in limited instances where we rent console medical devices to customers on a month-to-month basis or for a longer specified period of time. Other service revenues are recognized as the services are performed.

In May 2014, the FASB, issued ASU 2014-09, Revenue from Contracts with Customers to provide updated guidance on revenue recognition. This new standard will replace most of the existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under the current accounting guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. We are implementing the necessary changes to its revenue recognition accounting policies and controls to support recognition and disclosure under the new standard. We will adopt ASU 2014-09 during the first quarter of fiscal 2019.

## Income Taxes

Our provision for income taxes is composed of a current and a deferred portion. The current income tax provision is calculated as the estimated taxes payable or refundable on tax returns for the current year. The deferred income tax provision is calculated for the estimated future tax effects attributable to temporary differences and net operating loss carryforwards using expected tax rates in effect in the years during which the differences are expected to reverse.

Deferred income taxes are recognized for the tax consequences in future years as the differences between the tax bases of assets and liabilities and their financial reporting amounts at each fiscal year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to impact taxable income.

We regularly assess our ability to realize our deferred tax assets. Assessing the realization of deferred tax assets requires significant management judgment. We consider whether a valuation allowance is needed on our deferred tax assets by evaluating all positive and negative evidence relative to our ability to recover deferred tax assets, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial results.

We recognize and measure uncertain tax positions using a two-step approach. The first step is to evaluate the tax position for recognition by determining if, based on the technical merits, it is more likely than not that the position will be sustained upon audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit at the largest amount that is more likely than not of being realized upon ultimate settlement. We reevaluate these uncertain tax positions on an ongoing basis, when applicable. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, new information and technical insights, and changes in tax laws. Any changes in these factors could result in the recognition of a tax benefit or an additional charge to the tax provision. When applicable, we accrue for the effects of uncertain tax positions and the related potential penalties and interest through income tax expense.

Effective April 1, 2017, we adopted the ASU 2016-09 which simplifies several aspects of the accounting for share-based payment transactions, including income tax consequences, recognition of stock compensation award forfeitures, classification of awards as either equity or liabilities, the calculation of diluted shares outstanding and classification on the statement of cash flows. The effects of this impact will be hard to predict and variable moving forward as such effects are dependent upon actual stock option exercises.

## Recent Accounting Pronouncements

Information regarding recent accounting pronouncements is included in Note 2. "Summary of Significant Accounting Policies" to our consolidated financial statements in this Report.

## Results of Operations

The following table sets forth certain consolidated statements of operations data for the periods indicated as a percentage of total revenues:

	Fiscal Years Ended March 31,		
	2018	2017	2016
Revenue	100.0 %	100.0 %	100.0 %
Costs and expenses as a percentage of total revenue:			
Cost of revenue	16.6	15.9	15.3
Research and development	12.7	14.9	15.1
Selling, general and administrative	44.2	49.0	49.8
Total costs and expenses	73.5	79.8	80.2
Income from operations	26.5	20.2	19.8
Other income and income tax provision	7.6	8.5	8.2
Net income as a percentage of total revenue	18.9 %	11.7 %	11.6 %

## *Fiscal Years Ended March 31, 2018 and March 31, 2017 (“fiscal 2018” and “fiscal 2017”)*

### **Revenue**

Our revenue is comprised of the following:

	Fiscal Years Ended March 31,	
	2018	2017
	(in \$000's)	
Impella product revenue	\$ 570,870	\$ 423,694
Service revenue	22,752	19,116
Other revenue	127	2,494
Total revenue	<u>\$ 593,749</u>	<u>\$ 445,304</u>

Impella product revenue encompasses Impella 2.5, Impella CP, Impella 5.0, Impella LD, Impella RP and Impella AIC product sales. Service and other revenue represents revenue earned on service maintenance contracts and preventative maintenance calls. Other revenue includes sales of the AB5000 that we no longer sell.

Total revenue for fiscal 2018 increased \$148.4 million, or 33%, to \$593.7 million from \$445.3 million for fiscal 2017. The increase in total revenue was primarily due to higher Impella product revenue from increased utilization in the U.S and Europe.

Impella product revenue for fiscal 2018 increased by \$147.2 million, or 35%, to \$570.9 million from \$423.7 million for fiscal 2017. Most of the increase in Impella product revenue was from greater device sales in the U.S., as we focus on increasing utilization of our disposable catheter products through continued investment in our field organization and physician training programs. Impella product revenue outside of the U.S. also increased primarily due to increased utilization in Germany. We expect revenue from our Impella devices to continue to increase with our recent PMA approvals in the U.S. and our continued controlled launch of Impella devices outside of the U.S. with a focus on Germany and Japan.

Service revenue for fiscal 2018 increased by \$3.7 million, or 19%, to \$22.8 million from \$19.1 million for fiscal 2017. The increase in service revenue was primarily due to an increase in preventative maintenance service contracts. We have expanded the number of Impella AIC consoles at many of our existing higher volume customer sites and continue to sell additional consoles to new customer sites. We expect service revenue growth to be slower than our Impella product revenue growth in the near future as most U.S. sites have service contracts that normally have three year terms.

The decrease in other revenue was due to a decline in AB5000 disposable sales. We are no longer selling the AB5000 revenue device and we do not expect to have any other revenue in the near future. We have transitioned our sales focus in the surgical suite from the AB5000 to Impella 5.0, Impella LD and Impella RP devices.

### **Costs and Expenses**

#### ***Cost of Revenue***

Cost of revenue for fiscal 2018 increased by \$28.0 million, or 40%, to \$98.6 million from \$70.6 million for fiscal 2017. Gross margin was 83% for fiscal 2018 and 84% for fiscal 2017. The increase in cost of revenue was related to increased growing demand for Impella devices and higher production volume and costs to support growing demand for our Impella devices. The decrease in gross margin was primarily due to an increased investment in direct labor and overhead as we expand our manufacturing capacity, increased shipments of AIC consoles and geographic mix.

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

Research and development expenses for fiscal 2018 increased by \$8.9 million, or 13%, to \$75.3 million from \$66.4 million for fiscal 2017. The increase in research and development expenses was primarily due to product development initiatives on our existing products, such as optical sensor technology, product initiatives, such as Impella 5.5™ and Impella ECP™ devices, the expansion of our engineering organization, increased clinical spending primarily related to our STEMI trial and cVAD registry and our continued focus on quality initiatives for our Impella devices.

We expect research and development expenses to continue to increase as we continue to increase clinical spending related to our cVAD registry and the STEMI trial and incur additional costs as we continue to focus on engineering initiatives to improve our existing products and develop new technologies.

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

Selling, general and administrative expenses for fiscal 2018 increased by \$44.5 million, or 20%, to \$262.7 million from \$218.2 million for fiscal 2017. The increase in selling, general and administrative expenses was primarily due to the hiring of additional field sales and clinical personnel in the U.S. and Germany, the commercial launch in Japan, increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support after receiving PMAs in the U.S. for our Impella products, higher stock-based compensation expense and higher legal expenses related to ongoing patent litigation and other legal matters discussed in “Note 11. Commitments and Contingencies—Litigation,” to our consolidated financial statements.

We expect to continue to increase our expenditures on sales and marketing activities, with particular investments in field sales and clinical personnel with cath lab expertise to drive recovery awareness for acute heart failure patients. We also plan to increase our marketing, service and training investments as a result of recent PMA approvals in the U.S. for our Impella devices and as we continue our expansion in Japan and other new markets outside of the U.S. We also expect to continue to incur significant legal expenses for the foreseeable future related to ongoing patent litigation and other legal matters discussed in “Note 11. Commitment and Contingencies – Litigation,” to our consolidated financial statements.

## ***Income Tax Provision***

In the first quarter of fiscal 2018, we adopted ASU 2016-09 which requires that all excess tax benefits and tax deficiencies related share-based compensation arrangements be recognized as income tax benefit or expense, instead of in stockholders’ equity as previous guidance required. In addition, effective January 1, 2018, the Tax Reform Act, among other items, reduced the U.S. federal statutory corporate income tax rate from 35% to 21%.

The income tax provision increased by \$9.1 million, or 23%, to \$48.3 million for fiscal 2018, compared to \$39.2 million for fiscal 2017. The increase in income tax provision for fiscal 2018 was due primarily to higher income before income taxes in fiscal 2018 due to higher Impella product revenue. Our effective income tax rate was 30.1% and 43.0% for the years ended March 31, 2018 and 2017. The decrease in our effective tax rate was primarily due to the excess tax benefits associated with stock-based awards of \$31.0 million as an income tax benefit for the year ended March 31, 2018. These excess tax benefits were related to the adoption of the new accounting standard for stock-based compensation on April 1, 2017, which required restricted stock units that vested or stock options that were exercised during the year ended March 31, 2018 to be recorded in the statement of operations. The decrease in the effective tax rate was offset by a \$21.4 million income tax expense estimate from the re-measurement of our net deferred tax assets due to the Tax Reform Act, as discussed in “Note 10. Income Taxes.”

## ***Net Income***

For fiscal 2018, we recognized net income of \$112.2 million, or \$2.54 per basic share and \$2.45 per diluted share, compared to \$52.1 million, or \$1.21 per basic share and \$1.17 per diluted share for fiscal 2017. The increase in our net income for fiscal 2018 was driven primarily to higher Impella product revenue due to greater utilization of our Impella devices in the U.S. and Europe. Further, the adoption of ASU 2016-09 resulted in an increase of net income of \$31.0 million, or \$0.70 per basic and \$0.68 per diluted share for the year ended March 31, 2018. Additionally, the enactment of the Tax Reform Act resulted in a decrease in net income of \$21.4 million, or \$0.48 per basic and \$0.47 per diluted share for the year ended March 31, 2018.

## ***Fiscal Years Ended March 31, 2017 and March 31, 2016 (“fiscal 2017” and “fiscal 2016”)***

### ***Revenue***

Our revenue is comprised of the following:

	Fiscal Years Ended March 31,	
	2017	2016
	(in \$000's)	
Impella product revenue	\$ 423,694	\$ 310,138
Service revenue	19,116	16,588
Other revenue	2,494	2,817
Total revenue	<u>\$ 445,304</u>	<u>\$ 329,543</u>

Impella product revenue encompasses Impella 2.5, Impella CP, Impella 5.0, Impella LD, Impella RP and Impella AIC device product sales. Service and other revenue represents revenue earned on service maintenance contracts and preventative maintenance calls. Other revenue includes AB5000 that we no longer sell.

Total revenue for fiscal 2017 increased by \$115.8 million, or 35%, to \$445.3 million from \$329.5 million for fiscal 2016. The increase in total revenue was primarily due to increased Impella product revenue from increased utilization in the U.S. and Germany. Impella product revenue was higher as a result of recent PMA approvals in the U.S. in March 2015 for elective and high risk PCI procedures for Impella 2.5 and in April 2016 for cardiogenic shock for Impella 2.5, Impella CP, Impella 5.0 and Impella LD and in December 2016, to add Impella CP device for use in elective and high risk procedures.

Impella product revenue for fiscal 2017 increased by \$113.6 million, or 37%, to \$423.7 million from \$310.1 million for fiscal 2016. Most of the increase in Impella product revenue was from increased device sales in the U.S. related to our recent PMA approvals, as we focus on increasing utilization of our disposable catheter products through continued investment in our field organization and physician training programs. Impella product revenue outside of the U.S. grew in fiscal 2017 primarily due to increased utilization in Germany as we expand our field organization in that country.

Service revenue for fiscal 2017 increased by \$2.5 million, or 15%, to \$19.1 million from \$16.6 million for fiscal 2016. The increase in service revenue was primarily due to an increase in preventative maintenance service contracts. We have expanded the number of Impella AIC consoles to most of our using sites and placed more consoles at existing higher using sites. Many of these sites have entered into service contracts for maintenance support of their consoles.

Other revenue for fiscal 2017 decreased by \$0.3 million, or 11%, to \$2.5 million from \$2.8 million for fiscal 2016. Most of the decrease was due to lower AB5000 sales in the U.S.

## **Costs and Expenses**

### ***Cost of Revenue***

Cost of revenue for fiscal 2017 increased by \$20.2 million, or 40%, to \$70.6 million from \$50.4 million for fiscal 2016. Gross margin was 84% for fiscal 2017 and 85% for fiscal 2016. The increase in cost of revenue was related to increased demand for Impella devices and higher production volume and costs to support growing demand for our Impella devices. The decrease in gross margin was primarily due to larger number of shipments of AICs during fiscal 2017 and an increased investment in direct labor and overhead as we expand our manufacturing capacity.

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

Research and development expenses for fiscal 2017 increased by \$16.6 million, or 33%, to \$66.4 million from \$49.8 million in fiscal 2016. The increase in research and development expenses was primarily due to product development initiatives on our existing products and new technologies as we expanded our engineering organization, increased clinical spending primarily related to our cVAD Registry™ and our continued focus on quality initiatives for our Impella devices.

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

Selling, general and administrative expenses for fiscal 2017 increased by \$53.9 million, or 33%, to \$218.2 million from \$164.3 million in fiscal 2016. The increase in selling, general and administrative expenses was primarily due to the hiring of additional field sales and clinical personnel in the U.S. and Germany, increased spending on marketing initiatives as we continue to educate physicians on the benefits of hemodynamic support after receiving PMAs in the U.S. for Impella 2.5, Impella CP, Impella 5.0 and Impella LD devices, higher stock-based compensation expense and higher legal expenses related to ongoing patent litigation and other legal matters discussed in “Note 11. Commitments and Contingencies—Litigation,” to our consolidated financial statements.

### ***Income Tax Provision***

We recorded an income tax provision of \$39.2 million in fiscal 2017 compared to \$27.7 million in fiscal 2016. The increase in income tax provision for fiscal 2017 was due primarily to higher income in fiscal 2017 due to higher Impella product revenue.

## **Net Income**

For fiscal 2017, we recognized net income of \$52.1 million, or \$1.21 per basic share and \$1.17 per diluted share, compared to \$38.1 million, or \$0.90 per basic share and \$0.85 per diluted share for fiscal 2016. Our net income for fiscal 2017 was driven primarily to higher Impella product revenue due to greater utilization of our Impella devices in the U.S. and Europe.

## Liquidity and Capital Resources

At March 31, 2018, our total cash, cash equivalents, and short and long-term marketable securities totaled \$399.8 million, an increase of \$122.7 million compared to \$277.1 million at March 31, 2017. The increase in our cash, cash equivalents, and short and long-term marketable securities was due primarily to positive cash flows from operations in fiscal 2018.

A summary of our cash flow activities is as follows:

	For the Year Ended March 31,		
	2018	2017	2016
Net cash provided by operating activities	\$ 192,546	\$ 115,116	\$ 76,795
Net cash used for investing activities	(180,762)	(126,333)	(57,710)
Net cash (used for) provided by financing activities	(9,137)	3,867	7,160
Effect of exchange rate changes on cash	1,288	(1,841)	(415)
Net increase (decrease) in cash and cash equivalents	\$ 3,935	\$ (9,191)	\$ 25,830

### Cash Provided by Operating Activities

For the year ended March 31, 2018, cash provided by operating activities consisted of net income of \$112.2 million, adjustments for non-cash items of \$99.3 million less used in working capital of \$18.9 million. The increase in net income was primarily due to higher revenue from increased utilization of our Impella devices. Adjustments for non-cash items consisted primarily of \$40.4 million of stock-based compensation expense, a \$42.6 million change in deferred tax provision, \$11.0 million of depreciation of property and equipment, \$3.9 million in inventory and other write-downs and \$1.3 million of changes in fair value of consideration. The decrease in cash from changes in working capital included a \$15.3 million increase in accounts receivable associated with higher revenues and a \$15.7 million increase in inventory to support growing demand for our Impella devices offset by a \$12.1 million increase in accounts payable and accrued expenses and a \$4.4 million increase in deferred revenue.

For the year ended March 31, 2017, cash provided by operating activities consisted of net income of \$52.1 million, adjustments for non-cash items of \$57.7 million and cash provided from working capital of \$5.3 million. Our net income for fiscal 2017 was driven primarily to higher Impella product revenue due to greater utilization of our Impella devices in the U.S. and Europe, partially offset by the increase in income tax provision for fiscal 2017. Adjustments for non-cash items consisted primarily of \$32.9 million of stock-based compensation expense, a \$25.8 million change in deferred tax provision, \$12.0 million in excess tax benefits on stock-based awards, \$6.2 million of depreciation and amortization of property, plant and equipment, \$3.1 million of write-downs of inventory and \$1.6 million of changes in fair value of consideration. The increase in cash from changes in working capital included a \$11.6 million increase in accounts receivable associated with higher revenues, a \$12.3 million increase in inventory as we build up inventory safety stock to support growing demand for our Impella devices, a \$29.8 million increase in accounts payable and accrued expenses due to increase in operating expenses.

For the year ended March 31, 2016, cash provided by operating activities consisted of net income of \$38.1 million, adjustments for non-cash items of \$54.2 million and cash used in working capital of \$15.6 million. Our net income for fiscal 2016 was driven primarily to higher Impella product revenue due to greater utilization of our Impella devices in the U.S. and Europe, partially offset by the increase in income tax provision for fiscal 2016. Adjustments for non-cash items consisted primarily of \$29.1 million of stock-based compensation expense, a \$22.3 million change in deferred tax provision and \$3.3 million of depreciation and amortization of property, plant and equipment. The decrease in cash from changes in working capital included a \$10.9 million increase in accounts receivable associated with higher revenues, a \$11.5 million increase in inventory as we build up inventory safety stock to support growing demand for our Impella devices, a \$7.4 million increase in accounts payable and accrued expenses due to increase in operating expenses.

### Cash Used in Investing Activities

For the year ended March 31, 2018, net cash used for investing activities included \$118.5 million in purchases (net of maturities) of marketable securities and \$55.9 million for the purchase of property and equipment mostly related to the purchase of our corporate headquarters building in Danvers, Massachusetts; the continued expansion of manufacturing capacity, office space and research and development facilities in Danvers and Aachen, Germany; and investments in enhancing information systems. We also have made \$6.4 million of investments in private medical technology companies during fiscal 2018.

For the year ended March 31, 2017, net cash used for investing activities included \$73.0 million in purchases (net of maturities) of marketable securities and \$50.4 million for the purchase of property and equipment mostly related to the purchase of the Aachen, Germany facility, expansion of manufacturing cleanroom capacity and office space in Danvers, Massachusetts and Aachen, Germany and investments in enhancing information systems. We also made \$2.9 million of investments in private medical technology companies during fiscal 2017.

For the year ended March 31, 2016, net cash used for investing activities included \$41.3 million in purchases (net of maturities) of marketable securities and \$15.6 million for the purchase of property and equipment mostly related to expansion of manufacturing cleanroom capacity and office space in Danvers, Massachusetts and Aachen, Germany as well as investments in enhancing information systems. We also made a \$0.8 million investment in a private medical technology company during fiscal 2016.

Capital expenditures for fiscal 2019 are estimated to range from \$35 million to \$45 million, including additional capital expenditures for manufacturing capacity expansions in our Danvers, Massachusetts and Aachen, Germany facilities, additional office space, building and leasehold improvements and information systems development projects.

### ***Cash Provided by Financing Activities***

For the year ended March 31, 2018, net cash used for financing activities included \$20.3 million in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards offset by \$9.3 million in proceeds from the exercise of stock options and \$2.4 million in proceeds from the issuance of stock under the employee stock purchase plan.

For the year ended March 31, 2017, net cash provided by financing activities included \$10.7 million in proceeds from the exercise of stock options, \$1.7 million in proceeds from the issuance of stock under the employee stock purchase plan and \$12.0 million in excess tax benefits on stock-based awards. These amounts were partially offset by \$20.1 million in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards and \$0.4 million in principal payments on capital lease obligation.

For the year ended March 31, 2016, net cash provided by financing activities included \$9.8 million in proceeds from the exercise of stock options, \$1.1 million in proceeds from the issuance of stock under the employee stock purchase plan and \$3.6 million in excess tax benefits on stock-based awards. These amounts were partially offset by \$7.3 million in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards.

### ***Operating Capital and Liquidity Requirements***

We believe that our revenue from product sales together with existing resources will be sufficient to fund our operations for at least the next twelve months, exclusive of activities involving any future acquisitions of products or companies that complement or augment our existing line of products.

Our primary liquidity requirements are to fund the expansion of our commercial and operational infrastructure, increase our manufacturing capacity, incur additional capital expenditures as we expand our office space and manufacturing capacity in Danvers and Aachen, increase our inventory levels in order to meet growing customer demand for our Impella devices, fund new product and business development initiatives, continue our commercial launch in Japan and expand to potential new markets, increase clinical spending, legal expenses related to ongoing patent litigation and other legal matters, payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards and to provide for general working capital needs. To date, we have primarily funded our operations through product sales and the sale of equity securities.

Our liquidity is influenced by our ability to sell our products in a competitive industry and our customers' ability to pay for our products. Factors that may affect liquidity include our ability to penetrate the market for our products, maintain or reduce the length of the selling cycle for our products, capital expenditures, investments in collaborative arrangements with other partners, and our ability to collect cash from customers after our products are sold. We also expect to continue to incur legal expenses for the foreseeable future related to ongoing patent litigation and other legal matters. We continue to review our short-term and long-term cash needs on a regular basis. At March 31, 2018, we had no long-term debt outstanding.

Marketable securities at March 31, 2018 consisted of \$356.8 million held in funds that invest in U.S. Treasury, commercial paper, government-backed securities and corporate debt securities. We are not a party to any interest rate swaps, currency hedges or derivative contracts of any type and we currently have no exposure to auction rate securities markets.



Cash and cash equivalents held by our foreign subsidiaries totaled \$13.3 million and \$8.2 million at March 31, 2018 and March 31, 2017, respectively. Our operating income outside the U.S. is deemed to be permanently reinvested in foreign jurisdictions. The recently enacted Tax Reform Act allows for a 100% deduction for the repatriation of foreign subsidiary earnings with minimal U.S. income tax consequences other than the one-time deemed repatriation toll charge. Since most of our cash and cash equivalents are held by foreign subsidiaries which are disregarded entities for domestic tax purposes, any repatriation of such funds to the U.S. would likely have a nominal tax impact, if any.

### Contractual Obligations and Commercial Commitments

The following table summarizes our contractual obligations at March 31, 2018 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

	Payments Due By Fiscal Year (in \$000's)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease commitments (1)	10,089	2,078	3,789	2,299	1,923
Contractual obligations (2)	1,721	569	1,152	—	—
<b>Total obligations</b>	<b>\$ 11,810</b>	<b>\$ 2,647</b>	<b>\$ 4,941</b>	<b>\$ 2,299</b>	<b>\$ 1,923</b>

- (1) See Note 11 to our consolidated financial statements entitled “Commitments and Contingencies—Leases” for disclosures related to our operating lease obligations.
- (2) Contractual obligations represent future cash commitments and potential liabilities under agreements with third parties, primarily for research and development activities, such as clinical trials and material purchases for new product testing. In April 2014, we entered into an exclusive license agreement for the rights to certain optical sensor technologies in the field of cardio-circulatory assist devices. Pursuant to the terms of the license agreement, we agreed to make potential payments of \$6.0 million. Through March 31, 2018, we have made \$3.5 million in milestones payments which included a \$1.5 million upfront payment upon the execution of the agreement. Any potential future milestone payment amounts have not been included in the contractual obligations table above due to the uncertainty related to the successful achievement of these milestones.

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

Our business and financial results are affected by fluctuations in world financial markets, including changes in currency exchange rates and interest rates. We manage these risks through a combination of normal operating and financing activities. We do not use derivative financial instruments.

#### Investment and Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. Our investment strategy is focused on preserving capital and supporting our liquidity requirements, while earning a reasonable market return. We invest in a variety of U.S. government and agency securities and corporate debt securities. The market value of our investments may decline if current market interest rates rise. Marketable securities at March 31, 2018 consisted of \$356.8 million held in funds that invest in U.S. Treasury and government-backed securities. If market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2018, we believe the decline in fair market value of our investment portfolio would be immaterial. Any such declines would only result in a realized loss if we choose or are forced to sell the investments before the scheduled maturity, which we currently do not anticipate.

#### Currency Exchange Rates

We have foreign currency exposure to exchange rate fluctuations and particularly with respect to the Euro, British pound sterling, Japanese yen, and Singapore dollar. Therefore, our investment in our subsidiaries 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 component of stockholders' equity. If foreign exchange rates for our international subsidiaries were to have depreciated immediately and uniformly by 10% relative to the U.S. dollar from levels at March 31, 2018, the result would have been a reduction of stockholders' equity of approximately \$14.2 million.

## ***Concentrations of Risk***

In the normal course of business, we provide credit to customers in the health care industry, perform credit evaluations of these customers, and maintain allowances for potential credit losses, which have historically been adequate compared to actual losses. In fiscal 2018, we had no customers that represented 10% or more of our total net sales or accounts receivable.

## ***Other Investment Risk***

We are exposed to investment risks related to changes in the underlying financial condition and credit capacity of certain of our other investments. We periodically make investments in private medical device companies that focus on heart failure and heart pump technologies. The aggregate carrying amount of our other investments was \$12.6 million and \$7.2 million at March 31, 2018 and 2017, respectively, and is classified within other assets in the consolidated balance sheets. We periodically monitor these investments for other than temporary declines in market value. Should these companies experience a decline in financial condition or credit capacity, or fail to meet certain development milestones, a decline in the investments' values may occur, resulting in unrealized or realized losses.

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

The information required by this item is incorporated by reference from the discussion under the heading Part IV, Item 15 “Exhibits, Financial Statement Schedules” of this Annual Report on Form 10-K.

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

None.

## **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, or the Exchange Act, as of March 31, 2018. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2018, 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, 2018, 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 (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment under the framework in *Internal Control—Integrated Framework (2013)*, our management concluded that our internal control over financial reporting was effective as of March 31, 2018.

### ***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 our 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 fiscal year ended March 31, 2018, included in this annual report, has issued an attestation report on the effectiveness of our internal control over financial reporting. This report is set forth below:

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

### Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of ABIOMED, Inc. and subsidiaries (the “Company”) as of March 31, 2018, based on criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended March 31, 2018, of the Company and our report dated May 24, 2018, expressed an unqualified opinion on those financial statements and included an explanatory paragraph referring to the Company’s adoption of Accounting Standards Update No. 2016-09, *Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting*.

### Basis for Opinion

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, included in the accompanying “Management’s Report on Internal Control over Financial Reporting”. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### Definition and Limitations of Internal Control over Financial Reporting

A company’s 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. 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 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.

/s/ Deloitte & Touche LLP

Boston, Massachusetts  
May 24, 2018

**ITEM 9B. *OTHER INFORMATION***

Not applicable.

### **PART III**

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

The information required by Item 10 is incorporated by reference from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

We have a Code of Conduct and Compliance Policy that applies to all of our directors, officers, and employees. Our Code of Conduct and Compliance Policy is posted on our website and a paper copy of this document may be obtained free of charge by writing to the Company's Chief Compliance Officer at our principal executive offices located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, or by email at IR@abiomed.com. We intend to disclose any future amendments to, or waivers from, the Code of Conduct and Compliance Policy through a posting on our website.

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

The information required by Item 11 is incorporated by reference from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by Item 12 is incorporated by reference from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by Item 13 is incorporated by reference from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by Item 14 is incorporated by reference from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this Annual Report on Form 10-K.

## PART IV

### ITEM 15. EXHIBITS, 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, 2018 are attached hereto.

	Page
Report of Independent Registered Public Accounting Firm.....	F-2
Consolidated Balance Sheets as of March 31, 2018 and 2017 .....	F-3
Consolidated Statements of Operations for the Fiscal Years Ended March 31, 2018, 2017 and 2016.....	F-4
Consolidated Statements of Comprehensive Income for the Fiscal Years Ended March 31, 2018, 2017 and 2016 .....	F-5
Consolidated Statements of Stockholders' Equity for the Fiscal Years Ended March 31, 2018, 2017 and 2016.....	F-6
Consolidated Statements of Cash Flows for the Fiscal Years Ended March 31, 2018, 2017 and 2016.....	F-7
Notes to Consolidated Financial Statements .....	F-8

(2) Consolidated financial statement schedule

Information is contained within Note 4. "Accounts Receivable" to our consolidated financial statements in this Report.

(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 (File No. 001-09585)	May 16, 2005	2.1
2.2	Agreement on the Sale and Transfer of all shares in ECP Entwicklungsgesellschaft mbH		8-K (File No. 001-09585)	July 7, 2014	2.1
2.3	Agreement on the Sale and Transfer of all shares in AIS GmbH Aachen Innovative Solutions		8-K (File No. 001-09585)	July 7, 2014	2.2
3.1	Restated Certificate of Incorporation.		S-3	September 29, 1997	3.1
3.2	Restated By-Laws, as amended.		10-K (File No. 001-09585)	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 (File No. 001-09585)	March 21, 2007	3.4
4.1 <sup>P</sup>	Specimen Certificate of common stock.		S-1	June 5, 1987	4.1
10.1* <sup>P</sup>	Form of Indemnification Agreement for Directors and Officers.		S-1	June 5, 1987	10.13
10.2*	Amendment to 1992 Combination Stock Option Plan.		10-Q (File No. 001-09585)	October 14, 1997	10.2
10.3*	1988 Employee Stock Purchase Plan, as amended.		10-Q (File No. 001-09585)	February 8, 2005	10.11
10.4*	1989 Non-Qualified Stock Option Plan for Non-Employee Directors.		10-Q (File No. 001-09585)	October 27, 1995	10.1

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
10.5*	1998 Equity Incentive Plan.		10-Q/A (File No. 001-09585)	January 8, 1999	10
10.6*	2000 Stock Incentive Plan Agreement, as amended.		Sch. 14A (File No. 001-09585)	July 15, 2005	Appendix A
10.7*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Directors.		10-Q (File No. 001-09585)	February 9, 2006	10.16
10.8*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Employees or Consultants.		10-Q (File No. 001-09585)	February 9, 2006	10.17
10.9*	Fourth Amended and Restated 2008 Stock Incentive Plan.		10-K (File No. 001-09585)	May 28, 2015	10.9
10.10*	Form of Non-Statutory Stock Option Agreement for Employees and Consultants under 2008 Stock Incentive Plan.		8-K (File No. 001-09585)	August 18, 2008	10.1
10.11*	Form of Non-Statutory Stock Option Agreement for Non-Employee Directors under 2008 Stock Incentive Plan.		8-K (File No. 001-09585)	August 18, 2008	10.2
10.12*	Form of Restricted Stock Agreement under 2008 Stock Incentive Plan.		8-K (File No. 001-09585)	August 18, 2008	10.3
10.13*	2015 Omnibus Incentive Plan.		Sch. 14A (File No. 001-09585)	July 2, 2015	Appendix A
10.14*	Form of TSR Award (Performance and Time-Based RSU).		10-Q (File No. 001-09585)	August 6, 2015	10.4
10.15*	TSR Award Agreement (Performance- and Time-Based RSU) of Michael R. Minogue dated November 14, 2016.		10-Q (File No. 001-09585)	February 3, 2017	10.1
10.16*	Form of Employee Time-Based RSU Agreement under the 2015 Omnibus Incentive Plan.		10-K (File No. 001-09585)	May 25, 2017	10.16
10.17*	Form of Non-Employee Director Time-Based RSU Agreement under the 2015 Omnibus Incentive Plan.		10-Q (File No. 001-09585)	February 5, 2016	10.4
10.18*	Form of Field Employee Time-Based Option Agreement under the 2015 Omnibus Incentive Plan.		10-K (File No. 001-09585)	May 25, 2017	10.18
10.19*	Form of Performance-Based RSU Agreement under the 2015 Omnibus Incentive Plan.		10-K (File No. 001-09585)	May 25, 2017	10.19
10.20*	Form of Non-Employee Director Time-Based Option Agreement.		10-Q (File No. 001-09585)	February 5, 2016	10.7
10.21*	Employment Agreement of Michael R. Minogue dated April 5, 2004 (including Change in Control Agreement).		10-Q (File No. 001-09585)	August 9, 2004	10.10
10.22*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008.		10-Q (File No. 001-09585)	February 9, 2009	10.3
10.23*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008.		10-Q (File No. 001-09585)	February 9, 2009	10.4
10.24*	Inducement stock option granted to Michael R. Minogue dated April 5, 2004.		10-Q (File No. 001-09585)	August 9, 2004	10.11



Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
10.25*	Restricted Stock Agreement between Abiomed, Inc. and Michael R. Minogue.		10-Q (File No. 001-09585)	October 9, 2005	10.15
10.26*	Offer letter with David Weber dated April 23, 2007.		10-Q (File No. 001-09585)	August 9, 2007	10.1
10.27*	Summary of Executive Compensation.	X			
10.28*	Form of Employment, Nondisclosure and Non-Competition Agreement.	X			
10.29	Lease agreement dated July 29, 2013 for the facility located in Aachen, Germany.		10-Q (File No. 001-09585)	November 8, 2013	10.1
10.30	Lease agreement for additional commercial space dated October 19, 2015 for the facility located in Aachen, Germany.		10-Q (File No. 001-09585)	November 4, 2015	10.1
10.31	Supplemental contract no. 1 dated October 19, 2015, to the lease agreement dated July 29, 2013 for the facility located in Aachen, Germany.		10-Q (File No. 001-09585)	November 4, 2015	10.2
10.32	Amended and Restated Lease dated as of February 24, 2014 between Abiomed, Inc. and Leo C. Thibeault, Jr., Trustee of The Thibeault Nominee Trust.		10-K (File No. 001-09585)	May 28, 2014	10.27
10.33	Amended Lease dated as of April 30, 2015 between Abiomed, Inc. and Leo C. Thibeault, Jr., Trustee of The Thibeault Nominee Trust.		10-K (File No. 001-09585)	May 28, 2015	10.29
10.34*	Form of Change of Control Agreement.		8-K (File No. 001-09585)	August 18, 2008	10.4
10.35	Purchase and Sale Agreement dated as of December 9, 2015 between Abiomed, Inc. and Thibeault Nominee Trust.		10-Q (File No. 001-09585)	February 5, 2016	10.1
10.36	First Amendment to Purchase and Sale Agreement dated as of January 19, 2016 between Abiomed, Inc. and Thibeault Nominee Trust.		10-Q (File No. 001-09585)	February 5, 2016	10.2
10.37	Lease Agreement dated August 12, 2016 between Abiomed, Inc. and Leo C. Thibeault, Jr., Trustee of the Thibeault Nominee Trust.		10-Q (File No. 001-09585)	November 4, 2016	10.1
10.38	Purchase and Sale Agreement dated as of December 16, 2016 between Abiomed, Inc. and gewoge AG and Thibeault Nominee Trust for the facility located in Aachen, Germany		10-K (File No. 001-09585)	May 25, 2017	10.42
10.39*	Form of Employee Time-Based Option Agreement under the 2015 Omnibus Incentive Plan.		10-K (File No. 001-09585)	May 25, 2017	10.43

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		Exhibit No.
			Form	Filing Date	
10.40	Notice of Exercise of Option to Buy, dated September 12, 2017.		10-Q (File No. 001-09585)	November 2, 2017	10.1
10.41	Lease agreement for additional space in Danvers, Massachusetts dated February 2, 2017		10-Q (File No. 001-09585)	February 6, 2018	10.1
10.42	Lease agreement amendment for additional space in Danvers, Massachusetts dated December 14, 2017		10-Q (File No. 001-09585)	February 6, 2018	10.2
10.43*	Offer letter with Todd A. Trapp dated March 30, 2018	X			
10.44*	Change of Control Severance Agreement between Abiomed, Inc. and Todd Trapp dated April 6, 2018	X			
10.45	Lease Agreement for Additional Space in Danvers, Massachusetts dated March 2, 2018	X			
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			
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			
101	The following financial information from the ABIOMED, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of March 31, 2018 and 2017; (ii) Consolidated Statements of Operations for the fiscal years ended March 31, 2018, 2017 and 2016; (iii) Consolidated Statements of Comprehensive Income for the fiscal years ended March 31, 2018, 2017 and 2016; (iv) Consolidated Statements of Stockholders' Equity for the fiscal years ended March 2018, 2017 and 2016; (v) Consolidated Statements of Cash Flows for the fiscal years ended March 31, 2018, 2017 and 2016; and (vi) Notes to Consolidated Financial Statements.	X			

\* Management contract or compensatory plan.

P Exhibit filed by paper

#### Item 16. Form 10-K Summary.

None.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ABIOMED, Inc.

Dated: May 24, 2018

By           /s/ TODD A. TRAPP            
**Todd A. Trapp**  
**Vice President, Chief Financial Officer**  
**(Principal Financial and Accounting Officer)**

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
<u>/s/ MICHAEL R. MINOGUE</u> <b>Michael R. Minogue</b>	Chairman, President and Chief Executive Officer (Principal Executive Officer)	May 24, 2018
<u>/s/ TODD A. TRAPP</u> <b>Todd A. Trapp</b>	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	May 24, 2018
<u>/s/ DOROTHY E. PUHY</u> <b>Dorothy E. Puhly</b>	Director	May 24, 2018
<u>/s/ JEANNINE M. RIVET</u> <b>Jeannine M. Rivet</b>	Director	May 24, 2018
<u>/s/ ERIC A. ROSE, M.D.</u> <b>Eric A. Rose, M.D.</b>	Director	May 24, 2018
<u>/s/ MARTIN P. SUTTER</u> <b>Martin P. Sutter</b>	Director	May 24, 2018
<u>/s/ PAUL G. THOMAS</u> <b>Paul G. Thomas</b>	Director	May 24, 2018
<u>/s/ CHRIS D. VAN GORDER</u> <b>Chris D. Van Gorder</b>	Director	May 24, 2018



**ABIOMED, INC.**  
**Consolidated Financial Statements**  
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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ABIOMED, Inc. and subsidiaries (the “Company”) as of March 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended March 31, 2018, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company’s internal control over financial reporting as of March 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated May 24, 2018 expressed an unqualified opinion on the Company’s internal control over financial reporting.

### Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for share-based payment transactions beginning April 1, 2017 due to the adoption of Accounting Standards Update No. 2016-09, *Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting*.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts  
May 24, 2018

We have served as the Company's auditor since fiscal 2007.

**ABIOMED, INC. AND SUBSIDIARIES**

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

	March 31, 2018	March 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 42,975	\$ 39,040
Short-term marketable securities	319,274	190,908
Accounts receivable, net	70,010	54,055
Inventories	50,204	34,931
Prepaid expenses and other current assets	11,808	8,024
Total current assets	494,271	326,958
Long-term marketable securities	37,502	47,143
Property and equipment, net	117,167	87,777
Goodwill	35,808	31,045
In-process research and development	16,705	14,482
Long-term deferred tax assets, net	70,746	34,723
Other assets	14,176	8,286
Total assets	<u>\$ 786,375</u>	<u>\$ 550,414</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 23,565	\$ 20,620
Accrued expenses and other liabilities	46,147	37,703
Deferred revenue	14,970	10,495
Current portion of capital lease obligation	—	799
Total current liabilities	84,682	69,617
Other long-term liabilities	776	3,251
Contingent consideration	10,490	9,153
Long-term deferred tax liabilities	903	783
Capital lease obligation, net of current portion	—	15,539
Total liabilities	<u>96,851</u>	<u>98,343</u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Class B Preferred Stock, \$.01 par value	—	—
Authorized - 1,000,000 shares; Issued and outstanding - none		
Common stock, \$.01 par value	444	437
Authorized - 100,000,000 shares; Issued - 46,100,649 shares at March 31, 2018 and 45,249,281 shares at March 31, 2017;		
Outstanding - 44,375,337 shares at March 31, 2018 and 43,673,286 shares at March 31, 2017		
Additional paid in capital	619,905	565,962
Retained earnings (Accumulated deficit)	140,457	(46,959)
Treasury stock at cost - 1,725,312 shares at March 31, 2018 and 1,575,995 shares at March 31, 2017	(67,078)	(46,763)
Accumulated other comprehensive loss	(4,204)	(20,606)
Total stockholders' equity	<u>689,524</u>	<u>452,071</u>
Total liabilities and stockholders' equity	<u>\$ 786,375</u>	<u>\$ 550,414</u>

*The accompanying notes are an integral part of the consolidated financial statements.*

**ABIOMED, INC. AND SUBSIDIARIES**

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

	Fiscal Years Ended March 31,		
	2018	2017	2016
Revenue	\$ 593,749	\$ 445,304	\$ 329,543
Costs and expenses:			
Cost of revenue	98,581	70,627	50,419
Research and development	75,297	66,386	49,759
Selling, general and administrative	262,734	218,153	164,261
	<u>436,612</u>	<u>355,166</u>	<u>264,439</u>
Income from operations	157,137	90,138	65,104
Other income:			
Investment income, net	3,688	1,554	395
Other (expense) income, net	(388)	(349)	339
	<u>3,300</u>	<u>1,205</u>	<u>734</u>
Income before income taxes	160,437	91,343	65,838
Income tax provision	48,267	39,227	27,691
Net income	<u>\$ 112,170</u>	<u>\$ 52,116</u>	<u>\$ 38,147</u>
Basic net income per share	\$ 2.54	\$ 1.21	\$ 0.90
Basic weighted average shares outstanding	44,153	43,238	42,204
Diluted net income per share	\$ 2.45	\$ 1.17	\$ 0.85
Diluted weighted average shares outstanding	45,849	44,658	44,895

*The accompanying notes are an integral part of the consolidated financial statements.*



**ABIOMED, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Comprehensive Income**  
**(in thousands)**

	Fiscal Years Ended March 31,		
	2018	2017	2016
Net income	\$ 112,170	\$ 52,116	\$ 38,147
Other comprehensive income (loss):			
Foreign currency translation gains (losses)	16,862	(5,855)	2,724
Net unrealized (losses) gain on marketable securities	(460)	(211)	66
Other comprehensive income (loss)	16,402	(6,066)	2,790
Comprehensive income	<u>\$ 128,572</u>	<u>\$ 46,050</u>	<u>\$ 40,937</u>

*The accompanying notes are an integral part of the consolidated financial statements.*

**ABIOMED, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Stockholders' Equity**  
(dollars in thousands)

	Common Stock		Treasury Stock		Additional Paid in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Number of shares	Par value	Number of shares	Amount				
Balance, March 31, 2015	41,335,773	\$ 413	1,282,944	\$ (19,347)	\$ 465,046	\$ (137,222)	\$ (17,330)	\$ 291,560
Restricted stock units issued	507,471	5	-	-	(5)	-	-	-
Stock options exercised	829,385	8	-	-	9,763	-	-	9,771
Stock issued under employee stock purchase plan	16,772	-	-	-	1,135	-	-	1,135
Stock issued to directors	774	-	-	-	65	-	-	65
Return of common stock to pay withholding taxes on restricted stock	(93,947)	-	93,947	(7,313)	-	-	-	(7,313)
Stock compensation expense	-	-	-	-	29,053	-	-	29,053
Excess tax benefit from stock-based awards	-	-	-	-	3,567	-	-	3,567
Other comprehensive income (loss)	-	-	-	-	-	-	2,790	2,790
Net income	-	-	-	-	-	38,147	-	38,147
Balance, March 31, 2016	42,596,228	\$ 426	1,376,891	\$ (26,660)	\$ 508,624	\$ (99,075)	\$ (14,540)	\$ 368,775
Restricted stock units issued	502,417	5	-	-	(5)	-	-	-
Stock options exercised	754,893	8	-	-	10,652	-	-	10,660
Stock issued under employee stock purchase plan	18,288	-	-	-	1,720	-	-	1,720
Stock issued to directors	564	-	-	-	67	-	-	67
Return of common stock to pay withholding taxes on restricted stock	(199,104)	(2)	199,104	(20,103)	-	-	-	(20,105)
Stock compensation expense	-	-	-	-	32,866	-	-	32,866
Excess tax benefit from stock-based awards	-	-	-	-	12,038	-	-	12,038
Other comprehensive income (loss)	-	-	-	-	-	-	(6,066)	(6,066)
Net income	-	-	-	-	-	52,116	-	52,116
Balance, March 31, 2017	43,673,286	\$ 437	1,575,995	\$ (46,763)	\$ 565,962	\$ (46,959)	\$ (20,606)	\$ 452,071
Cumulative effect of adoption of new accounting standard	-	-	-	-	1,835	75,246	-	77,081
Restricted stock units issued	371,940	4	-	-	(4)	-	-	-
Stock options exercised	459,777	5	-	-	9,298	-	-	9,303
Stock issued under employee stock purchase plan	19,286	-	-	-	2,394	-	-	2,394
Stock issued to directors	365	-	-	-	67	-	-	67
Return of common stock to pay withholding taxes on restricted stock	(149,317)	(2)	149,317	(20,315)	-	-	-	(20,317)
Stock compensation expense	-	-	-	-	40,353	-	-	40,353
Other comprehensive income (loss)	-	-	-	-	-	-	16,402	16,402
Net income	-	-	-	-	-	112,170	-	112,170
Balance, March 31, 2018	44,375,337	\$ 444	1,725,312	\$ (67,078)	\$ 619,905	\$ 140,457	\$ (4,204)	\$ 689,524

*The accompanying notes are an integral part of the consolidated financial statements.*

**ABIOMED, INC. AND SUBSIDIARIES**

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

	Fiscal Years Ended March 31,		
	2018	2017	2016
<b>Operating activities:</b>			
Net income	\$ 112,170	\$ 52,116	\$ 38,147
Adjustments required to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	11,005	6,202	3,277
Bad debt expense	38	159	42
Stock-based compensation	40,353	32,866	29,053
Write-down of inventory and other	3,946	3,085	2,094
Excess tax benefit from stock-based awards	—	(12,038)	(3,567)
Deferred tax provision	42,624	25,803	22,296
Change in fair value of contingent consideration	1,337	1,590	1,053
Changes in assets and liabilities:			
Accounts receivable	(15,289)	(11,550)	(10,930)
Inventories	(15,686)	(12,284)	(11,473)
Prepaid expenses and other assets	(4,466)	(2,366)	(2,290)
Accounts payable	4,412	7,565	(2,645)
Accrued expenses and other liabilities	7,722	22,223	10,020
Deferred revenue	4,380	1,745	1,718
Net cash provided by operating activities	192,546	115,116	76,795
<b>Investing activities:</b>			
Purchases of marketable securities	(325,408)	(278,501)	(260,975)
Proceeds from the sale and maturity of marketable securities	206,909	205,482	219,639
Purchase of other investment	(6,400)	(2,899)	(750)
Purchases of property and equipment	(55,863)	(50,415)	(15,624)
Net cash used for investing activities	(180,762)	(126,333)	(57,710)
<b>Financing activities:</b>			
Proceeds from the exercise of stock options	9,303	10,660	9,771
Excess tax benefit from stock-based awards	—	12,038	3,567
Taxes paid related to net share settlement upon vesting of stock awards	(20,317)	(20,105)	(7,313)
Proceeds from the issuance of stock under employee stock purchase plan	2,394	1,720	1,135
Principal payments on capital lease obligation	(517)	(446)	—
Net cash (used for) provided by financing activities	(9,137)	3,867	7,160
Effect of exchange rate changes on cash	1,288	(1,841)	(415)
Net increase in cash and cash equivalents	3,935	(9,191)	25,830
Cash and cash equivalents at beginning of year	39,040	48,231	22,401
Cash and cash equivalents at end of year	\$ 42,975	\$ 39,040	\$ 48,231
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for income taxes	\$ 4,641	\$ 1,405	\$ 848
Cash paid for interest on capital lease obligation	302	354	—
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
Property and equipment under capital lease obligation	—	16,784	—
Property and equipment in accounts payable and accrued expenses	3,338	5,692	1,797

*The accompanying notes are an integral part of the consolidated financial statements.*

**ABIOMED, INC. AND SUBSIDIARIES**  
**Notes to Consolidated Financial Statements**  
**(Dollars in thousands, except per share data)**

**Note 1. Nature of Operations**

ABIOMED, Inc. (the “Company” or “Abiomed”) is a provider of mechanical circulatory support devices and offers a continuum of care to heart failure patients. The Company develops, manufactures and markets proprietary products that are designed to enable the heart to rest, heal and recover by improving blood flow and/or performing the pumping function of the heart. The Company’s products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists and in the heart surgery suite by heart surgeons for patients who are in need of hemodynamic support prophylactically or emergently before, during or after angioplasty or heart surgery procedures.

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

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

**Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

**Use of Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles of the United States of America, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, 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. The Company bases its estimates on historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, collectability of receivables, realizability of inventory, property and equipment, goodwill, intangible and other long-lived assets, accrued expenses, stock-based compensation, income taxes including deferred tax assets and liabilities, contingencies and litigation. Provisions for depreciation are based on their estimated useful lives using the straight-line method. Some of these estimates can be subjective and complex and, consequently, actual results may differ from these estimates under different assumptions or conditions.

**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.

The Company classifies any marketable 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 marketable securities. Marketable 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 marketable securities. If the Company does not have the intent and ability to hold a marketable security to maturity, it reports the investment as available-for-sale marketable securities. The Company reports available-for-sale marketable securities at fair value, and includes unrealized gains and, to the extent deemed temporary, unrealized losses in stockholders’ equity. If any adjustment to fair value reflects a decline in the value of the investment, the Company considers available evidence to evaluate whether the decline is “other than temporary” and, if so, marks the marketable security to market through a charge reflected on the consolidated statements of operations.

**Major Customers and Concentrations of Credit Risk**

The Company primarily sells its products to hospitals and distributors. No customer accounted for more than 10% of total revenues in fiscal years ended March 31, 2018, 2017 or 2016. No individual customer had an accounts receivable balance greater than 10% of total accounts receivable at March 31, 2018 and 2017.

Credit is extended based on an evaluation of a customer's historical financial condition and generally collateral is not required. The Company's history of credit losses has not been significant and the Company maintains an allowance for doubtful accounts based on its assessment of the collectability of accounts receivable. Accounts receivables are geographically dispersed, primarily throughout the U.S., as well as in Europe and other foreign countries where formal distributor agreements exist in certain countries.

Financial instruments which potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents, marketable securities, short and long-term marketable securities and accounts receivable. Management mitigates credit risk by limiting the investment type and maturity to securities that preserve capital, maintain liquidity and have a high credit quality.

### **Financial Instruments**

The Company's financial instruments are comprised of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and contingent consideration. The carrying amounts of accounts receivable and accounts payable are considered reasonable estimates of their fair value, due to the short maturity of these investments.

### **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 that it believes to be impaired. Management considers forecast demand in relation to the inventory on hand, competitiveness of product offerings, market conditions and product life cycles when determining excess and obsolescence and net realizable value adjustments. Once inventory is written down and a new cost basis is established, it is not written back up if demand increases.

### **Property and Equipment**

Property and equipment is recorded at cost less accumulated depreciation. Land is carried at cost and is not depreciated. Depreciation is computed using the straight line method based on estimated useful lives of three to five years for machinery and equipment, computer software, and furniture and fixtures. Building and building improvements are depreciated using the straight-line method over estimated useful lives of seven to thirty-three years. 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. Upon retirement or other disposition of assets, the costs and related accumulated depreciation are eliminated from the accounts and the resulting gain or loss is reflected in operating expenses.

Property and equipment is 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 or asset group exceeds its fair value. Fair value is determined primarily using the estimated future cash flows associated with the asset or asset group under review discounted at a rate commensurate with the risk involved and other valuation techniques.

### **Leases**

Lease agreements are evaluated to determine whether they are capital or operating leases in accordance with Financial Accounting Standards Board, or ASC, 840, *Leases*. When any one of the four test criteria in ASC 840 is met, the lease then qualifies as a capital lease. Capital leases are capitalized at the lower of the net present value of the total amount payable under the leasing agreement (excluding finance charges) or the fair market value of the leased asset. Capital lease assets are depreciated on a straight-line basis, over a period consistent with the Company's normal depreciation policy for tangible fixed assets. Interest charges are expensed over the period of the term of the capital lease obligation in relation to the carrying value of the capital lease.

Rent expense for operating leases, which may include free rent or fixed escalation amounts in addition to minimum lease payments, is recognized on a straight-line basis over the duration of each lease term.

### **Goodwill**

Goodwill is recorded when consideration for an acquisition exceeds the fair value of the net tangible and intangible assets acquired. Goodwill is not amortized, instead the Company evaluates goodwill for impairment at least annually at October 31, as well as whenever events or changes in circumstances suggest that the carrying amount may not be recoverable.

Goodwill impairment assessments are performed at the reporting unit level. The goodwill test involves a two-step process. The first step is a comparison of the reporting unit's fair value to its carrying value. If the reporting unit's fair value exceeds its carrying value, no further procedures are required. However, if the reporting unit's fair value is less than the carrying value, an impairment of goodwill may exist, requiring a second step to measure the amount of impairment loss. If the implied fair value of goodwill is less than the recorded goodwill, an impairment charge is recorded for the difference.

In applying the goodwill impairment test, the Company may assess qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying value. Qualitative factors may include, but are not limited to, macroeconomic conditions, industry conditions, the competitive environment, changes in the market for our products and services, regulatory and political developments, cost factors, and entity specific factors such as strategies and overall financial performance. If, after assessing these qualitative factors, the Company determines it is not more likely than not that the fair value of a reporting unit is less than its carrying value, then performing the two-step impairment test is unnecessary.

The goodwill impairment test is performed at the reporting unit level by comparing the reporting unit's carrying value, including goodwill, to the fair value of the reporting unit. The Company estimates the fair value of its single reporting unit using a combination of the income approach and the market approach. The income approach incorporates the use of a discounted cash flow method in which the estimated future cash flows and terminal values for the reporting unit is discounted to a present value using an appropriate discount rate. Cash flow projections are based on management's estimates of economic and market conditions which drive key assumptions of revenue growth rates, operating margins, cash flows, capital expenditures and working capital requirements. The discount rate is based on the specific risk characteristics of the reporting unit and its underlying forecast. The market approach estimates fair value by comparing publicly traded companies with similar operating and investment characteristics as the reporting unit. The fair values determined by the market approach and income approach, are weighted to determine the fair value for the reporting unit based primarily on the similarity of the operating and investment characteristics of the reporting unit to the comparable publicly traded companies used in the market approach.

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

In-process research and development, or IPR&D, assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D assets represent the fair value assigned to technologies that are acquired, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period that the IPR&D assets are considered indefinite-lived, they are tested for impairment on an annual basis on October 31, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying values. If and when development is complete, which generally occurs upon regulatory approval and the Company is able to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value.

### **Contingent Consideration**

Contingent consideration represents potential milestones that the Company could pay additional consideration for a business acquisition and is recorded as a liability and is measured at fair value using a combination of 1) an income approach, based on various revenue and cost assumptions and applying a probability to each outcome and 2) a Monte-Carlo valuation model that simulates outcomes based on management estimates. With the income approach, probabilities were applied to each potential scenario and the resulting values were discounted using a rate that considers the weighted average cost of capital, the related projections, and the overall business. The Monte-Carlo valuation model simulates estimated future revenues during the earn out-period using management's best estimates. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones could result in a significantly higher or lower fair value of the contingent consideration liability. The fair value of the contingent consideration at each reporting date is updated by reflecting the changes in fair value reflected within research and development expenses in the Company's consolidated statement of operations.

### **Accrued Expenses**

As part of the process of preparing its financial statements, the Company is required to estimate accrued expenses. This process includes identifying services that third parties have performed and estimating the level of service performed and the associated cost incurred on these services as of each balance sheet date in its financial statements. Examples of estimated accrued expenses include contract service fees, such as amounts due to clinical research organizations, investigators in conjunction with clinical trials, professional service fees, such as attorneys and accountants, and third party expenses relating to marketing efforts associated with commercialization of the Company's product and product candidates. Accrued expenses also include estimates for payroll costs, such

as bonuses and commissions. In the event that the Company does not identify certain costs that have been incurred or it under or over-estimates the level of services or the costs of such services, reported expenses for a reporting period could be overstated or understated. The dates in which certain services commence and end, the level of services performed on or before a given date and the cost of services is often subject to the Company's judgment. The Company makes these judgments and estimates based upon known facts and circumstances.

### **Revenue Recognition**

The Company recognizes revenue when evidence of an arrangement exists, title has passed or services have been rendered, the selling price is fixed or determinable and collectability is reasonably assured.

Revenue from product sales to customers is recognized when delivery has occurred. All costs related to product sales are recognized at time of delivery. The Company does not provide for rights of return to customers on product sales and therefore does not record a provision for returns.

Maintenance and service support contract revenues are included in revenue and are recognized ratably over the term of the service contracts. Revenue is recognized as earned in limited instances where the Company rents its console medical devices on a month-to-month basis or for a longer specified period of time to customers.

In May 2014, the FASB, issued ASU 2014-09, Revenue from Contracts with Customers to provide updated guidance on revenue recognition. This new standard will replace most of the existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under the current accounting guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The Company is implementing the necessary changes to its revenue recognition accounting policies and controls to support recognition and disclosure under the new standard. The Company will adopt ASU 2014-09 during the first quarter of fiscal 2019.

### **Product Warranty**

The Company generally provides a one-year warranty for certain products sold in which estimated contractual warranty obligations are recorded as an expense at the time of shipment. The Company's products are subject to regulatory and quality standards. Future warranty costs are estimated based on historical product performance rates and related costs to repair given products. The accounting estimate related to product warranty expense involves judgment in determining future estimated warranty costs. Should actual performance rates or repair costs differ from estimates, revisions to the estimated warranty liability would be required.

### **Accumulated Other Comprehensive Income (Loss)**

Comprehensive income (loss) is comprised of net income, plus all changes in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including any foreign currency translation adjustments. These changes in equity are recorded as adjustments to accumulated other comprehensive income (loss) in the Company's consolidated balance sheet. The components of accumulated other comprehensive income (loss) consist of foreign currency translation adjustments and changes in unrealized gains (losses) on marketable securities. There were no reclassifications out of accumulated other comprehensive income (loss) during the fiscal years ended March 31, 2018, 2017 and 2016.

### **Translation of Foreign Currencies**

The functional currency of the Company's foreign subsidiaries is their local currency. The assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars at exchange rates in effect at the balance sheet date. Income and expense items in the Company's consolidated statement of operations are translated at the average exchange rates prevailing during the period. The cumulative translation effect for subsidiaries using a functional currency other than the U.S. dollar is included in accumulated other comprehensive income (loss) as a separate component of stockholders' equity.

The Company's intercompany accounts are denominated in the functional currency of the foreign subsidiary. Gains and losses resulting from the remeasurement of intercompany receivables that the Company considers to be of a long-term investment nature are recorded in accumulated other comprehensive income or loss as a separate component of stockholders' equity, while gains and losses resulting from the remeasurement of intercompany receivables from those foreign subsidiaries for which the Company anticipates settlement in the foreseeable future are recorded in the consolidated statement of operations. The net foreign currency translation gains and losses recorded in the consolidated statements of operations for the fiscal years ended March 31, 2018, 2017 and 2016 were not significant.

### Net Income Per Share

Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding during the fiscal year. Diluted net income per share is computed using the treasury stock method by dividing net income by the weighted average number of dilutive common shares outstanding during the fiscal year. Diluted shares outstanding is calculated by adding to the weighted average shares outstanding any potential dilutive securities outstanding for the fiscal year. Potential dilutive securities include stock options, restricted stock units, performance-based restricted stock units and shares to be purchased under the Company's employee stock purchase plan. In fiscal years when a net loss is reported, 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 periods when a loss is reported basic and dilutive loss per share are the same. For the fiscal years ended March 31, 2018, 2017 and 2016, the Company's basic and diluted net income per share were as follows (in thousands, except per share data):

	Fiscal Years Ended March 31,		
	2018	2017	2016
<b>Basic Net Income Per Share</b>			
Net income	\$ 112,170	\$ 52,116	\$ 38,147
Weighted average shares used in computing basic net income per share	44,153	43,238	42,204
Net income per share - basic	<u>\$ 2.54</u>	<u>\$ 1.21</u>	<u>\$ 0.90</u>
	Fiscal Years Ended March 31,		
	2018	2017	2016
<b>Diluted Net Income Per Share</b>			
Net income	\$ 112,170	\$ 52,116	\$ 38,147
Weighted average shares used in computing basic net income per share	44,153	43,238	42,204
Effect of dilutive securities	1,696	1,420	2,691
Weighted average shares used in computing diluted net income per share	45,849	44,658	44,895
Net income per share - diluted	<u>\$ 2.45</u>	<u>\$ 1.17</u>	<u>\$ 0.85</u>

For the fiscal years ended March 31, 2018, 2017 and 2016, approximately 155,000, 24,000 and 62,000 shares of common stock underlying outstanding securities primarily related to out-of-the-money stock options and performance-based awards where milestones were not met were not included in the computation of diluted earnings per share because their inclusion would be anti-dilutive.

### Stock-Based Compensation

The Company's stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense over the requisite service period.



The fair value of stock option grants is estimated using the Black-Scholes option pricing model. Use of the valuation model requires management to make certain assumptions with respect to selected model inputs. The risk-free interest rate is based on the U.S. 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 historical volatility of the Company's stock. The Company estimates the expected term of options based on historical exercise experience and estimates of future exercises of unexercised options. 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. Forfeitures are recorded as they occur instead of estimating forfeitures that are expected to occur. An accounting policy change was made by the Company related to the recording of forfeitures during the quarter ended June 30, 2017 as a result of the adoption of ASU 2016-09, "*Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*" discussed further below.

For awards with service conditions only, the Company recognizes stock-based compensation expense on a straight-line basis over the requisite service period. For awards with service, performance and market-based conditions, the Company recognizes stock-based compensation expense using the graded vesting method over the requisite service period. Estimates of stock-based compensation expense for an award with performance conditions are based on the probable outcome of the performance conditions. The cumulative effect of changes in the probability outcomes are recorded in the period in which the changes occur. For awards with market-based conditions, the Company uses a Monte Carlo simulation model to estimate that the grant-date fair value. The fair value related to market-based awards is recorded as stock-based compensation expense over the vesting period regardless of whether the market condition is achieved or not.

## **Income Taxes**

The Company's provision for income taxes is comprised of a current and deferred provision. The current income tax provision is calculated as the estimated taxes payable or refundable on income tax returns for the current fiscal year. The deferred income tax provision is calculated for the estimated future income tax effects attributable to temporary differences and carryforwards using expected tax rates in effect in the years during which the temporary differences are expected to reverse.

Deferred income taxes are recognized for the tax consequences in future years as the differences between the tax bases of assets and liabilities and their financial reporting amounts at each fiscal year end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to impact taxable income.

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realization of deferred tax assets requires significant management judgment. Valuation allowances are established when necessary to reduce net deferred tax assets to the amount that is more likely than not to be realized.

The Company recognizes and measures uncertain tax positions using a two-step approach. The first step is to evaluate the tax position for recognition by determining if, based on the technical merits, it is more likely than not that the position will be sustained upon audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit at the largest amount that is more likely than not of being realized upon ultimate settlement. The Company reevaluates these uncertain tax positions on an ongoing basis, when applicable. This evaluation is based on factors including, but not limited to, changes in facts or circumstances, new information and technical insights, and changes in tax laws. Any changes in these factors could result in the recognition of a tax benefit or an additional charge to the tax provision. Please refer to "Note 10. Income Taxes" for further information related to the Tax Reform Act (defined below) and its impact on the Company's financial statements. When applicable, the Company accrues for the effects of uncertain tax positions and the related potential penalties and interest through income tax expense.

## **New Accounting Pronouncements Adopted**

Effective April 1, 2017, the Company adopted the Financial Accounting Standards Board, FASB, standard update ASU 2016-09, "*Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*," ASU 2016-09, which simplifies several aspects of the accounting for share-based payment transactions, including income tax consequences, recognition of stock compensation award forfeitures, classification of awards as either equity or liabilities, the calculation of diluted shares outstanding and classification on the statement of cash flows.

The following table summarizes the most significant impacts of ASU 2016-09 for the year ended March 31, 2018:

<b>Description of Change:</b>	<b>Impact of Change Upon Adoption on April 1, 2017 and for the Year Ended March 31, 2018:</b>	<b>Adoption Method:</b>
The new standard eliminates the requirement that excess tax benefits be realized through a reduction in income taxes payable before a company can recognize them in the statement of operations.	As a result, on April 1, 2017, the Company recorded a cumulative-effect adjustment to increase retained earnings and deferred tax assets by \$76.4 million for excess tax benefits not previously recognized.	Modified-retrospective (required)
Excess tax benefits related to restricted stock unit vestings or stock option exercises are recorded through the statement of operations.	The income tax benefit for the year ended March 31, 2018 included excess tax benefits of \$31.0 million. These recognized excess tax benefits resulted from restricted stock units that vested or stock options that were exercised during the year ended March 31, 2018.	Prospective (required)
Excess tax benefits related to restricted stock unit vestings or stock option exercises are classified as operating cash flows instead of financing cash flows.	Increase in cash flow from operating activities and decrease in cash flow from financing activities by approximately \$31.0 million for the year ended March 31, 2018. The statement of cash flows for the prior period has not been adjusted.	Prospective (elected)
Calculation of diluted weighted average shares outstanding under the treasury method no longer assume that tax benefits related to stock-based awards are used to repurchase common stock.	The Company excluded the related tax benefits when applying the treasury stock method for computing diluted shares outstanding on a prospective basis as required by ASU 2016-09.	Prospective (required)
An accounting policy election can be made to reduce stock-based compensation expense for forfeitures as they occur instead of estimating forfeitures that are expected to occur.	The Company made an accounting policy election to account for forfeitures as they occur with the change applied on a modified retrospective basis with a cumulative effect adjustment on April 1, 2017 to increase additional paid-in capital by \$1.8 million, increase deferred tax assets by \$0.7 million and decrease retained earnings by \$1.1 million. The Company elected to make this accounting policy change to simplify the accounting for stock-based compensation and believes this method provides a more accurate reflection of periodic stock based compensation cost. Prior to the adoption of this accounting standard, the Company estimated at grant the likelihood that the award would ultimately vest, and revised the estimate, if necessary, in future periods if the actual forfeiture rate differed.	Modified-retrospective (elected)
Cash payments to tax authorities for shares withheld to meet employee tax withholding requirements on restricted stock units are classified as financing cash flow instead of operating cash flow.	No change since the Company has historically presented these amounts as a financing activity. Prior to ASU 2016-09, U.S. GAAP has not specified how these types of transactions should be classified in the statement of cash flows.	N/A

See table below for the changes in beginning stockholders' equity as a result of this implementation.

	<u>Common Stock</u>		<u>Treasury Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Total Stockholders' Equity</u>
	<u>Number of shares</u>	<u>Par value</u>	<u>Number of shares</u>	<u>Amount</u>				
Balance, March 31, 2017	<u>43,673,286</u>	<u>\$ 437</u>	<u>1,575,995</u>	<u>\$ (46,763)</u>	<u>\$ 565,962</u>	<u>\$ (46,959)</u>	<u>(20,606)</u>	<u>452,071</u>
Cumulative effect of adoption of new accounting standard					1,835	75,246		77,081
Balance, April 1, 2017	<u>43,673,286</u>	<u>\$ 437</u>	<u>1,575,995</u>	<u>\$ (46,763)</u>	<u>\$ 567,797</u>	<u>\$ 28,287</u>	<u>(20,606)</u>	<u>529,152</u>

## Recent Accounting Pronouncements

In May 2014, the FASB, issued ASU 2014-09, *Revenue from Contracts with Customers* to provide updated guidance on revenue recognition. This new standard will replace most of the existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under the current accounting guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract.

The Company established an implementation team to assist with its assessment of the impact of the new revenue guidance on its operations, consolidated financial statements and related disclosures. The Company's assessment has included performing analysis for each revenue stream identified, assessing the potential differences in recognition and measurement that may result from adopting this standard and assessing whether the Company meets certain practical expedients. Based on the results of the assessment, the adoption of this standard will not have a material impact on the timing or amount of revenue recognized upon adoption and there is no significant cumulative prior period adjustment to be recorded to the opening balance of retained earnings upon adoption. The Company also anticipates changes to its disclosures to comply with the new disclosure requirements. The Company is implementing the necessary changes to its revenue recognition accounting policies and controls to support recognition and disclosure under the new standard.

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. ASU 2016-01 requires equity investments, except those accounted for under the equity method of accounting or those that result in consolidation of the investees, to be measured at fair value with changes in fair value recognized in net income. ASU 2016-01 also includes a simplified impairment assessment of equity investments without readily determinable fair values and presentation and disclosure changes. ASU 2016-01 is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted with specific application guidance. The Company does not expect the adoption of this standard to have a material impact to its consolidated financial statements. The Company will adopt ASU 2016-01 during the first quarter of fiscal 2019.

In February 2016, the FASB issued ASU 2016-02, *Leases*. The principal difference in ASU 2016-02 from previous guidance is that effective upon adoption, the lease assets and lease liabilities arising from operating leases will be recognized in the balance sheet. In transition, the Company is required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach, including the option to utilize a number of practical expedients. The Company is in the process of evaluating its lessee and lessor arrangements to determine the impact of this amendment on the Company's consolidated financial statements. This evaluation includes an extensive review of revenue through leasing arrangements as well as lease expenses. The Company expects that most of its operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon adoption, which will increase total assets and total liabilities that the Company reports relative to such amounts prior to adoption. ASU 2016-02 will become effective for the Company beginning in fiscal 2020.

### Note 3. Cash Equivalents, Marketable Securities and Fair Value Measurements

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. The Company's marketable securities are classified as available-for-sale securities and, accordingly, are recorded at fair value. The difference between amortized cost and fair value is included in stockholders' equity. At March 31, 2018 and 2017, the Company's financial instruments consist primarily of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and contingent consideration. The carrying amounts of accounts receivable and accounts payable are considered reasonable estimates of their fair value, due to the short maturity of these investments.

The Company's cash equivalents and marketable securities at March 31, 2018 and 2017 are classified on the balance sheet as follows:

	March 31, 2018	March 31, 2017
	(in \$000's)	
Cash equivalents (within 90 days at the time of purchase to maturity)	\$ 22,595	\$ 23,975
Short-term marketable securities (within one year to maturity)	319,274	190,908
Long-term marketable securities (one to two years to maturity)	37,502	47,143
	<u>\$ 379,371</u>	<u>\$ 262,026</u>

The Company's cash equivalents and marketable securities at March 31, 2018 and 2017 are invested in the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in \$000's)			
<b>March 31, 2018:</b>				
Money market funds	\$ 5,845	\$ —	\$ —	\$ 5,845
Repurchase agreements	16,750	—	—	16,750
Short-term U.S. Treasury mutual fund securities	18,132	—	(29)	18,103
Short-term government-backed securities	212,255	3	(538)	211,720
Short-term corporate debt securities	52,737	—	(161)	52,576
Short-term commercial paper	36,936	2	(63)	36,875
Long-term U.S. Treasury mutual fund securities	10,953	—	(16)	10,937
Long-term government-backed securities	24,798	1	(12)	24,787
Long-term corporate debt securities	1,777	1	—	1,778
	<u>\$ 380,183</u>	<u>\$ 7</u>	<u>\$ (819)</u>	<u>\$ 379,371</u>

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in \$000's)			
<b>March 31, 2017:</b>				
Money market funds	\$ 11,975	\$ —	\$ —	\$ 11,975
Repurchase agreements	12,000	—	—	12,000
Short-term U.S. Treasury mutual fund securities	45,199	—	(13)	45,186
Short-term government-backed securities	90,199	1	(87)	90,113
Short-term corporate debt securities	13,161	—	(6)	13,155
Short-term commercial paper	42,304	—	(25)	42,279
Long-term U.S. Treasury mutual fund securities	1,998	—	(3)	1,995
Long-term government-backed securities	43,484	5	(18)	43,471
Long-term corporate debt securities	1,853	—	(1)	1,852
	<u>\$ 262,173</u>	<u>\$ 6</u>	<u>\$ (153)</u>	<u>\$ 262,026</u>

### Fair Value Hierarchy

Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

Level 1 primarily consists of financial instruments whose values are based on quoted market prices such as exchange-traded instruments and listed equities.

Level 2 includes financial instruments that are valued using models or other valuation methodologies. These models are primarily industry-standard models that consider various assumptions, including time value, yield curve, volatility factors, prepayment speeds, default rates, loss severity, current market and contractual prices for the underlying financial instruments, as well as other relevant economic measures. Substantially all of these assumptions are observable in the marketplace, can be derived from observable data or are supported by observable levels at which transactions are executed in the marketplace.

Level 3 is comprised of unobservable inputs that are supported by little or no market activity. Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable.

The following table presents the Company's fair value hierarchy for its financial instruments measured at fair value as of March 31, 2018 and 2017:

	Level 1	Level 2	Level 3	Total
<b>March 31, 2018:</b>				
(in \$000's)				
<b>Assets</b>				
Money market funds	\$ 5,845	\$ —	\$ —	\$ 5,845
Repurchase agreements	—	16,750	—	16,750
Short-term U.S. Treasury mutual fund securities	—	18,103	—	18,103
Short-term government-backed securities	—	211,720	—	211,720
Short-term corporate debt securities	—	52,576	—	52,576
Short-term commercial paper	—	36,875	—	36,875
Long-term U.S. Treasury mutual fund securities	—	10,937	—	10,937
Long-term government-backed securities	—	24,787	—	24,787
Long-term corporate debt securities	—	1,778	—	1,778
<b>Liabilities</b>				
Contingent consideration	—	—	10,490	10,490
<b>March 31, 2017:</b>				
(in \$000's)				
<b>Assets</b>				
Money market funds	\$ 11,975	\$ —	\$ —	\$ 11,975
Repurchase agreements	—	12,000	—	12,000
Short-term U.S. Treasury mutual fund securities	—	45,186	—	45,186
Short-term government-backed securities	—	90,113	—	90,113
Short-term corporate debt securities	—	13,155	—	13,155
Short-term commercial paper	—	42,279	—	42,279
Long-term U.S. Treasury mutual fund securities	—	1,995	—	1,995
Long-term government-backed securities	—	43,471	—	43,471
Long-term corporate debt securities	—	1,852	—	1,852
<b>Liabilities</b>				
Contingent consideration	—	—	9,153	9,153

The Company has determined that the estimated fair value of its money market funds are reported as Level 1 financial assets as they are valued at quoted market prices in active markets.

The Company has determined that the estimated fair value of its U.S. Treasury mutual fund securities, government-backed securities, corporate debt securities, repurchase agreements and commercial paper are reported as Level 2 financial assets as they are not exchange-traded instruments.

The Company's financial liabilities consisted of contingent consideration potentially payable related to the acquisition of ECP Entwicklungsgesellschaft mbH, or ECP and AIS GmbH Aachen Innovative Solutions, or AIS, in July 2014. The Company acquired ECP for \$13.0 million in cash, with additional potential payouts totaling \$15.0 million based on the achievement of CE Mark approval in the European Union and a revenue-based milestone related to the development of the future Impella ECP™ expandable catheter pump technology. These potential milestone payments may be made, at the Company's option, by a combination of cash or Abiomed common stock. As of March 31, 2018, the Company used a combination of an income approach, based on various revenue and cost assumptions and applying a probability to each outcome and a Monte-Carlo valuation model. For the clinical and regulatory milestone, probabilities were applied to each potential scenario and the resulting values were discounted using a rate that considers weighted average cost of capital as well as a specific risk premium associated with the riskiness of the earn out itself, the related projections, and the overall business. The revenue-based milestone is valued using a Monte-Carlo valuation model, which simulates estimated future revenues during the earn out-period using management's best estimates. Projected revenues are based on our most recent internal operational budgets and long-range strategic plans.

This liability is reported as Level 3 as the estimated fair value of the contingent consideration related to the acquisition of ECP requires significant management judgment or estimation and is calculated using the following valuation methods:

	Fair Value at March 31, 2018 (in \$000's)	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Clinical and regulatory milestone	\$ 5,631	Probability weighted income approach	Projected fiscal year of milestone payments	2019 to 2022
			Discount rate	3.2% to 3.8%
			Probability of occurrence	Probability adjusted level of 40% for the base case scenario and 12% to 30% for various upside and downside scenarios
Revenue-based milestone	4,859	Monte Carlo simulation model	Projected fiscal year of milestone payments	2023 to 2035
			Discount rate	18%
			Expected volatility for forecasted revenues	50%
			Probability of payment (risk-neutral)	78.5%
	<u>\$ 10,490</u>			

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the contingent consideration for the fiscal years ended March 31, 2018, 2017 and 2016:

	Fiscal Years Ended March 31,		
	2018	2017	2016
	(in \$000's)		
Level 3 liabilities, beginning balance	\$ 9,153	\$ 7,563	\$ 6,510
Additions	—	—	—
Payments	—	—	—
Change in fair value	1,337	1,590	1,053
Level 3 liabilities, ending balance	<u>\$ 10,490</u>	<u>\$ 9,153</u>	<u>\$ 7,563</u>

The change in fair value of the contingent consideration was primarily due to the passage of time on the fair value measurement of milestones related to the ECP acquisition. Adjustments associated with the change in fair value of contingent consideration are included in research and development expenses in the Company's consolidated statements of operations. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones could result in a significantly higher or lower fair value of the liability. The fair value of the contingent consideration at each reporting date is updated by reflecting the changes in fair value reflected in the Company's consolidated statement of operations. There is no assurance that any of the conditions for the milestone payments will be met.

#### Other Investments

The Company periodically makes investments in private medical device companies that focus on heart failure, heart pump and other medical device technologies. The aggregate carrying amount of the Company's portfolio of other investments was \$12.6 million and \$7.2 million at March 31, 2018 and 2017, respectively, and is classified within other assets in the consolidated balance sheets. During the years ended March 31, 2018 and 2017, respectively, the Company made investments of \$6.4 million and \$2.9 million in private medical device companies. The Company determined that it is not practicable to estimate the fair value of these investments. As such, these investments are accounted for using the cost method and are evaluated for impairment and measured at fair value only if there are identified events or changes in circumstances that may have a significant adverse effect on the fair value of these investments.

#### Note 4. Accounts Receivable

The components of accounts receivable are as follows:

	March 31, 2018	March 31, 2017
	(in \$000's)	
Trade receivables	\$ 70,330	\$ 54,337
Allowance for doubtful accounts	(320)	(282)
	<u>\$ 70,010</u>	<u>\$ 54,055</u>

The following table summarizes activity in the Company's allowance for doubtful accounts:

	Fiscal Years Ended March 31,		
	2018	2017	2016
	(in \$000's)		
Balance at beginning of year	\$ 282	\$ 124	\$ 177
Additions	38	159	42
Write-offs	—	(1)	(95)
Balance at end of year	<u>\$ 320</u>	<u>\$ 282</u>	<u>\$ 124</u>

#### Note 5. Inventories

The components of inventories are as follows:

	March 31, 2018	March 31, 2017
	(in \$000's)	
Raw materials and supplies	\$ 16,481	\$ 9,784
Work-in-progress	23,179	16,504
Finished goods	10,544	8,643
	<u>\$ 50,204</u>	<u>\$ 34,931</u>

The Company's inventories relate to its Impella® product platform. Finished goods and work-in-process inventories consist of direct material, labor and overhead.

## Note 6. Property and Equipment

The components of property and equipment are as follows:

	March 31, 2018	March 31, 2017
	(in \$000's)	
Land	\$ 7,680	\$ 4,046
Building and building improvements	63,700	10,900
Capital lease asset	—	16,784
Leasehold improvements	2,905	34,854
Machinery and equipment	42,787	27,989
Furniture and fixtures	8,104	3,899
Construction in progress	19,850	9,257
Total cost	145,026	107,729
Less accumulated depreciation	(27,859)	(19,952)
	<u>\$ 117,167</u>	<u>\$ 87,777</u>

In October 2017, the Company acquired its corporate headquarters that it had been leasing in Danvers, Massachusetts. The total acquisition cost for the land and building was approximately \$16.5 million, with \$3.0 million being recorded to land and \$13.0 million being recorded to building and building improvements. In addition, the Company reclassified \$32.6 million in leasehold improvements to building and building improvements due to the termination of the lease agreement upon the property acquisition.

In February 2017, the Company acquired its existing European headquarters in Aachen, Germany, consisting of 33,000 square feet of space. The acquisition cost for the land and building was approximately \$12.6 million, with \$4.0 million being recorded to land and \$8.6 million being recorded to the building and building improvements.

Depreciation expense related to property and equipment was \$11.0 million, \$6.2 million, and \$3.3 million for the fiscal years ending March 31, 2018, 2017 and 2016, respectively.

## Note 7. Goodwill and In-Process Research and Development

The carrying amount of goodwill at March 31, 2018 and 2017 was \$35.8 million and \$31.0 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG, or Impella, in May 2005 and ECP and AIS in July 2014. The goodwill activity is as follows:

	(in \$000's)
Balance at March 31, 2016	\$ 33,003
Foreign currency translation impact	(1,958)
Balance at March 31, 2017	\$ 31,045
Foreign currency translation impact	4,763
Balance at March 31, 2018	<u>\$ 35,808</u>

The Company has no accumulated impairment losses on goodwill. The Company performed a qualitative assessment during the annual impairment review for fiscal 2018 as of October 31, 2017 and concluded that it is not more likely than not that the fair value of the Company's single reporting unit is less than its carrying amount. Therefore, the two-step goodwill impairment test for the reporting unit was not necessary in fiscal 2018.

In July 2014, the Company acquired ECP and AIS and recorded \$18.5 million of IPR&D assets. The estimated fair value of the IPR&D assets was determined using a probability-weighted income approach, which discounts expected future cash flows to present value. The projected cash flows for the future Impella ECP™ expandable catheter pump technology were based on certain key assumptions, including estimates of future revenue and expenses, taking into account the stage of development of the technology at the acquisition date and the time and resources needed to complete development. The Company used a discount rate of 21.5% and cash flows that have been probability adjusted to reflect the risks of product commercialization, which the Company believes are appropriate and representative of market participant assumptions.



The carrying value of the Company's IPR&D assets and the change in the balance for the fiscal years ended March 31, 2018 and 2017 is as follows:

	(in \$000's)
Balance at March 31, 2016	\$ 15,396
Foreign currency translation impact	(914)
Balance at March 31, 2017	\$ 14,482
Foreign currency translation impact	2,223
Balance at March 31, 2018	<u>\$ 16,705</u>

The Company tests IPR&D assets for impairment at least annually, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D assets is less than its carrying amount. The Company performed its annual impairment review for fiscal 2018 as of October 31, 2017 and concluded that it is not more likely than not that the fair value of the IPR&D assets is less than its carrying amount.

## **Note 8. Stockholders' Equity**

### **Class B Preferred Stock**

The Company has authorized 1,000,000 shares of Class B Preferred Stock, \$.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.

## **Note 9. Stock Award Plans and Stock-Based Compensation**

### **Stock Award Plans**

The Company grants stock options and restricted stock awards to employees and others. All outstanding stock options of the Company as of March 31, 2018 were granted with an exercise price equal to the fair market value on the date of grant. Outstanding stock options, if not exercised, expire 10 years from the date of grant.

#### ***2015 Stock Incentive Plan***

The Company's 2015 Stock Incentive Plan (the "2015 Plan") authorizes the grant of a variety of equity awards to the Company's officers, directors, employees, consultants and advisers, including awards of unrestricted and restricted stock, restricted stock units, incentive and nonqualified stock options to purchase shares of common stock, performance share awards and stock appreciation rights. The 2015 Plan provides that options may only be granted at the current market value on the date of grant. Each share of stock issued pursuant to a stock option or stock appreciation right counts as one share against the maximum number of shares issuable under the 2015 Plan, while each share of stock issued pursuant to any other type of award counts as 1.8 shares against the maximum number of shares issuable under the 2015 Plan. The Company's policy for issuing shares upon exercise of stock options or the vesting of its restricted stock awards and restricted stock units is to issue shares of common stock at the time of exercise or conversion. At March 31, 2018, a total of approximately 2,542,000 shares were available for future issuance under the 2015 Plan.

#### ***2008 Stock Incentive Plan***

The Company's 2008 Stock Incentive Plan (the "2008 Plan") authorizes the grant of a variety of equity awards to the Company's officers, directors, employees, consultants and advisers, including awards of unrestricted and restricted stock, restricted stock units, incentive and nonqualified stock options to purchase shares of common stock, performance share awards and stock appreciation rights. The 2008 Plan provides that options may only be granted at the current market value on the date of grant. Each share of stock issued pursuant to a stock option or stock appreciation right counts as one share against the maximum number of shares issuable under the 2008 Plan, while each share of stock currently issued pursuant to any other type of award counts as 1.58 shares against the maximum number of shares issuable under the 2008 Plan. The Company's policy for issuing shares upon exercise of stock options or the vesting of its restricted stock awards and restricted stock units is to issue shares of common stock at the time of exercise or conversion. At March 31, 2018, a total of approximately 270,000 shares were available for future issuance under the 2008 Plan.

## Stock-Based Compensation

The following table summarizes stock-based compensation expense by financial statement line item in the Company's consolidated statements of operations for the fiscal years ended March 31, 2018, 2017 and 2016:

	Fiscal Years Ended March 31,		
	2018	2017	2016
	(in \$000's)		
Cost of revenue	\$ 1,721	\$ 1,061	\$ 895
Research and development	5,895	6,050	3,950
Selling, general and administrative	32,737	25,755	24,208
	<u>\$ 40,353</u>	<u>\$ 32,866</u>	<u>\$ 29,053</u>

The components of stock-based compensation for the fiscal years ended March 31, 2018, 2017 and 2016 were as follows:

	Fiscal Years Ended March 31,		
	2018	2017	2016
	(in \$000's)		
Restricted stock units	\$ 34,559	\$ 26,570	\$ 23,708
Stock options	5,202	5,829	4,866
Employee stock purchase plan	592	467	479
	<u>\$ 40,353</u>	<u>\$ 32,866</u>	<u>\$ 29,053</u>

## Stock Options

The following table summarized stock option activity for the fiscal year ended March 31, 2018:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at beginning of period	1,646	\$ 32.09	5.46	
Granted	155	143.52		
Exercised	(460)	20.23		
Cancelled and expired	(59)	98.21		
Outstanding at end of period	<u>1,282</u>	<u>\$ 46.81</u>	5.31	\$ 313,158
Exercisable at end of period	<u>965</u>	<u>\$ 24.88</u>	4.29	\$ 256,891
Options vested and expected to vest at end of period	<u>1,259</u>	<u>\$ 46.18</u>	5.27	\$ 308,252

Stock options generally vest and become exercisable annually over three years. The remaining unrecognized stock-based compensation expense for unvested stock option awards at March 31, 2018 was approximately \$9.5 million and the weighted-average period over which this cost will be recognized is 2.2 years.

The aggregate intrinsic value of options exercised for fiscal years 2018, 2017 and 2016 was \$66.4 million, \$74.8 million and \$58.6 million, respectively. The total cash received as a result of employee stock option exercises during the fiscal years ended March 31, 2018, 2017 and 2016 was approximately \$9.3 million, \$10.7 million and \$9.8 million, respectively.

The Company estimates the fair value of each stock option granted at the grant date using the Black-Scholes option valuation model. The weighted average grant-date fair values and weighted average assumptions used in the calculation of fair value of options granted during the fiscal years ended March 31, 2018, 2017 and 2016 was as follows:

	Fiscal Years Ended March 31,		
	2018	2017	2016
Valuation assumptions:			
Weighted average grant-date fair value	\$ 52.34	\$ 42.40	\$29.57
Risk-free interest rate	1.87%	1.41%	1.55%
Expected option life (years)	4.07	4.14	4.15
Expected volatility	43.5%	48.9%	49.7%

The risk-free interest rate is based on the U.S. 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 the historical volatility of the Company's stock. The Company estimates the expected term of options based on historical exercise experience and estimates of future exercises of unexercised options. 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. Forfeitures are recorded as they occur instead of estimating forfeitures that are expected to occur. An accounting policy change was made related to the recording of forfeitures during the quarter ended June 30, 2017 as a result of the adoption of ASU 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting" discussed in Note 2.

### Restricted Stock Units

The following table summarizes restricted stock unit activity for the fiscal year ended March 31, 2018:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value (per share)
Restricted stock units at beginning of period	1,056	\$ 80.50
Granted	296	\$ 137.40
Vested	(372)	\$ 53.40
Forfeited	(100)	\$ 98.47
Restricted stock units at end of period	880	\$ 109.01

Restricted stock units generally vest annually over three years. The remaining unrecognized compensation expense for outstanding restricted stock units, including performance-based awards, as of March 31, 2018 was \$32.2 million and the weighted-average period over which this cost will be recognized is 1.8 years.

The weighted average grant-date fair value for restricted stock units granted during the fiscal years ended March 31, 2018, 2017 and 2016 was \$137.40, \$97.43 and \$87.45 per share, respectively. The total fair value of restricted stock units vested in fiscal years 2018, 2017 and 2016 was \$51.0 million, \$51.3 million and \$39.6 million, respectively.

### Performance and Market-Based Awards

Restricted stock units include certain awards that vest subject to certain performance and market-based criteria. The remaining unrecognized compensation expense for outstanding performance and market-based restricted stock units as of March 31, 2018 was \$14.5 million and the weighted-average period over which this cost will be recognized is 1.8 years.

### *Performance-Based Awards*

In May 2017, performance-based awards of restricted stock units for the potential issuance of 159,000 shares of common stock were issued to certain executive officers and employees, which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. The Company met the prescribed performance milestones in fiscal 2018 such that the remaining outstanding 152,000 shares of common stock as of March 31, 2018 will vest subject to service requirements for vesting for these employees and stock-based compensation expense is being recognized accordingly over the employee's service term.

In May 2016, performance-based awards of restricted stock units for the potential issuance of 190,890 shares of common stock were issued to certain executive officers and employees, which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. The Company met a portion of the prescribed performance milestones in fiscal 2017 such that the remaining outstanding 82,000 shares of common stock as of March 31, 2018 will vest subject to service requirements for vesting for these employees and stock-based compensation expense is being recognized accordingly over the employee's service term.

In May 2015, performance-based awards of restricted stock units for the potential issuance of 183,940 shares of common stock were issued to certain executive officers and employees, which vest upon achievement of prescribed service milestones by the award recipients and performance milestones by the Company. The Company met the prescribed performance milestones in fiscal 2016 such that the remaining outstanding 55,000 shares of common stock as of March 31, 2018 will vest subject to service requirements for vesting for these employees and stock-based compensation expense is being recognized accordingly over the employee's service term.

### *Market-Based Awards*

In June 2015, the Company awarded certain executive officers a total of up to 322,980 market-based restricted share units, of which 281,530 units remain outstanding. These restricted stock units will vest and result in the issuance of common stock based on continuing employment and the relative ranking of the total shareholder return, or TSR of the Company's common stock in relation to the TSR of the component companies in the S&P Health Care Equipment Select Industry Index over a three-year performance period based on a comparison of average closing stock prices between June 2015 and June 2018. The actual number of market-based restricted stock units that may be earned can range from 0% to 300% of the target number of shares. One-half of the market-based restricted stock units earned will vest in June 2018 and the remaining restricted stock units will vest one year thereafter provided the executive officers are still employed with the Company.

In November 2016, the Company awarded an executive officer a total of up to 41,526 restricted stock units. The restricted stock units are subject to both performance-and time-based vesting. These restricted stock units will vest and result in the issuance of common stock based on continuing employment, the Company achieving positive net profits measured in the aggregate over the first four full fiscal quarters following the grant date and the relative ranking of the TSR of the Company's common stock in relation to the TSR of the component companies in the S&P Health Care Equipment Select Industry Index over a three-year performance period based on a comparison of average closing stock prices in June 2015 and June 2018. The actual number of restricted stock units that may be earned ranges from 0% to 100% of the target number of shares. One-half of the restricted stock units will potentially vest in June 2018 based on performance criteria described above and the remaining half of the restricted stock units will vest one year thereafter.

The Company used a Monte Carlo simulation model to estimate the grant-date fair value of the restricted stock units granted in June 2015 and November 2016. The fair value related to the restricted stock units is being recorded as stock compensation expense over the period from date of grant to June 2019 regardless of the actual TSR outcome achieved.

The table below sets forth the assumptions used to value the market-based awards and the estimated grant-date fair value:

	June 2015 Awards	November 2016 Awards
Risk-free interest rate	1.10%	0.90%
Dividend yield	0%	0%
Remaining performance period (years)	0.21	0.21
Expected volatility	47.2%	50.6%
Estimated grant date fair value (per share)	\$ 93.49 - 107.10	\$ 62.55
Target performance (number of shares)	107,660	41,526

### ***Employee Stock Purchase Plan***

The Company has an employee stock purchase plan, or ESPP. Under the ESPP, eligible employees, including officers and directors, who have completed at least 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 of the employee's income 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 six-month payment period, the amount withheld is used to purchase shares of the Company's 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.

### **Note 10. Income Taxes**

On December 22, 2017, the Tax Cuts and Jobs Act, or the Tax Reform Act, was signed into law. The Tax Reform Act included significant changes to existing law, including among other items, a reduction to the U.S. federal statutory corporate tax rate from 35% to 21% effective January 1, 2018. ASC 740, *Income Taxes (Topic 740)*, or ASC 740, requires that the effects of changes in tax laws or rates be recognized in the period in which the law is enacted. Those effects, both current and deferred, are reported as part of the tax provision, regardless of income in which the underlying pretax income (expense) or asset (liability) was or will be reported.

The Company's estimated fiscal 2018 blended U.S. federal statutory corporate income tax rate of 31.5% was applied in the computation of the income tax provision for the year ended March 31, 2018. The blended U.S. federal statutory corporate tax rate of 31.5% represents the average rate between the pre-enactment U.S. federal statutory corporate tax rate of 35% prior to the January 1, 2018 effective date and the post-enactment U.S. federal statutory corporate tax rate of 21% thereafter.

The Company's income tax provision was \$48.3 million, \$39.2 million and \$27.7 million for the fiscal years ended March 31, 2018, 2017 and 2016, respectively. The Company's effective tax rate was 30.1%, 43.0% and 42.1% for the fiscal years ended March 31, 2018, 2017 and 2016. Consistent with guidance issued by the U.S. Securities and Exchange Commission, or SEC, which provides for a measurement period of one year from the enactment date to finalize the accounting for effects of the Tax Reform Act, the Company provisionally recorded an income tax expense adjustment of \$21.4 million during the year ended March 31, 2018, due to the re-measurement of its net deferred tax assets due to the lower U.S. federal statutory corporate tax rate. This provisional estimate reflects estimable current year impacts of the Tax Reform Act on the Company's estimated annual effective tax rate and discrete items resulting directly from the enactment of the Tax Reform Act based on the information available, prepared, or analyzed (including computations) in reasonable detail. Any adjustments to this provisional estimate will be recorded as adjustments to income tax expense in the period in which those adjustments become estimable and/or are finalized, if necessary. As a result of the Tax Reform Act, the Company is currently evaluating the realizability of its tax attributes, such as net operating losses, foreign tax credits, and research credits along with potential planning strategies.

As discussed in "Note 2. Basis of Presentation and Summary of Significant Accounting Policies," the Company adopted ASU 2016-09 in the first quarter of fiscal 2018. ASU 2016-09 requires excess tax benefits and shortfalls to be recognized in the income tax provision as discrete items in the period when restricted stock units vest or stock option exercises occur, whereas previously such income tax effects were recorded as part of additional paid-in capital only when the related tax deduction resulted in a reduction of current income taxes payable. The Company recognized excess tax benefits associated with stock-based awards of \$31.0 million as an income tax benefit for fiscal year ended March 31, 2018. These recognized excess tax benefits resulted from restricted stock units that vested or stock options that were exercised during the fiscal year ended March 31, 2018. The amount of future excess tax benefits or shortfalls will likely fluctuate from period to period based on the price of the Company's stock, the number of restricted stock unit vestings or stock option exercises, and the fair value assigned to such stock-based awards under U.S. GAAP. Accordingly, the Company expects that the adoption of ASU 2016-09 will result in more volatility to its effective income tax rate, net income and earnings per share in future periods.

The components of the Company's income tax provision for the fiscal years ended March 31, 2018, 2017 and 2016 are as follows:

	<u>2018</u>	<u>2017</u>	<u>2016</u>
	(in \$000's)		
<b>Income before provision for income taxes:</b>			
United States	\$ 134,006	\$ 78,172	\$ 54,406
Foreign	26,431	13,170	11,432
Income before income taxes	<u>\$ 160,437</u>	<u>\$ 91,342</u>	<u>\$ 65,838</u>
<b>Current tax expense:</b>			
Federal	\$ 752	\$ 7,313	\$ 1,690
State	1,491	5,045	2,113
Foreign	3,400	1,066	1,592
	<u>5,643</u>	<u>13,424</u>	<u>5,395</u>
<b>Deferred tax expense (benefit):</b>			
Federal	38,848	23,008	18,769
State	(1,014)	(349)	1,284
Foreign	4,790	3,144	2,243
	<u>42,624</u>	<u>25,803</u>	<u>22,296</u>
Total income tax provision	<u>\$ 48,267</u>	<u>\$ 39,227</u>	<u>\$ 27,691</u>

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

	<u>March 31,</u>	
	<u>2018</u>	<u>2017</u>
	(in \$000's)	
<b>Deferred tax assets</b>		
Non-operating loss and tax credit carryforwards	\$ 48,724	\$ 8,814
Stock-based compensation	13,271	16,560
Nondeductible reserves and accruals	8,290	10,303
Foreign non-operating loss carryforwards	9,598	13,634
Deferred revenue	3,770	4,308
Depreciation and amortization	826	2,135
Other, net	822	1,308
	<u>85,301</u>	<u>57,062</u>
<b>Deferred tax liabilities</b>		
Goodwill	(6,787)	(9,444)
In-process research and development	(5,045)	(4,374)
Depreciation	(1,011)	—
Domestic deferred tax liability on foreign non-operating loss carryforwards	(963)	(6,836)
	<u>(13,806)</u>	<u>(20,654)</u>
Net deferred tax assets	71,495	36,408
Valuation allowance	(1,652)	(2,468)
Net deferred tax assets	<u>\$ 69,843</u>	<u>\$ 33,940</u>
<b>Reported as:</b>		
Long-term deferred tax assets, net	\$ 70,746	\$ 34,723
Long-term deferred tax liabilities	(903)	(783)
Net deferred tax assets	<u>\$ 69,843</u>	<u>\$ 33,940</u>

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows for the fiscal years ended March 31, 2018, 2017, and 2016:

	<u>2018</u>	<u>2017</u>	<u>2016</u>
Statutory income tax rate	31.5 %	35.0 %	35.0 %
(Decrease) increase resulting from:			
Change in valuation allowance	0.5	0.2	0.7
Credits	(4.9)	(3.3)	(4.1)
Foreign taxes	2.2	2.0	2.5
State taxes, net	2.0	3.8	3.7
Permanent differences	2.4	3.3	3.0
Stock-based compensation	(17.2)	0.2	0.3
Rate differential on foreign operations	—	0.1	—
Effect of the Tax Reform Act on net deferred tax assets	13.0	—	—
Other	0.6	1.7	1.0
Effective tax rate	<u>30.1 %</u>	<u>43.0 %</u>	<u>42.1 %</u>

The Company regularly assesses its ability to realize its deferred tax assets. Assessing the realization of deferred tax assets requires significant management judgment. In determining whether its deferred tax assets are more likely than not realizable, the Company evaluates all available positive and negative evidence, and weights the evidence based on its objectivity.

As of March 31, 2018 and 2017, respectively, the Company maintained a valuation allowance of \$1.7 million and \$2.5 million for deferred tax assets primarily related to non-operating loss, or NOL, carryforwards in certain foreign jurisdictions in which the Company has had limited or no history of profitability. Based on the review of all available evidence, the Company recorded a valuation allowance to reduce these deferred tax assets to the amount that is more likely than not to be realizable as of March 31, 2018 and 2017.

Changes in the valuation allowance for deferred tax assets during the fiscal years ended March 31, 2018, 2017 and 2016 were as follows:

	<u>2018</u>	<u>2017</u>	<u>2016</u>
		(in \$000's)	
Balance at beginning of year	\$ 2,468	\$ 2,418	\$ 2,912
Increases	325	50	677
Decreases	(1,141)	—	(1,171)
Balance at end of year	<u>\$ 1,652</u>	<u>\$ 2,468</u>	<u>\$ 2,418</u>

At March 31, 2018, the Company had NOLs, of approximately \$72.2 million which expire in varying years from fiscal 2019 through fiscal 2035. At March 31, 2018, the Company had foreign NOLs of approximately \$3.9 million, primarily in Germany and France, which do not expire. In addition, at March 31, 2018, the Company had federal and state research and development credit carryforwards of approximately \$16.6 million and \$9.0 million, respectively, which expire in varying years from fiscal 2019 through fiscal 2038.

As of March 31, 2018 and 2017, the Company has no material uncertain tax positions and no interest and penalties were recognized during the years ended March 31, 2018, 2017 and 2016, respectively.

The Company and its subsidiaries are subject to U.S. federal income tax, as well as income tax of multiple state and foreign jurisdictions. Fiscal years 2012 through 2017 remain open to examination in Germany and Abiomed Europe GmbH, the Company's main operating subsidiary in Germany, is currently being audited for fiscal years 2012 through 2015. In July 2017, the Company was notified by the Internal Revenue Service, or IRS, that it has selected the Company's federal tax return for fiscal 2016 for examination. In September 2017, the Company was notified by German tax authorities that our ECP subsidiary in Germany will be audited for the year ended December 31, 2014 and the three months ended March 31, 2015. The ECP audit was completed in fiscal 2018 and no adjustments were made as a result of the audit. All tax years remain subject to examination by the IRS and state tax authorities, because the Company has net operating loss and tax credit carryforwards which may be utilized in future years to offset taxable income, those years may also be subject to review by relevant taxing authorities if the carryforwards are utilized.

## Note 11. Commitments and Contingencies

### Commitments

#### *Leases*

The Company's corporate headquarters is located in Danvers, Massachusetts. This facility encompasses most of the Company's U.S. operations, including research and development, manufacturing, sales and marketing and general and administrative departments. In October 2017, the acquired its corporate headquarters for approximately \$16.5 million and terminated its existing lease arrangement (See Note 6).

Future minimum lease payments under non-cancelable leases as of March 31, 2018 are approximately as follows:

Fiscal Years Ending March 31,	Operating Leases
	(in \$000s)
2019	\$ 2,078
2020	1,888
2021	1,901
2022	1,408
2023	891
Thereafter	1,923
Total minimum lease payments	\$ 10,089

In February 2017, the Company entered into a lease agreement for an additional 21,603 square feet of office space in Danvers, Massachusetts which expires on July 31, 2022. In December 2017, the Company entered into an amendment to this lease to extend the term through August 31, 2025 and to add an additional 6,607 square feet of space in which rent would begin around June 1, 2018. The amendment also allows the Company a right of first offer to purchase the property from January 1, 2018 through August 31, 2035, if the lessor decides to sell the building or receives an offer to purchase the building from a third-party buyer. In March 2018, the Company entered into an amendment to the lease to add an additional 11,269 square feet of space for which rent will begin on or around June 1, 2018 through August 31, 2025. The annual rent expense for this lease agreement is estimated to be \$0.4 million.

In September 2016, the Company entered into a lease agreement in Berlin, Germany which commenced in May 2017 and expires in May 2024. The annual rent expense for the lease is estimated to be \$0.3 million.

In October 2016, the Company entered into a lease agreement for an office in Tokyo, Japan and expires in September 2021. The office houses administrative, regulatory, and training personnel in connection with the Company's commercial launch in Japan. The annual rent expense for the lease is estimated to be \$0.9 million.

#### *License Agreements*

In April 2014, the Company entered into an exclusive license agreement for the rights to certain optical sensor technologies in the field of cardio-circulatory assist devices. Pursuant to the terms of the license agreement, the Company agreed to make potential payments of \$6.0 million. Through March 31, 2018, the Company has made \$3.5 million in milestone payments which included a \$1.5 million upfront payment upon the execution of the agreement. Any potential future milestone payment amounts have not been included in the contractual obligations table above due to the uncertainty related to the successful achievement of these milestones.

### Contingencies

From time to time, the Company is involved in legal and administrative proceedings and claims of various types. In some actions, the claimants seek damages, as well as other relief, which, if granted, would require significant expenditures. The Company records a liability in its consolidated financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in liability and the amount of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in its consolidated financial statements.



### *Settlement Agreement*

On April 25, 2014, the Company received an administrative subpoena from the Boston regional office of the United States Department of Health and Human Services Office of Inspector General, or HHS-OIG, requesting materials relating to the Company's reimbursement of employee expenses and remuneration to healthcare providers from July 2012 through December 2012, in connection with a civil investigation under the False Claims Act. Subsequently, the Company received Civil Investigative Demands from the U.S. Attorney's Office for the District of Massachusetts, or the DOJ, that collectively sought additional information relating to this matter for the time period of January 1, 2011 through September 14, 2016. DOJ's investigation derived from a civil qui tam action, United States ex rel. Max Bennett v. Abiomed, 13-cv-12277, filed on behalf of the United States and certain individual states in the District of Massachusetts by a former employee. The complaint alleged violations of the Federal False Claims Act and analogous state false claims acts, as well as claims that the Company retaliated against Bennett in violation of federal and state law.

On March 6, 2018, the Company entered a Settlement Agreement (the "Settlement Agreement") with the DOJ, on behalf of HHS-OIG, and Bennett to resolve the claims relating to the Company's reimbursement of employee expenses for meals with healthcare providers. Under the terms of the Settlement Agreement, the Company agreed to pay \$3.1 million, plus approximately \$30,000 of accrued interest, to the U.S. government. The Company also agreed to pay \$150,000 to the former Company employee in settlement of his claims for reasonable expenses, costs and attorneys' fees. The Settlement Agreement contained no admission of liability on the part of the Company and did not require the Company to enter into a corporate integrity agreement. Pursuant to the Settlement Agreement, the U.S. government and the former Company employee agreed to release the Company from civil monetary liability arising from allegations that it caused third parties to submit false claims for payment to Medicare. In connection with the resolution, the various state claims were dismissed without prejudice.

The Settlement Agreement did not resolve the former Company employee's individual claims of employment retaliation, against which the Company intends to defend vigorously. The Company is not able to predict whether or how the former Company employee's remaining claims might be resolved, or their potential impact on the Company's financial position.

### *Thoratec Matters*

Thoratec Corporation, or Thoratec, a subsidiary of Abbott Laboratories, has challenged a number of Company owned patents in Europe in connection with the launch of their HeartMate PHP medical device, or PHP, in Europe. These actions relate to Thoratec's ability to manufacture and sell their PHP product in Europe. These actions do not relate to the Company's ability to manufacture or sell its Impella line of devices.

In December 2014, Thoratec filed a nullity suit in the German Federal Patent Court against a German "pigtail" patent owned by the Company with a flexible extension feature, and auxiliary pigtail, basket and funnel features. The validity hearing was held in November 2016 and the Federal Patent Court found the patent invalid. The Company is appealing this decision.

In August 2015, Thoratec filed a nullity action in the German Federal Patent Court against two Company owned patents covering a "magnetic clutch" feature. These magnetic clutch patents were acquired by the Company in July 2014, in connection with its acquisition of ECP and AIS. The validity hearing for the magnetic clutch patents was held in June 2017. The Company's patents were upheld in an amended form to focus on the structure and interaction of the magnets in the clutch. The Federal Patent Court found certain unamended claims to be invalid. The Company is appealing the decision with respect to the unamended claims.

In September 2015, the Company filed counterclaims in the magnetic clutch action in Germany asserting that the PHP product infringes the two magnetic clutch patents, a European pigtail patent, and the German pigtail patent. The infringement trial has been stayed, pending resolution of the German nullity actions.

In February 2017, Thoratec filed an opposition in the European Patent Office against a Company owned patent acquired in connection with the acquisition of ECP and AIS relating to a housing structure for an expandable pump. The Company filed an initial response to the opposition in July 2017. Oral proceedings are scheduled for October 26, 2018. In December 2017, Thoratec filed an opposition in the European Patent Office against a Company owned patent acquired in connection with the acquisition of ECP and AIS relating to a pump having a shaft cap with an atraumatic ball. The Company's due date for responding to the opposition is May 27, 2018.

### *Maquet Matters*

In December 2015, the Company received a letter from Maquet Cardiovascular LLC, or Maquet, a subsidiary of the Getinge Group, asserting that the Company's Impella devices infringe certain claims having guidewire, lumen and sensor features, which were in two Maquet patents and one pending patent application in the U.S. and elsewhere, and attached a draft litigation complaint and encouraged the Company to take a license from Maquet. In January 2016, the Company responded to Maquet stating that it believed that the cited claims were invalid and that its Impella devices did not infringe the cited patents. In May 2016, Maquet notified the Company that its pending U.S. patent application had been issued as a U.S. patent, repeated their earlier assertion and encouraged the Company to discuss taking a license from Maquet. The three patents expire September 2020, December 2020 and October 2021. In May 2016, the Company filed suit in U.S. District Court for the District of Massachusetts, or D. Mass., against Maquet seeking a declaratory judgment that the Company's Impella devices do not infringe Maquet's cited patent rights.

In August 2016, Maquet sent a letter to the Company identifying four new U.S. continuation patent filings with claims that Maquet alleges are infringed by the Company's Impella devices. Of the four U.S. continuation applications, one issued as a patent on January 17, 2017, one issued as a patent on February 7, 2017, one issued as a patent on March 21, 2017, and one issued as a patent on October 17, 2017. These four issued patents will expire in September 2020.

In September 2016, Maquet filed a response to the Company's suit in D. Mass., including various counterclaims alleging that the Company's Impella 2.5, Impella CP, Impella 5.0, and Impella RP heart pumps infringe certain claims of the three original issued U.S. patents ("2016 action"). On June 15, 2017, Maquet filed a motion for leave to amend its infringement counterclaims to add the first three additional U.S. continuation patents mentioned above and to file various false advertising, unfair competition claims under state law and under the Lanham Act, and a trademark cancellation in the pending case. Maquet's amended complaint and counterclaim, like those it originally filed, seek injunctive relief and monetary damages in the form of a reasonable royalty, with three times the amount for alleged willful infringement. The amended complaint admits that Maquet's currently commercially available products do not embody the claims of the asserted patents. On July 21, 2017, the Court granted the motion in part, allowing the three additional continuation patents to be added to the case, but denying addition of the false advertising claims, Lanham Act claims, and the trademark cancellation claims. On October 26, 2017, Maquet filed an amended answer, adding a new counterclaim alleging infringement of an additional seventh patent. Maquet did not seek leave to amend the pleadings and did not first consult with the Company concerning this addition. On November 11, 2017, after Maquet refused to withdraw the patent, the Company filed a motion to strike Maquet's counterclaims regarding the seventh patent on the grounds that Maquet did not seek leave to add the patent and had amended its pleadings after the deadline set by the Court. On November 15, 2017, Maquet informed the Court that it would agree to voluntarily withdraw the seventh patent. On November 22, 2017, Maquet filed a second lawsuit in D. Mass alleging that the Company's Impella 2.5, Impella CP, and Impella 5.0 heart pumps infringe certain claims of the seventh patent ("2017 action"). In the complaint, Maquet seeks injunctive relief and monetary damages in the form of a reasonable royalty, with three times the amount for alleged willful infringement.

With regard to the first six Maquet patents mentioned above, in March and April 2017, the Company filed requests for inter partes review, or IPR, at the U.S. Patent & Trademark Office's Patent Trial and Appeals Board, or PTAB, asserting that the claims are invalid in view of prior art blood pump technology. In September and October 2017, the PTAB denied institution on these IPR requests filed by the Company. In September 2017, the Company filed additional IPRs and in March and April 2018, the PTAB denied institution of these IPR petitions.

The Company cannot estimate what the potential outcome of these claims will be at this time. In the 2016 action, discovery is ongoing and, after the Court conducted a Markman hearing on claim interpretation in April 2018, the decision on claim interpretation is still pending. No schedule has been set in the 2017 action.

The Company is unable to estimate the potential liability with respect to the legal matters noted above. There are numerous factors that make it difficult to meaningfully estimate possible loss or range of loss at this stage of the legal proceedings, including that patent disputes with Thoratec and Maquet remain either in relatively early stages, or there are significant factual and legal issues to be resolved and information obtained or rulings made during any lawsuits or investigations that could affect the methodology for calculation.

## Note 12. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2018	March 31, 2017
	(in \$000's)	
Employee compensation	\$ 30,330	\$ 23,290
Sales and income taxes	4,562	3,180
Research and development	3,162	2,349
Marketing	2,305	1,827
Professional, legal and accounting fees	1,870	2,019
Warranty	1,081	717
Accrued capital expenditures	250	2,300
Other	2,587	2,021
	<u>\$ 46,147</u>	<u>\$ 37,703</u>

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at March 31, 2018 and 2017.

## Note 13. 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. International sales (sales outside the U.S. and primarily in Europe) accounted for 11%, 9% and 8% of total revenue during the fiscal years ended March 31, 2018, 2017 and 2016, respectively. As of March 31, 2018 and 2017, most of the Company's long-lived assets are located in the U.S. except for \$35.5 million and \$23.2 million at March 31, 2018 and 2017, respectively, which are located primarily in Germany.

## Note 14. Quarterly Results of Operation (Unaudited)

The following is a summary of the Company's unaudited quarterly results of operations for the fiscal years ending March 31, 2018 and 2017:

	Fiscal Year Ended March 31, 2018				
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total Year
	(in \$000's)				
Revenue	\$ 132,468	\$ 132,823	\$ 154,022	\$ 174,436	\$ 593,749
Cost of revenue	21,862	21,627	24,994	30,098	98,581
Other operating expenses	77,528	79,470	84,262	96,771	338,031
Other income, net	714	758	888	940	3,300
Income before income taxes	33,792	32,484	45,654	48,507	160,437
Income tax provision (1)(2)	(3,582)	7,981	32,208	11,660	48,267
Net income	<u>\$ 37,374</u>	<u>\$ 24,503</u>	<u>\$ 13,446</u>	<u>\$ 36,847</u>	<u>\$ 112,170</u>
Basic net income per share	\$ 0.85	\$ 0.56	\$ 0.30	\$ 0.83	\$ 2.54
Diluted net income per share	\$ 0.82	\$ 0.54	\$ 0.29	\$ 0.80	\$ 2.45

- (1) On December 22, 2017, the Tax Cuts and Jobs Act, or Tax Reform Act, was enacted into law. This new law, among other items, reduces the U.S. federal statutory corporate income tax rate from 35% to 21% effective January 1, 2018. During the year ended March 31, 2018, the Company recorded tax expense adjustments for \$21.4 million related to the revaluation of its deferred taxes due to a reduction of the U.S. federal statutory corporate income tax rate.

- (2) In the first quarter of fiscal 2018, the Company adopted Accounting Standards Update No. 2016-09, Improvements to Employee Share-Based Payment Accounting, which requires that all excess tax benefits and tax deficiencies related share-based compensation arrangements be recognized as income tax benefit or expense, instead of in stockholders' equity as previous guidance required. The income tax benefit for the year ended March 31, 2018 included excess tax benefits of \$31.0 million. These recognized excess tax benefits resulted from restricted stock units that vested or stock options that were exercised during the year ended March 31, 2018.

	<b>Fiscal Year Ended March 31, 2017</b>				
	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>	<u>Total Year</u>
	(in \$000's)				
Revenue	\$ 102,995	\$ 102,955	\$ 114,674	\$ 124,680	\$ 445,304
Cost of revenue	15,070	17,309	18,987	19,261	70,627
Other operating expenses	66,692	71,138	70,284	76,425	284,539
Other income, net	192	228	423	362	1,205
Income before income taxes	21,425	14,736	25,826	29,356	91,343
Income tax provision	8,515	5,861	10,394	14,457	39,227
Net income	<u>\$ 12,910</u>	<u>\$ 8,875</u>	<u>\$ 15,432</u>	<u>\$ 14,899</u>	<u>\$ 52,116</u>
Basic net income per share	\$ 0.30	\$ 0.21	\$ 0.36	\$ 0.34	\$ 1.21
Diluted net income per share	\$ 0.29	\$ 0.20	\$ 0.34	\$ 0.33	\$ 1.17

## OFFICES

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Voice: +81-(0) 3-4540-5600 Facsimile: +81-(0) 3-6740-1479

## 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 its 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, MA 01923, USA

## TRANSFER AGENT AND REGISTRAR

American Stock Transfer & Trust Company, LLC  
6201 15th Ave, Brooklyn, NY 11219 USA

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Deloitte & Touche LLP  
200 Berkeley Street, Boston, MA 02116, USA

## FACTORS THAT MAY AFFECT FUTURE RESULTS

Certain statements in this annual report, including statements made in the letter to the stockholders, 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 involve risks and uncertainties. The Company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, potential future losses, complex manufacturing, high-quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, future capital needs, uncertainty of additional financing, and other risks and challenges detailed in the Company's filings with the Securities and Exchange Commission, including the Annual Report filed on Form 10-K for the Company's fiscal year ended March 31, 2018. Readers are cautioned not to place undue reliance on any 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 revisions to these forward-looking statements that may be made to reflect any changes in the Company's expectations, or events or circumstances that occur after the date of this annual report or to reflect the occurrence of unanticipated events.

## SENIOR MANAGEMENT

MICHAEL R. MINOGUE  
Chairman, President and Chief Executive Officer

DAVID M. WEBER, PH.D.  
Chief Operating Officer

WILLIAM J. BOLT  
Senior Vice President, Global Quality, Regulatory and Clinical Operations

TODD A. TRAPP  
Vice President, Chief Financial Officer

ANDREW J. GREENFIELD  
Vice President and General Manager, Global Marketing

MICHAEL G. HOWLEY  
Vice President and General Manager, Global Sales

THORSTEN SIESS, PH.D.  
Chief Technology Officer

SETH BILAZARIAN, M.D.  
Chief Medical Officer

STEPHEN C. MCEVOY  
Vice President and General Counsel

KELLEY BOUCHER  
Vice President, Human Resources

## BOARD OF DIRECTORS

MICHAEL R. MINOGUE (CHAIRMAN)  
ABIOMED President and Chief Executive Officer

DOROTHY E. PUHY (LEAD DIRECTOR)  
Executive Vice President, and Chief Operating Officer  
Dana-Farber Cancer Institute, Inc.

JEANNINE M. RIVET  
Executive Vice President, UnitedHealth Group

ERIC A. ROSE, M.D.  
Executive Chairman, SIGA Technologies, Inc.

MARTIN P. SUTTER  
Managing Director and Co-Founder of EW Healthcare Partners

PAUL G. THOMAS  
President, Chief Executive Officer and Founder, Roka Bioscience  
(Retired January 2017)

CHRISTOPHER D. VAN GORDER  
President and Chief Executive Officer, Scripps Health

W. GERALD AUSTEN, M.D. (DIRECTOR EMERITUS)  
Distinguished Professor of Surgery Harvard Medical School and  
the Massachusetts General Hospital

All content in this document is for information purposes only and is not intended to provide specific instructions to hospitals or physicians on how to bill for medical procedures. Hospitals and physicians should consult appropriate insurers, including Medicare fiscal intermediaries and carriers for specific coding, billing and payment levels. This document represents no promise or guarantee by the Company, concerning medical necessity, levels of payment, coding, billing or coverage issues.

Nothing in this document shall be construed to encourage or require any health care provider or institution to provide inpatient, outpatient or any other services to patients; to order any goods or services from the Company; or otherwise to generate business for the Company. Customers utilizing this information should not knowingly or intentionally conduct themselves in a manner so as to violate the prohibition against fraud and abuse in connection with federal or state healthcare programs.

## RECOVERING HEARTS AND SAVING LIVES

Recovering hearts and saving lives is the founding principle and guiding compass of our organization. This is our highest recognition of success.

Recovering and preserving our patients' hearts enables them to return home to their families and enjoy an improved quality of life.

## GROWING SHAREHOLDER VALUE

Growing shareholder value rewards our investors and helps to ensure the company's financial stability, allowing for the continued pursuit of our mission. Shareholder value is driven by executing our goals and achieving positive financial results. For employees, growth of shareholder value provides financial security for our families and the pursuit of happiness for our future.



## LEADING IN TECHNOLOGY AND INNOVATION

We are committed to providing patients and health care providers with the highest quality devices and optimal cost-effective solutions.

We accomplish this through the relentless exploration of new ideas and approaches that allow us to address new clinical challenges for our customers and patients.

## SUSTAINING A WINNING CULTURE

Patients First. Our patients and customers are the motivation for all that we do and achieving our mission is dependent on their well-being. We must always act with integrity and honor and demand the best of ourselves. We work hard, have faith in each other, and have fun celebrating patient success stories.