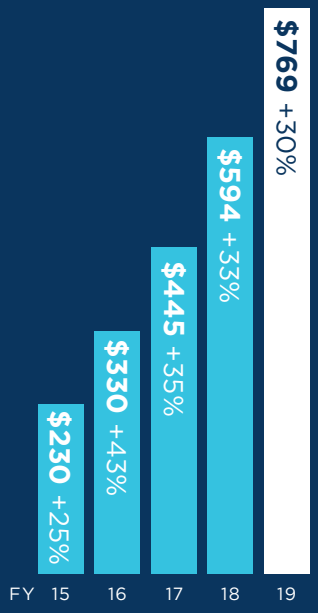
ABIOMED®

Recovering hearts. Saving lives.

FY 2019 ANNUAL REPORT

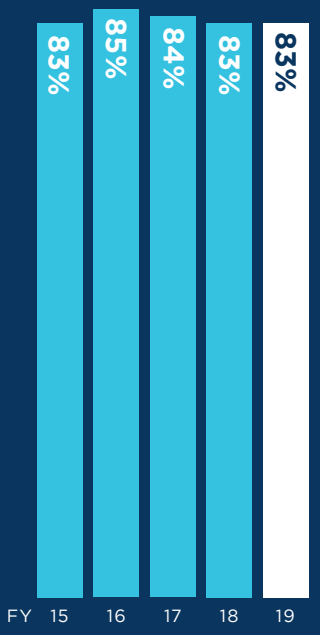
FINANCIAL PERFORMANCE

FY 2019

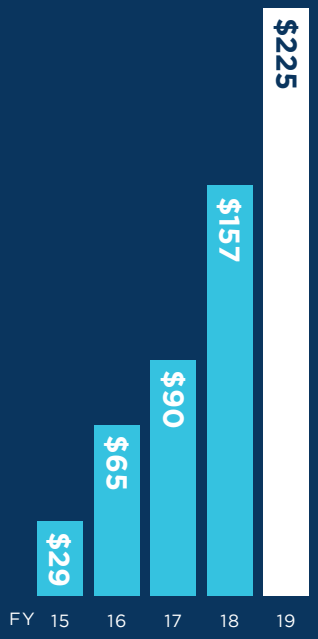


TOTAL REVENUE

DOLLARS IN MILLIONS

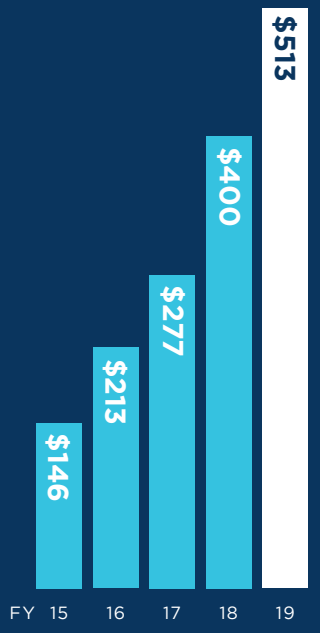


GROSS MARGIN



GAAP OPERATING INCOME

DOLLARS IN MILLIONS



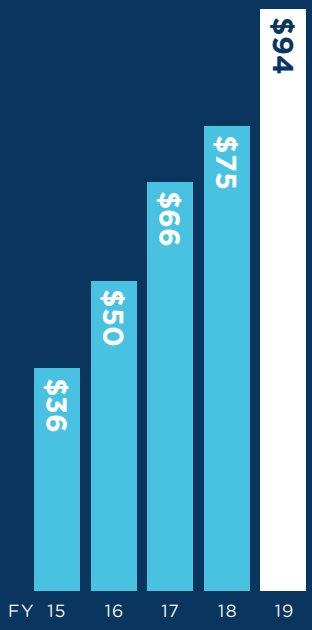
NET CASH BALANCES*

DOLLARS IN MILLIONS

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

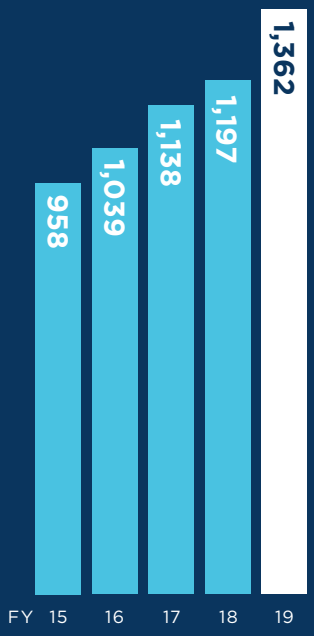
IMPELLA® DEVICE PROGRESS

FY 2019

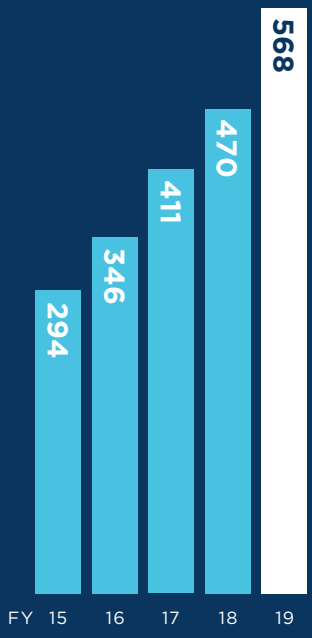


RESEARCH & DEVELOPMENT

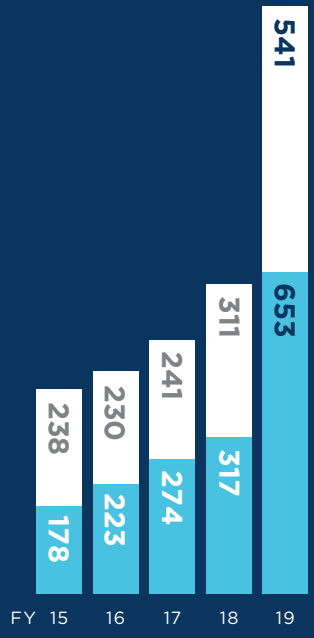
DOLLARS IN MILLIONS



IMPELLA U.S. SITES



IMPELLA PUBLICATIONS



TOTAL ABIOMED PATENT PORTFOLIO

PATENTS PATENTS PENDING

IN FY 2019, ABIOMED DEFINED OUR CULTURE AND CODE OF CONDUCT WITH OUR "I AM ABIOMED - PATIENTS FIRST COMMITMENT"

I AM ABIOMED.

I AM HEART RECOVERY.

Together with my teammates, we put Patients First and are committed to recovering hearts and saving lives. We sustain our winning culture by acting with honor and integrity in all that we do.

We are dedicated to ensuring that Abiomed's growth as the standard of care is based on innovation, improving outcomes and appropriate use. We advocate for every patient to receive the care we desire for our own family and friends, and we recognize the potential benefits of other products and treatments.

We inspire each other and have the courage and grit to explore new ideas and approaches that can change the world. We work together to achieve our goals and demand the best of ourselves.

We are dedicated to continuous improvement and strive for perfection. And we always seek opportunities to lead, manage, adapt and execute. **I AM ABIOMED.**

PATIENTS FIRST!




Heart Recovery Advocate



ABIOMED
HEART RECOVERY INSTITUTE



HEART ATTACK
JULY 3
CONQUER THE
COAST-SEPT 17





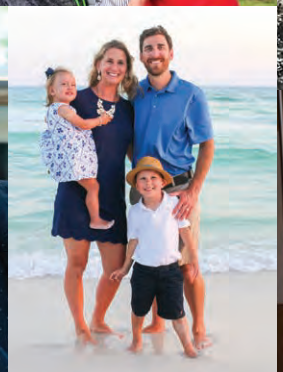


Heart Recovery Advo









LANDIN
Heart Recovery Advo

Adam Millar

WESTMINSTER, CO

IMPELLA CP® & IMPELLA RP®

Adam Millar, 19, a healthy and active teenager from Westminster, Colorado, devotes much of his time to hockey. On April 16, 2018, Adam developed flu-like symptoms. His mom, Debbie, brought him to a local urgent care where the staff determined he had atrial fibrillation. He was transferred to a local hospital where his condition worsened, and he went into cardiogenic shock.

Adam was transferred to St. Anthony's Central in Lakewood, Colorado, where interventional cardiologist Dr. Nima Aghili implanted the Impella CP® heart pump to support Adam's weak heart. He then placed the Impella RP® device to support the right side of Adam's heart, providing biventricular support. Adam continued to regain his strength and after two days, the Impella CP device was removed. Three days later, the Impella RP pump was also removed.

Adam was discharged home and quickly resumed all activities. Today, Adam's heart function is normal and he plans to play college hockey.

"Due to Adam's cardiogenic shock and biventricular failure, it was crucial to implant both the Impella CP and Impella RP devices. Adam's heart fully recovered with the support of the Impella technology. It warms my heart to see Adam back on the ice enjoying the sport he loves most."

— DR. NIMA AGHILI

Dr. Babu Eladasari

NAPERVILLE, IL

IMPELLA CP® & IMPELLA RP®

On October 20, 2018, Dr. Babu Eladasari, 67, a physician in Hines, Illinois, began experiencing chest pain while his wife, Pam, was driving them home. Moments later, Babu became unconscious and Pam quickly called 9-1-1. EMTs quickly administered CPR and rushed Babu to Edward Hospital in Naperville, Illinois, shocking him three times along the way.

Once in the catheterization lab, Drs. John Cahill and Tony DeMartini immediately identified that Babu was in cardiogenic shock and placed the Impella CP® device to support Babu's heart before placing stents. Following the hospital's protocol, the medical team evaluated Babu's hemodynamics with a pulmonary artery catheter and identified that he additionally needed right-side support. The physicians implanted the Impella RP®. After two days of biventricular support, Babu was transferred to Loyola University Medical Center in Hines, Illinois for a possible heart transplant; however, within a day, he showed significant improvements and the Impella RP was removed. The following day, the Impella CP was also removed, and a little over two weeks later, Babu was discharged home with his native heart and normal heart function. Today, he is back to work and enjoying every minute with his family.

"For patients like Babu, who arrest out of the hospital, timing is everything. Due to our hospital's cardiogenic shock protocol, Babu received immediate care and biventricular support that ultimately allowed his heart to recover. Revascularization alone, no matter how timely or complete, would not have been enough to save this man's life. It was the Impella that made the difference. To see this physician back to treating his patients is truly rewarding."

— DR. JOHN CAHILL

Mary Hanel

DINGMANS FERRY, PENNSYLVANIA

IMPELLA CP®

Mary Hanel, 81, from Dingmans Ferry, Pennsylvania, had double bypass surgery in 1985 and resumed normal life until a few years ago when her quality of life rapidly deteriorated. Mary had a persistent cough and shortness of breath, but when she began noticing pressure on her chest and pain in her arm, she decided to see Dr. Yaron Bareket, a cardiologist at Hackensack Medical Center. Dr. Bareket identified severe blockages in Mary's heart, but explained she was too high-risk for surgery and referred her to interventional cardiologist, Dr. Adam Raskin. Dr. Raskin and the heart team at Hackensack evaluated her case and recommended Protected PCI with the Impella heart pump.

On October 12, 2018, Dr. Raskin implanted the Impella CP® device, cleared blockages, and placed stents. The following day, Mary was discharged home. Today, Mary feels better than she has in years. She exercises three days a week and is back to traveling with her husband. Her husband now calls her the "dynamo" because of her endless energy.

"Mary struggled with shortness of breath that limited her quality of life. Our heart team identified her as an appropriate candidate for Protected PCI, which ultimately allowed Mary to return to her once active routine with even more energy."

— DR. ADAM RASKIN

Tory Dahle

ST. CLOUD, MINNESOTA

IMPELLA CP®

Tory Dahle, 84, a husband, father, and grandfather, always led an active lifestyle. Tory worked as an accomplished home builder for over 60 years. Though he had a history of heart disease, he managed his health and maintained a normal quality of life. Then Tory began to experience shortness of breath and chest pain and quickly called his son, Dr. Thom Dahle, an interventional cardiologist at St. Cloud Hospital in St. Cloud, Minnesota. Tory was admitted to St. Cloud Hospital where a diagnostic angiogram revealed severe blockages. A team of physicians determined Tory was an appropriate candidate for a Protected PCI procedure with the Impella heart pump as he was too high-risk for open heart surgery.

Interventional cardiologist Dr. Brian Stegman implanted the Impella CP® device to support Tory's heart while he placed stents to restore blood flow. Tory returned home the next day.

Tory quickly resumed his active routine, walking almost three miles a day. Today, Tory's heart function is normal, and he enjoys every moment with his wife, children, and grandchildren.

"When I'm helping patients make treatment decisions, I approach it as what I would do if it was my own family member. What makes this case unique and special is that the patient was my father. I was confident the Impella would support his heart during the high-risk procedure to enable complete revascularization and allow him to return to his normal quality of life."

— DR. THOM DAHLE

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
CORONARY ARTERY DISEASE/HEART FAILURE: 875,000 DEATHS (1 IN 3 DEATHS)	LOW EJECTION FRACTION & FIRST HEART ATTACK (AMI)	CARDIOGENIC SHOCK	TREATING HEART CONDITIONS ($204B)

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

1. 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
2. Historic Survival without Impella Support/Protocols:1990-2006: ~50% Mortality ; 2017 CULPRIT SHOCK Study: ~50% Mortality, *NEJM* ; Jeger, et al. *Ann Intern Med.* 2008
3. 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

IMPELLA® HEART PUMP PLATFORM

IMPELLA 2.5®

IMPELLA CP®

IMPELLA 5.0®/LD®

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™ (AIC), SMARTASSIST™ AND IMPELLA CONNECT® TECHNOLOGIES

The AIC controls the Impella catheter performance. SmartAssist for Impella is designed to improve patient outcomes with advanced algorithms and simplified patient management. Impella Connect allows for real-time access to patient metrics on support in the cloud.

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.

Dear Shareholders,

Our special patient speakers at the 2019 Abiomed Annual Meeting in Boston.

In Fiscal Year 2019, Abiomed achieved a milestone with Impella heart pumps cumulatively supporting more than 100,000 patients and amassed more clinical data than ever before on our journey to create the new Field of Heart Recovery. From a financial perspective, Abiomed remains one of the fastest growing GAAP-profitable medtech companies and has grown more than 20% for five consecutive years. I want to thank our patients for sharing their stories that inspire us daily. I also want to thank our employees and customers for their hard work and dedication to our mission. Our outstanding results are built on our Abiomed four principles: recovering hearts and saving lives, leading in technology and innovation, growing shareholder value and sustaining a winning culture. This year we defined our culture and code of conduct with our "I am Abiomed - Patients First Commitment." This commitment is our "why" and inspires our daily execution and grit.

Abiomed had record-setting financial performance in FY19 with revenue of $769 million, an increase of $175 million, or 30% growth versus prior year. Operating income grew $68 million, or 43% versus prior year, to $225 million, and operating margins expanded 270 basis points to 29.2%.

We invested over $180 million in research and development, clinical data, strategic investments in medical device technologies, infrastructure and manufacturing capacity while increasing our net cash position by over $110 million. As a result, we ended FY19 with $513 million in cash while remaining debt-free. As a company, Abiomed has now invested more than $500 million in research and development on the Impella® heart pump platform and has a library of more than 560 clinical publications, and a patent portfolio of 653 patents and 541 patents pending. Abiomed has approximately 1,350 employees worldwide, with offices in Danvers, Massachusetts, Aachen and Berlin, Germany, and Tokyo, Japan.

Outside the U.S., we saw continued strong growth in our key markets. Japan performance was strong with revenue growth of 512%, on a constant currency basis, to approximately $18 million. Impella is currently used in ~60 sites out of a potential ~350

Abiomed's global clinical team celebrating its Patients First culture at the 2019 Annual Meeting.

Impella RP patient Nancy Wilkins with members of the Abiomed manufacturing team who built her Impella heart pump.

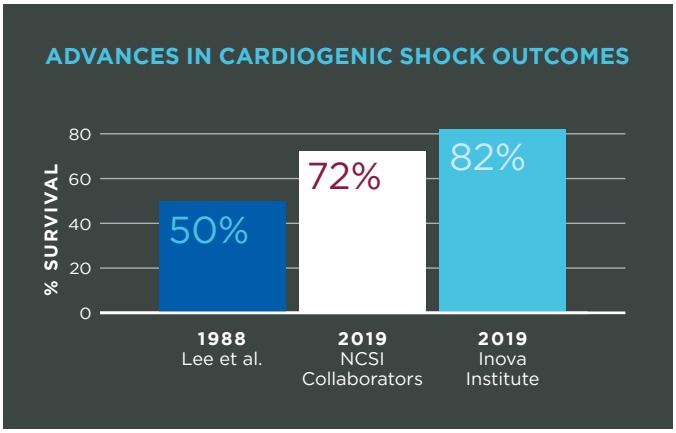
hospital sites, and this year we earned Japanese PMDA approval for the Impella CP®, substantiating the clinical need for Impella heart pumps in Japan. Further, European revenue was $81.7 million with German revenue contributing $57.5 million, increasing 37% and 29% respectively, on a constant currency basis. What has been most rewarding for FY19 is that Abiomed is transforming the care for high-risk percutaneous coronary intervention (PCI) and cardiogenic shock patients, demonstrated by multiple studies highlighting improved outcomes, survival, and native heart recovery.

Transforming the Standard of Care

Coronary artery disease is the number one killer in the U.S. and cardiogenic shock has become a clinical crisis, carrying one of the highest mortality rates of approximately 50% nationwide over the last 20 years without the Impella technology. In the U.S., 47% of women and 36% of men over 45 years old die within five years of their first heart attack. The Impella family of heart pumps creates treatment options for these extremely ill patients who have historically had few treatment options.

Our exclusive FDA-approved percutaneous devices are transforming the standard of care by enabling more high-risk PCI procedures in the catheterization lab, and by providing a therapy that protects, supports and recovers the heart muscle. We believe our U.S. "Current Addressable Market" (CAM) includes 231,000 annual, appropriate patients clinically in need of Impella support for FDA approved, Medicare reimbursed and guideline recommended Protected PCI procedures and cardiogenic shock hemodynamic support.

In FY19, Abiomed's extensive pool of clinical data was expanded, further validating the efficacy of the Impella heart pump platform. Abiomed remains dedicated to improving patient outcomes and survival through identifying and validating best practices in our real-world Impella Quality (IQ) Database and audited cVAD Study. Abiomed's clinical experience and research has stimulated educational collaborations and led to physician-driven initiatives like the National Cardiogenic Shock Initiative (NCSI), Shock Working Group, Training and Education in Advanced Cardiovascular Hemodynamics (TEACH) and Acute Cardiac Unloading and Recovery (A-CURE). The NCSI with Impella best practices demonstrates 72% survival with 98% native heart recovery, improving upon the historical survival rate in AMI cardiogenic shock of 50%. Similarly, this year the Inova Heart and Vascular Institute implemented best practices including the use of Impella and saw AMI cardiogenic shock survival at 30 days rise from 44% to 82%.[1]



Abiomed provides customers full-service, industry-leading, on-site and on-call patient support. Our Clinical Support Center provides 24x7 expert evaluation of Impella data and collaborative patient care. We are launching innovative new technologies, like Impella with SmartAssist™, designed to improve patient outcomes with advanced algorithms and simplified patient management. We are also piloting Impella Connect®, which allows medical providers real-time access to patient metrics on support in the cloud with monitoring from Abiomed personnel. The SmartAssist and Impella Connect technologies represent Abiomed's continued commitment to provide world-class innovation and service to help physicians, nurses and ICU staff improve both ease of use and clinical outcomes.

1. Tehrani et al, Journal of the American College of Cardiology. Standardized Team-Based Care for Cardiogenic Shock, 2019

Abiomed celebrates national Go Red for Women Day during heart month.

This year, we also increased our training and educational programs by 50%, reaching physicians and Protected PCI Coordinators at our Heart Recovery Institute and at off-site training courses and symposiums. We have become more comprehensive in our approach, providing additional education around access and closure, and are expanding into the surgical suite. We believe our adoption success is a formula of training, data and time.

A Long Runway for Growth

As we begin FY20, we are addressing a new wave of physicians and are working to go deeper at our existing sites. We will build upon our continued execution through new physicians, indications, products, and geographies. We believe there is a larger "Total Addressable Market" (TAM) that includes expanded indications approved in 2018 and possible future indications under clinical studies that will expand our "Current Addressable Market" (CAM).

We are preparing for the U.S. launch of the Impella 5.5™ heart pump at the end of FY20. The Impella 5.5 provides physicians with a minimally invasive, ambulatory, weanable, forward-flow, unloading heart pump with peak flows of more than six liters per minute. We believe the Impella 5.5, and the future Impella Bridge to Recovery (BTR™) heart pump under development, have the potential to revolutionize the treatment of a subset of Class III heart failure patients (~100,000 patients) that are frequently admitted to the hospital each year (~1,000,000 admissions).[2] We also continue to invest in the development of products like the Impella ECP™ and the expandable sheath for the Impella CP which allow for smaller access and closure, helping us meet the needs of a broader range of physicians.

We continue to expand in international markets. Germany and Japan remain our top priority outside of the U.S., as we believe success in these countries will drive Impella to become the standard of care across the world. Outside of the U.S., Germany and Japan, we are planting seeds at Heart Recovery Centers of Excellence and have treated patients in several additional countries such as Italy, Australia, India, Israel, Saudi Arabia and the United Arab Emirates.

Finally, last November, we presented our successful FDA STEMI DTU safety and feasibility study and received FDA approval to move forward with a pivotal randomized controlled trial (RCT). The prospective, multi-center, two-arm trial with two-year follow-up plans to enroll 668 patients undergoing treatment for a STEMI heart attack. With a successful pivotal study, Abiomed has the potential to transform the standard of care with a Class I recommendation, to reach an incremental new patient population of 4 million worldwide heart attack patients each year (200,000 U.S.), potentially slowing the growing epidemic of heart failure worldwide. However, we have to execute the plan.

In conclusion, Abiomed is positioned for sustainable growth and is committed to building the new Field of Heart Recovery with disciplined execution. We are dedicated to ensuring that Abiomed's growth as the standard of care is based on innovation, improving outcomes and appropriate use. The science of unloading is growing and Impella technology is well-positioned to transform the standard of care for hundreds of thousands of critically ill patients each year. I am proud of our employees and appreciate their dedication to continuously put Patients First, and I am thankful to our customers and shareholders for their continued support. We enter FY20 with a confidence in our mission and are more motivated than ever to recover hearts and save lives.

I am Abiomed. I am Heart Recovery. Patients First.

Sincerely,

Michael R. Minogue
CHAIRMAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER

2. Felker et al, Circulation Heart Failure. Loop Diuretics in Acute Decompensated Heart Failure, 2009

ABIOMED

PATIENT ADVOCACY PROGRAM

Abiomed's patient-focused culture continues to serve as a major contributor to the Company's success. Abiomed frequently welcomes Impella patients to our headquarters in Danvers, Massachusetts, our office in Aachen, Germany, and our office in Tokyo, Japan throughout the year to engage with employees, share their stories of heart recovery and meet other Impella patients. These efforts remind us of our commitment to always put Patients First.

ABIOMED

HEART RECOVERY REUNIONS

Abiomed collaborates with hospitals on Heart Recovery Reunions, which reconnect Impella patients with the medical teams who treated them. These events, hosted at hospitals across the country, highlight successful Impella programs and protocols, along with the exceptional dedication and care of the medical staff.

ABIOMED CITIZENSHIP AND GIVE BACK PROGRAM

"SANPO YOSHI"

At Abiomed, we are committed to giving back to the community on a local and national scale. The Abiomed Citizenship and Give Back Program supports multiple national organizations including those that support heart health and U.S. military veterans. The program also supports education and local service organizations in Massachusetts and the North Shore community.

NATIONAL

American Heart Association.

MVPvets

NATIONAL ORGANIZATION ON DISABILITY

SAVE THE MOMMIES

END ALZ

MASSACHUSETTS

THE INNER-CITY SCHOLARSHIP FUND

MassBioEd

THE IRELAND FUNDS

BOYS & GIRLS CLUB OF BOSTON

PATRIOTS FOUNDATION
CELEBRATE VOLUNTEERISM

NORTH SHORE COMMUNITY

POLICE DANVERS MASSACHUSETTS

D.A.R.E. TO RESIST DRUGS AND VIOLENCE.

DRUG ABUSE RESISTANCE EDUCATION SCHOOL POLICE PARENTS

DANVERS FIRE RESCUE MASSACHUSETTS ORG. 1830

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 non-profit dedicated to helping returning military veterans transition to careers in the life science industries.

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, 2019

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	**04-2743260**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
22 Cherry Hill Drive **Danvers, Massachusetts** (Address of Principal Executive Offices)	**01923** (Zip Code)

(978) 646-1400
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	**Trading symbol**	**Name of each exchange on which registered**
Common Stock, $0.01 par value	ABMD	The NASDAQ Stock Market LLC

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No

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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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 Act). Yes No ☒

As of September 28, 2018, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates was $19,419,916,261. As of April 30, 2019, 45,124,729 shares of the registrant's common stock, $0.01 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the 2019 Annual Meeting of Stockholders are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

TABLE OF CONTENTS

EXPLANATORY NOTES

Pending Trademarks and Registered Marks

Throughout this annual report on Form 10-K (the "report"), we refer to various trademarks, service marks and trade names that we use in our business. ABIOMED, IMPELLA, IMPELLA 2.5, IMPELLA 5.0, IMPELLA LD, IMPELLA CP, IMPELLA RP, and IMPELLA CONNECT are registered trademarks of ABIOMED, Inc., and are registered in the U.S. and certain foreign countries. IMPELLA BTR, IMPELLA 5.5, IMPELLA ECP, cVAD Study and SMARTASSIST are pending trademarks of ABIOMED, Inc. Other trademarks and service marks appearing in this Report are the property of their respective holders.

Company References

Throughout this report, "ABIOMED, Inc.," the "Company," "we," "us" and "our" refer to ABIOMED, Inc. and its consolidated subsidiaries.

Industry Data and Forecasts

This report includes data, including forecasts, obtained from industry publications and surveys and other information available to us. Data and other metrics included in this report to describe our industry or our products are inherently uncertain and speculative in nature, and actual results for any period may materially differ. Estimates and forecasts involve uncertainties and risks and are subject to change based on various factors, including those discussed above under "Forward-Looking Statements." While we are not aware of any misstatements regarding the third-party industry data presented in this report, we have not independently verified any of the data from third-party sources, nor have we ascertained the underlying assumptions relied upon therein.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including the documents incorporated by reference in this report, includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, may be 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," "should," "likely," "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. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include:

- our dependence on Impella® products for all of our revenues;
- our ability to successfully compete against our existing or potential competitors;
- the acceptance of our products by cardiac surgeons and interventional cardiologists, especially those with significant influence over medical device selection and purchasing decisions;
- long sales and training cycles associated with expansion into new hospital cardiac centers;
- reduced market acceptance of our products due to lengthy clinician training process;
- our ability to effectively manage our growth;
- our ability to successfully commercialize our products;
- our ability to obtain regulatory approvals and market and sell our products in certain jurisdictions;
- enforcement actions and product liability suits relating to off-label uses of our products;
- unsuccessful clinical trials or procedures relating to products under development;
- our ability to maintain compliance with regulatory requirements;
- mandatory or voluntary product recalls;
- shutdowns of the U.S. federal government;
- third-party payers' failure to provide reimbursement of our products;
- changes in healthcare reimbursement systems in the U.S. and other foreign jurisdictions;
- our failure to comply with healthcare "fraud and abuse" laws;
- our failure to comply with the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations;
- uncertainties associated with our product development efforts;
- our ability to increase manufacturing capacity to support continued demand for our products;
- our or our vendors' failure to achieve and maintain high manufacturing standards;
- our ability to attract and retain key personnel;
- our suppliers' failure to provide the components we require;
- our ability to expand our direct sales activities into international markets;
- the economic effects of "Brexit";
- poor performance of our distributors in the international markets;
- our ability to sustain profitability;
- our potential "ownership change" for U.S. federal income tax purposes and our limited utilization of net operating losses from prior tax years;
- impact of changes in tax laws, including recently enacted U.S. Tax Reform;
- our ability to develop and commercialize new products or acquire desirable companies, products or technologies;
- our failure to protect our intellectual property or develop or acquire additional intellectual property;

- increased risk of material product liability claims;
- inventory write-downs and other costs due to product quality problems;
- liabilities due to failure to protect the confidentiality of patient health information;
- disruptions of critical information systems or material breaches in the security of our systems;
- risks and liabilities associated with acquisitions of other companies or businesses;
- changes in accounting standards, tax laws and financial reporting requirements;
- changes in methods, estimates and judgments we use in applying our accounting policies;
- liabilities, expenses and restrictions associated with environmental and health safety laws;
- fluctuations in foreign currency exchange rates; and
- other factors discussed in “Part I, Item 1A. Risk Factors” of this report.

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. Any forward-looking statement made in this report speaks only as of the date hereof. 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 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*

Corporate Background

Our Company was founded in 1981 and is 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, our annual reports 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 or furnishing such reports to the U.S. Securities and Exchange Commission, or SEC. We also use our website for the distribution of Company information. The information we post on our website may be deemed to be material information. Accordingly, investors should monitor our website, in addition to following our press releases, SEC filings and public conference calls and webcasts. The contents of our website are not incorporated by reference into this report.

Our Company

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. We expect that all of our product and service revenue in the near future will be from our Impella devices.

Our Impella 2.5, Impella 5.0, Impella LD, Impella CP and Impella RP devices have U.S. Food and Drug Administration, or FDA, CE Mark and Health Canada approval, which allows us to market these devices in the U.S., European Union and Canada. Our Impella 2.5, Impella 5.0 and Impella CP devices have regulatory approval from the Japanese Ministry of Health Labour & Welfare, or MHLW. We expect to continue to make additional premarket approval, or PMA, supplement submissions for our Impella portfolio of devices for additional indications.

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.

In March 2015, we received a PMA from the FDA for the use of the Impella 2.5 device during elective and urgent high-risk percutaneous coronary intervention, or PCI, procedures. With this PMA, the Impella 2.5 device became the first FDA approved hemodynamic support device for use during high-risk PCI procedures. Under this 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 PMA supplement for certain of our devices, including our Impella 2.5 device, 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. The Impella 2.5 catheter, in conjunction with the Automated Impella Controller, or AIC, was approved as a temporary ventricular support device intended for short term use (≤ 4 days) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction 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 convention treatment measures include volume loading and use of pressors and inotropes, with or without an intra-aortic balloon pump, or IABP.

In September 2016, we received Pharmaceuticals and Medical Device Agency, or PMDA, approval from the Japanese Ministry of Health, Labour & Welfare, or MHLW, for our Impella 2.5 heart pump 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 heart pump. Reimbursement in Japan for the Impella 2.5 is equivalent to our average Impella sales price in the U.S.

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

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.

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 April 2016, the FDA approved a PMA supplement for certain of our devices, including our Impella CP device, 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. The Impella CP catheter, in conjunction with the AIC, was approved as a temporary ventricular support device intended for short term use (≤ 4 days) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction 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 convention treatment measures include volume loading and use of pressors and inotropes, with or without an intra-aortic balloon pump, or IABP.

In December 2016, the FDA expanded a previously received PMA that granted approval for the use of the Impella CP device during elective and urgent high-risk PCI procedures in the U.S. With this indication, the Impella CP and the Impella 2.5 devices provide the only minimally invasive treatment options indicated for use during high-risk PCI procedures in the U.S.

In February 2018, we received two expanded PMAs from the FDA for certain of our Impella heart pumps. The first expanded PMA includes the Impella CP heart pump for use on patients with cardiogenic shock associated with cardiomyopathy, including peripartum and postpartum cardiomyopathy. The second expanded PMA includes the Impella CP heart pump for use during elective and high-risk PCI procedures, and it confirms Impella support as appropriate in patients with severe coronary artery disease, complex anatomy and extensive comorbidities, with or without depressed ejection fraction. These PMAs allow the Impella CP to be used as a temporary (≤ 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.

In April 2018, we received FDA approval for our Impella CP SmartAssist™ platform. The SmartAssist platform includes optical sensor technology for improved positioning, the use of algorithms that enable improved native heart assessment during the weaning process and cloud-based technology that enables secure, real-time, remote viewing of the Impella console for physicians and hospital staff from anywhere with internet connectivity. The platform is intended to provide enhanced monitoring capability, reduce setup time and improve ease of use for physicians. The SmartAssist platform is also approved under CE Mark in the European Union and other countries that require a CE Mark approval. We have begun a controlled roll-out of the SmartAssist platform at certain hospital sites.

In November 2018, we announced the results of our FDA approved prospective multi-center feasibility study, "STEMI Door to Unloading with Impella CP system in acute myocardial infarction" (STEMI DTU). The trial focused 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, enrolled 50 patients at 10 sites. 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. The intent of this study was to 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.

In April 2019, the FDA approved the initiation of the STEMI DTU pivotal randomized controlled trial. The prospective, multi-center, two-arm trial plans to enroll 668 patients undergoing treatment for a STEMI heart attack. Half the patients will be randomized to receive delayed reperfusion after 30 minutes of left ventricular unloading with the Impella CP. The other half will receive immediate reperfusion, the current standard of care. The trial will test the hypothesis that unloading the left ventricle for 30 minutes prior to reperfusion will reduce myocardial damage from a heart attack and lead to a reduction in future heart failure related events. We expect this trial to begin in October 2019 and we estimate that it will take three to four years to complete enrollment. The trial allows for an adaptive design, which permits adjustments to the study sample size after an interim analysis.

In March 2019, we received PMDA approval from MHLW for our Impella CP heart pump in Japan. We expect to start selling the Impella CP heart pump as an additional product offering in Japan later in calendar year 2019.

The Impella CP device has CE Mark approval in the European Union and other countries that require a CE Mark approval for up to five days of use.

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 a 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 devices are normally used by 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.

In April 2016, the FDA approved a PMA supplement for certain of our devices, including our 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. The Impella 5.0 and LD catheters, in conjunction with the AIC, were approved as temporary ventricular support devices intended for short term use ($\leq$ 6 days) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction 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.

In September 2016, we received PMDA approval from the Japanese MHLW for our Impella 5.0 heart pump to provide treatment of drug-resistant acute heart failure in Japan. In July 2017, we received approval from the Japanese MHLW for reimbursement for the Impella 5.0 heart pump. Reimbursement in Japan for the Impella 5.0 is equivalent to our average Impella sales price in the U.S.

In February 2018, we received an expanded PMA from the FDA for use of the 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, 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.

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 September 2017, we received a PMA from the FDA for the Impella RP heart pump. This latest approval follows the prior FDA humanitarian device exemption, or HDE, received in January 2015 and adds the Impella RP heart pump to our platform of devices with PMAs. 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 ≥1.5 m^2 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 January 2019, we proactively sent physicians who use Impella RP post-approval study data that provides additional evidence of the benefits of following proper protocols for placement of Impella RP such as early placement and following proper inclusion and exclusion criteria when selecting patients for Impella RP. In February 2019, the FDA released a letter to health care providers on the Impella RP heart pump reiterating to physicians to follow proper protocols for the use of Impella RP. In March 2019, we presented survival data from the 18-month post-approval study of 42 Impella RP patients at the American College of Cardiology's Annual Scientific Session. This interim post-approval study data showed an improved survival rate for cardiogenic shock patients who followed the Recover Right protocol, which are patients who met the inclusion and exclusion criteria of the Recover Right FDA PMA trial, when compared to salvage patients outside the Recover Right protocol (>48 hours in cardiogenic shock from right side failure). In May 2019, the FDA issued an update to its February 2019 letter to inform the health care community of these interim post-approval study results which validated that the Impella RP heart pump is safe and effective for the treatment of right heart failure. The data showed a 64% survival rate and 90% heart recovery for the subgroup of PAS patients who met the enrollment criteria of Impella RP's premarket clinical studies. Impella RP is the most studied right-sided device and the only percutaneous technology with FDA approval designating it as safe and effective for right heart support.

The Impella RP device has CE Mark approval for commercial sale in the European Union and other countries that require a CE Mark approval from 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. The Impella 5.5 pump has not been approved for commercial use or sale in the U.S. We hope to receive regulatory approval of the Impella 5.5 in the U.S. in calendar year 2019.

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 expect to conduct a first-in-human trial outside of the U.S. in fiscal year 2020. The Impella ECP pump is still in development and has not been approved for commercial use or sale.

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.

Our Markets

According to the American Heart Association, or AHA's Heart Disease and Stroke Statistics 2019 Update Report, coronary heart disease, or CHD, is the number one cause of death in the U.S. According to the 2019 updated report, 47% of women and 36% of men over the age of 45 will die within five years of their first heart attack, and 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.

Percutaneous assist devices, like the Impella portfolio of devices, are mechanical devices that help the failing heart pump blood or take over the pumping function of the failing heart. 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. 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. 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, 2019, our research and development staff consisted of 235 full-time employees. We expended $93.5 million, $75.3 million and $66.4 million on research and development in fiscal years 2019, 2018 and 2017, 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, 2019, our worldwide sales, clinical support, marketing and field service teams included 554 full-time employees, 443 of whom are in the U.S. and Canada and 111 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.

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 have recently expanded our manufacturing capacity in both our Aachen and Danvers facilities to support the growing demand for our Impella devices. We believe our existing manufacturing facilities provide sufficient physical capacity to produce sufficient quantities of products to meet anticipated demand for at least the next twelve months based on our current revenue forecast. We expect to 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 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, Impella ECP, and Impella BTR devices, are in the form of trade secrets and 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. Patents filed both in the U.S. and Europe generally have a life of 20 years from the filing date. Our U.S. and foreign patents have expiration dates ranging from 2019 to 2036. 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, our foreign patent estate may not adequately protect our technology.

The medical device industry is characterized by a large number of patents and by frequent and consequential 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 greater 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 cardiac assist 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, LivaNova, 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 hospitals 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. If governmental and private payers’ policies do not cover surgical procedures performed using our products, we may not be able to generate the revenues necessary to support our business.

Medicare payment may be made, in appropriate cases, for procedures performed in the in-patient hospital setting using our technology. Medicare generally reimburses hospitals 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. Thus, hospitals may decide not to use our products if reimbursement amounts are insufficient to cover any additional costs incurred when purchasing our products.

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 August 2018, CMS released final Medicare payment levels for CMS fiscal year 2019 (October 1, 2018 through September 30, 2019) under the Inpatient Prospective Payment System, or IPPS. Prior to October 1, 2018, Impella heart pump related procedures were previously assigned to Medical Severity Diagnosis Related Groups, or MS-DRGs 216-221 for assistance in the catheterization lab only. Effective October 1, 2018, the Impella heart pump uni-ventricular implantation is to be coded to MS-DRG 215, Other Heart Assist Systems Implant. CMS also eliminated the originally proposed reduction of 24% and concluded there would be no reduction versus the prior year for MS-DRG 215. The final rule on this topic, or the Final Rule, is effective for the year beginning October 1, 2018 for all Medicare hospital inpatient discharges. The Final Rule also maintains open and bi-ventricular Impella heart pump insertion with removal in MS-DRGs 1-2, the reimbursement rates of which were increased by 5%. Additionally, the reimbursement rates for MS-DRGs 268-269, covering Impella heart pump hospital transfer and support for the receiving hospital, were increased by 4%.

In April 2019, CMS released a proposed set of hospital payment levels for patient discharges after October 1, 2019. The April 2019 proposed rule, or the Proposed Rule, for the IPPS update includes ICD-10 coding and confirms assignment of percutaneous Impella implantation to MS-DRG 215 for Other Heart Assist System Implant. The Proposed Rule also maintains 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. The Proposed Rule proposes new payment levels for all hospital MS-DRGs, including those most relevant to Impella related procedures. The AHA and CMS have completed a system of care around the utilization of percutaneous heart pumps. The history and creation of this dedicated payment system with Impella implant/explant, bi-venticular and transfer reimbursement allows some of the most critically ill patients in the system to have the potential to survive and improve/achieve native heart recovery. The IPPS also continues to recognize the exclusive FDA approvals and recent expansion of indications for high-risk PCI, cardiogenic shock, and bi-ventricular heart support. The MS-DRG 215 proposed rate is lower than that of 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 2019. The final rulemaking may differ substantially from this proposal and will take effect for the year beginning October 1, 2019.

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. Physicians may choose not to use our products if reimbursement amounts do not justify the additional costs expended when employing our products.

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. In March 2019, we receive PMDA approval for our Impella CP pump. We commenced commercialization in Japan in September 2017 and are continuing our controlled launch of Impella in Japan.

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 FFDCA. 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 delays that adversely affect the marketing and sale of our products. Some 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 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 FFDCA. 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 investigational device exemption, or 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 FFDCA 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 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 from the FDA for the Impella RP heart pump. In February 2018, we received an expanded FDA PMA 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 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 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 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 and security 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;
- domestic and foreign laws and regulations that protect personal data, such as the European Union's General Data Protection Regulation, or the GDPR, that require, among other things, consent to process personal data of individuals, disclosures to individuals regarding the processing of personal data, the security and confidentiality of personal data and notification in the event of data breaches;
- 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 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 material costs and expenses associated with investigation enforcement activities, and individual settlement agreements that impose a government monitor for a period of several years.

Other Regulations

We are also subject to various local, state, federal, and international 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. We believe we have been, and we are in compliance with all applicable laws and regulations (including environmental laws and regulations). We currently have no liabilities under such requirements that could reasonably be expected to materially harm our business, results of operations or financial condition.

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, 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. With the enactment of the Tax Cuts and Jobs Act in December 2017, the ACA's former individual mandate penalty for not having health insurance coverage has been eliminated.

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, in light of the stated policies of the U.S executive administration and actions of certain members of the U.S. Congress, the outlook for ACA-compliant insurance plans is still uncertain. The current U.S. executive administration has encouraged 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. While any legislative and regulatory changes will likely take time to develop and may or may not have an impact on the regulatory regime to which we are subject, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

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 47%, 45%, and 46% of total fiscal year net sales for fiscal 2019, 2018 and 2017, 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 for our products.

Employees

As of March 31, 2019, we had 1,371 full-time employees, including:

- 235 in product engineering, research and development, clinical development and regulatory;
- 554 in sales, clinical support, marketing, field service and related support;
- 457 in manufacturing; and
- 125 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*

You should carefully consider the following risks and all other information set forth in this report, including, without limitation, our consolidated financial statements and the related notes thereto and "Part II, Item 7. Management Discussion and Analysis of Financial Condition and Results of Operations." 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.

Risks Related to Our Business

We depend on Impella® products and services for all 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 and related services. 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 of our Impella devices and services. Our ability to generate revenues from our Impella devices and services 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;
- announcements by the FDA relating to our products and their impact on market perception of our product, including short-term impact;
- lack of acceptance or continued acceptance by physicians, hospitals, or patients;
- our reliance on specialized suppliers for certain components and materials;
- manufacturing or quality control problems;
- reputational risk relating to customer reviews of our products;
- 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 greater 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;
- our ability to complete clinical trials and regulatory approval processes;

- success and timing of new product development and introductions;
- physician and hospital acceptance of our products and the amount of time to convert physicians and hospitals into users of our products;
- reimbursement approval from health care insurance providers and the cost-effectiveness of these reimbursements to our hospital customers;
- penetration into existing and new geographic markets; and
- intellectual property protection.

Our customers are primarily hospitals that have limited budgets. Physicians endorse our products to hospitals that will then choose to purchase our products and subsequently pass the cost on to patients. Physicians will recommend our products based on public information regarding patient outcomes, clinical trials, and the costs and benefits of using our products when compared to other substitutes available in the market. 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 and maintain 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 cardiac assist 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.

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 in light of reimbursement policies with respect to our products. 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 due to training and education regarding the use of the products. Hospitals also need to perform internal 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 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 operational resources. In order to achieve our business objectives, we will need to continue to grow. However, continued growth presents numerous challenges, including:

- developing and retaining 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 existing products and products under development is unproven, and we may be unable to successfully commercialize our products.

Our existing products, which have received regulatory approval for commercialization only in the last few years, and our products under development may not enjoy commercial acceptance or success, thus adversely affecting our business and operational results. We need to create new indications 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 must gain and maintain 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;
- willingness of physicians to recommend the use of our product;
- timing and amount of reimbursement for these products, if any, by third-party payers, and the cost-effectiveness of using our products by our customers given these reimbursement considerations;
- 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, recall or withdrawal, 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 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 other requirements, the interpretation of which can change. Compliance with QSR and similar legal requirements can be difficult and expensive. While we continue to monitor our quality management in order to improve our overall level of compliance, our facilities are subject to periodic and unannounced inspection by U.S. and foreign regulatory agencies to audit compliance with the QSR and comparable foreign regulations. 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 of 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.

Shutdowns of the U.S. federal government could materially impair our business and financial condition.

Development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, CMS and the SEC, have had to furlough their government employees and stop critical activities. If a prolonged government shutdown or budget sequestration occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to communicate with the SEC on various topics, such as shareholder proposals, or to have our registration statements declared effective, which could affect our ability to access the capital markets quickly.

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 August 2018, CMS released final Medicare payment levels for CMS fiscal year 2019 (October 1, 2018 through September 30, 2019) under the Inpatient Prospective Payment System, or IPPS. Prior to October 1, 2018, Impella heart pump related procedures were previously assigned to Medical Severity Diagnosis Related Groups, or MS-DRGs 216-221 for assistance in the catheterization lab only. Effective October 1, 2018, the Impella heart pump uni-ventricular implantation is to be coded to MS-DRG 215, Other Heart Assist Systems Implant. CMS also eliminated the originally proposed reduction of 24% and concluded there would be no reduction versus the prior year for MS-DRG 215. The final rule on this topic, or the Final Rule, is effective for the year beginning October 1, 2018 for all Medicare hospital inpatient discharges. The Final Rule also maintains open and bi-ventricular Impella heart pump insertion with removal in MS-DRGs 1-2, the reimbursement rates of which were increased by 5%. Additionally, the reimbursement rates for MS-DRGs 268-269, covering Impella heart pump hospital transfer and support for the receiving hospital, were increased by 4%.

In April 2019, CMS released a proposed set of hospital payment levels for patient discharges after October 1, 2019. The April 2019 proposed rule, or the Proposed Rule, for the IPPS update includes ICD-10 coding and confirms assignment of percutaneous Impella implantation to MS-DRG 215 for Other Heart Assist System Implant. The Proposed Rule also maintains 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. The Proposed Rule proposes new payment levels for all hospital MS-DRGs, including those most relevant to Impella related procedures. The AHA and CMS have completed a system of care around the utilization of percutaneous heart pumps. The history and creation of this dedicated payment system with Impella implant/explant, bi-ventricular and transfer reimbursement allows some of the most critically ill patients in the system to have the potential to survive and improve/achieve native heart recovery. The IPPS also continues to recognize the exclusive FDA approvals and recent expansion of indications for high-risk PCI, cardiogenic shock, and bi-ventricular heart support. The MS-DRG 215 proposed rate is lower than that of 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 2019. The final rulemaking may differ substantially from this proposal and will take effect for the year beginning October 1, 2019.

In addition, third-party payers are increasingly requiring evidence that medical devices are cost-effective. If we are unable to demonstrate that our devices are cost-effective, 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 Patient Protection and 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 significant portions of the ACA could be repealed or revised. Recent tax reform legislation removed the financial penalty for individuals who do not have health insurance effective in 2019, a change that likely will result in fewer individuals electing to purchase health insurance. 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. For example, CMS has indicated that it intends to increase flexibility in state Medicaid programs, including by expanding the scope of waivers under which states may implement Medicaid expansion provisions, imposing different eligibility or enrollment restrictions, or otherwise implementing programs that vary from federal standards

Any such future actions may have significant impact on the reimbursement for healthcare services generally, including reducing significantly the number of individuals who have health insurance that can pay for our products, which could lead our health care provider customers to be more cost conscious. At the same time, certain members of the U.S. Congress have proposed measures that would expand the role of government-sponsored coverage, including single payer or so-called "Medicare-for-All" proposals, which could have far-reaching implications for the healthcare industry if enacted. Such a system could reduce our customers' revenues, such as Medicare and other public reimbursement rates, on average could be lower than existing commercial health plan reimbursement rates. Even if legislation creating such a single-payer system is not enacted in the near term, continued introduction of legislation promoting a single-payer system by several members of the U.S. Congress could increase uncertainty for our customers and cause them to delay purchases of our products and services. 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 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, HIPAA;
- domestic and foreign laws and regulations that protect personal data, such as the E.U.'s GDPR, that require, among other things, consent to process personal data of individuals, disclosures to individuals regarding the processing of personal data, the security and confidentiality of personal data and notification in the event of data breaches;
- the 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.

To assist in our compliance efforts, we must 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. 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.

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 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.

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 continued to implement 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 select Impella sub-assembly production to our manufacturing facility in Danvers, Massachusetts and to third-party suppliers. We have 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 outsourcing 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 and divert remaining management's attention to seeking qualified replacements. Our ability to attract, train 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, train 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 excess 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, Singapore and Australia 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;
- uncertainty with respect to enforcement of legal rights by local regulatory or judicial authorities;
- 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;
- the adoption and expansion of trade restrictions, including the occurrence or escalation of a "trade war," or other governmental action related to tariffs or trade agreements or policies among the governments of the United States, China and other countries;
- regulatory changes and economic conditions leading up to and following "Brexit" (the United Kingdom's exit from the European Union), including uncertainties as to its timing and its effect on trade laws, tariffs and taxes;
- 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.

The economic effects of "Brexit" may affect relationships with existing and future customers and could have an adverse impact on our business and operating results.

On June 23, 2016, the United Kingdom, or the U.K., held a referendum in which voters approved an exit from the E.U., commonly referred to as "Brexit." While the U.K. and the E.U. were expected to reach an agreement by March 2019, political changes in the U.K. following the "Brexit" referendum and other factors leave it unclear when exactly the U.K. will exit and on what terms. The impact on us from Brexit will depend, in part, on the outcome of tariff, trade, regulatory and other negotiations. Because this is an unprecedented event, it is unclear what long-term economic, financial, trade and legal implications the withdrawal of the U.K. from the E.U. would have and how such withdrawal would affect the regulation applicable to our business globally and specifically in the region.

As a result of Brexit, the global markets and currencies have been adversely impacted, including a decline in the value of the British pound as compared to the U.S. dollar. A potential devaluation of the local currencies of our international buyers relative to the U.S. dollar may impair the purchasing power of our international buyers and could cause international buyers to decrease their participation in our marketplaces or use of our products. Further, volatility in exchange rates resulting from Brexit is expected to continue in the short term as the U.K. negotiates its exit from the E.U. We translate sales and other results of our activities in the U.K. denominated in British pounds into U.S. dollars for our financial statements. During periods of a strengthening dollar, our reported international sales and earnings could be reduced because foreign currencies may translate into fewer U.S. dollars. Finally, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate, and those laws and regulations may be cumbersome, difficult or costly in terms of compliance. Any of these effects of Brexit, among others, could adversely affect our business, financial condition, operating results and cash flows.

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 $259.0 million, $112.2 million and $52.1 million for the fiscal years ended March 31, 2019, 2018 and 2017, 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 PMAs 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., European and Japanese 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;
- announcements by the FDA relating to our products and their impact on market perception of our product, including short-term impact;
- reputational risk relating to customer reviews of our products;
- 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;
- gains or losses on our portfolio investments, such as Shockwave;
- 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, 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 Act, 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. Guidance issued by the SEC provided a measurement period of one year from the enactment date to finalize the accounting for effects of the Tax Reform Act. In fiscal 2018, we made a provisional estimate of the effects of the Tax Reform Act on our existing deferred tax balances. In fiscal 2019 the measurement period ended, and no adjustments were made to the Company's provisional estimate of the impacts of the Tax Reform.

The U.S. Treasury Department, the Internal Revenue Service and other standard-setting bodies could interpret or issue guidance on how provisions of the Tax Reform Act will be applied or otherwise administered that is different from our interpretation. Finally, foreign governments may enact tax laws in response to the Tax Reform Act that could result in further changes to global taxation and materially affect our financial position and results of operations. The uncertainty surrounding the effect of the reforms on our financial results and business could also weaken confidence among investors in our financial condition. This could, in turn, have a materially adverse effect on the price of our common stock.

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. We currently have no debt, and new sources of capital may not be available to us when we need it or may be available only on terms we would find unacceptable. 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 based on available working capital and cash from operations. 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 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 and 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 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, 2019, please see "Note 12. Commitment and Contingencies – Contingencies" to our consolidated financial statements in this report, 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. We have been and anticipate that as part of our ordinary course of business we may be, subject to product liability claims alleging defects in the design, manufacture or labeling of our products. 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 or our existing products and introduce more products, we face an increased risk that a material 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 inventory write-downs and other costs.

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 of inventory, injure our reputation and harm our business and financial results.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

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 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 or any of our service providers are found to be in violation of the promulgated patient privacy rules under HIPAA or the GDPR, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating 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, or IT, to store information, communicate with our business partners, 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.

In the current environment, there are numerous and evolving risks to cybersecurity and privacy, including criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, employee malfeasance and human or technological error. High-profile security breaches at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyber-attacks targeting businesses such as ours. Cyber-attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclosure information or unwittingly provide access to systems or data.

We have experienced and expect to continue to experience actual or attempted cyber-attacks of our IT systems or networks. However, none of these actual or attempted cyber-attacks has had a material effect on our operations or financial condition. 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, our customer confidence could be diminished, and our operations, including technical support for our devices, 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. Any of these may contribute to the loss of customers and have a material adverse effect on the Company.

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. 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 sizable expenses in integrating the operations and personnel of the acquired company into our operations. 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. Furthermore, we may acquire development-stage companies that are not yet profitable, and that 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 Entwicklungsgesellschaft mbH, or 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 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 investments in medical device companies was $80.8 million and $12.6 million at March 31, 2019 and 2018, respectively, and is classified within other assets in the consolidated balance sheets. During the years ended March 31, 2019 and 2018 the Company made investments of $39.9 million and $6.4 million, respectively, in medical device companies.

Revisions to accounting standards, tax laws and financial reporting 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, tax laws and financial reporting requirements set by the governing bodies and lawmakers in the U.S. and in other jurisdictions where we do business. From time to time, these governing bodies and lawmakers implement new and revised rules and laws, which may require changes to our accounting policies, financial reporting, and the related information we file with governing bodies. Implementing mandatory changes may require a significant expenditure of time, attention and resources. It is impossible to completely predict the impact, if any, of future changes to accounting standards and financial reporting requirements.

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 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. 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;
- announcements by the FDA relating to our products and their impact on market perception of our product, including short-term impact;
- reputational risk relating to customer reviews of 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 in Danvers, Massachusetts. The locations and uses of our major properties as of March 31, 2019, are listed below:

Location		Function
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, distribution, manufacturing, 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.

In February 2017, we acquired our existing European headquarters in Aachen, Germany, consisting of 33,000 square feet of space. The total acquisition cost for the land and building was approximately $12.6 million.

(2) Leased properties

In February 2017, we entered into a lease agreement to rent additional office and logistics space in Danvers, Massachusetts. We have entered into additional amendments to this lease agreement in which we have leased 63,343 square feet in total at this location through September 30, 2027. We also have a right of first offer to purchase the property from January 1, 2018 through August 31, 2035.

In September 2016, the Company entered into a lease agreement for an office in Berlin, Germany which commenced in May 2017 and expires in May 2024.

In October 2016, the Company 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 capacity to support our business operations.

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, 2019, please see "Note 12. Commitment and Contingencies – 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 Information

Our common stock is traded on the NASDAQ Global Market under the symbol "ABMD."

Stockholders

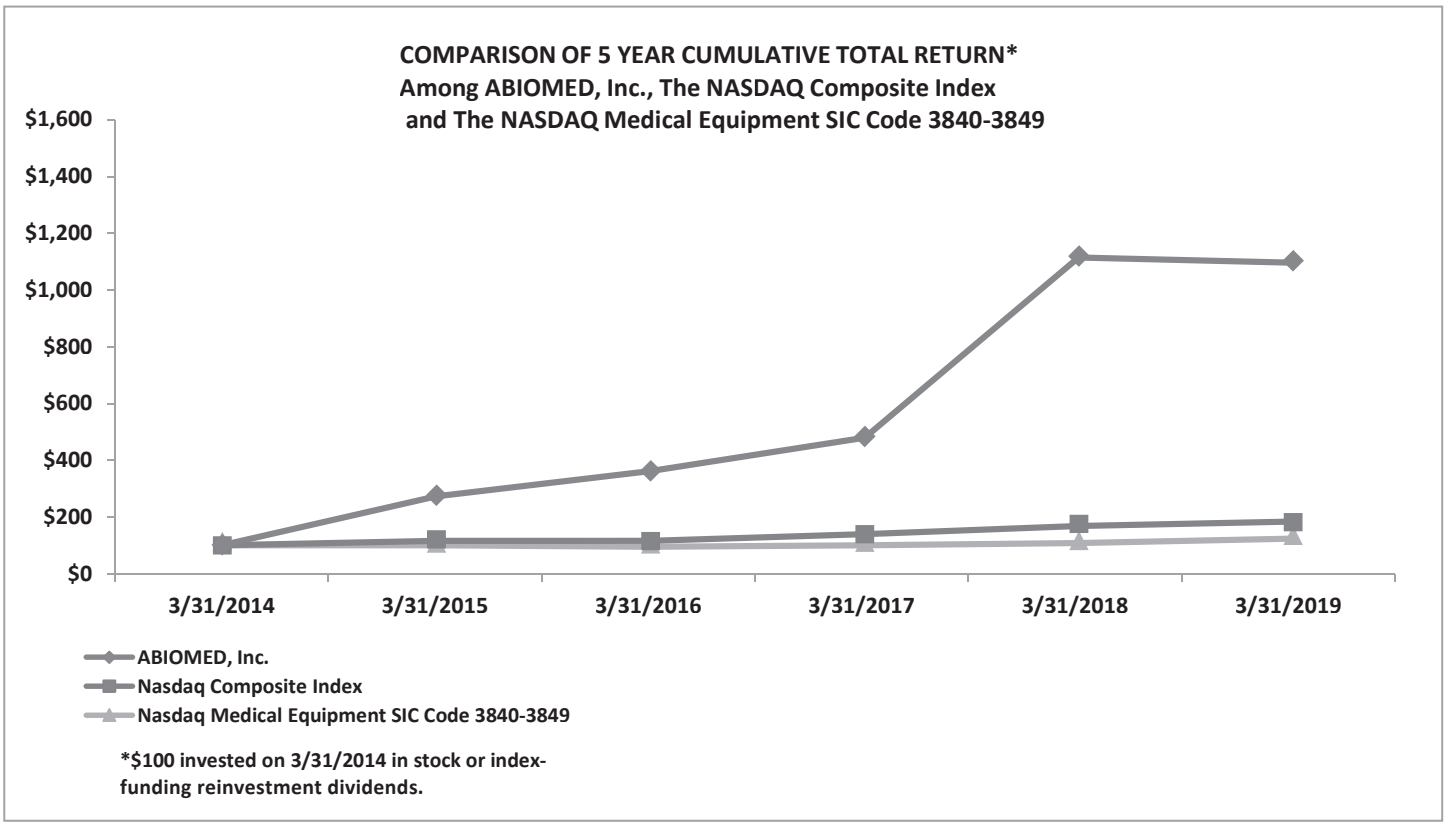
As of May 10, 2019, we had approximately 422 holders of record of our common stock, including Cede & Co., the nominee of the Depository Trust Company. The number of record holders may not be representative of the number of beneficial owners of our common stock, whose shares are held in street name by banks, brokers and other nominees.

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, 2014 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 ($)					
	3/31/2014	3/31/2015	3/31/2016	3/31/2017	3/31/2018	3/31/2019
ABIOMED, Inc.	100	275	364	481	1,117	1,097
Nasdaq Composite Index	100	117	116	141	168	184
Nasdaq Medical Equipment SIC Code 3840-3849	100	100	97	100	109	124

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.

ITEM 6. *SELECTED FINANCIAL DATA*

The following tables set forth, for the periods and at the dates indicated, our selected historical consolidated financial data. We have derived the selected consolidated financial data for the years ended March 31, 2019, 2018 and 2017, and as of March 31, 2019 and 2018, from our audited consolidated financial statements appearing elsewhere in this report. We have derived the selected consolidated financial data for the years ended March 31, 2016 and 2015, and as of March 31, 2017, 2016 and 2015 from our consolidated financial statements not appearing elsewhere in this report. Our historical results are not necessarily indicative of the results we may achieve in any future period. You should read the following information together with the more detailed information contained in "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the accompanying notes appearing elsewhere in this report.

SELECTED CONSOLIDATED FINANCIAL DATA

(In thousands, except per share data)

	Fiscal Years Ended March 31,				
Statement of Operations Data:	**2019**	**2018**	**2017**	**2016**	**2015**
Revenue	$ 769,432	$ 593,749	$ 445,304	$ 329,543	$ 230,311
Costs and expenses:					
Cost of revenue	129,567	98,581	70,627	50,419	39,945
Research and development	93,503	75,297	66,386	49,759	35,973
Selling, general and administrative	321,550	262,734	218,153	164,261	125,727
	544,620	436,612	355,166	264,439	201,645
Income from operations	224,812	157,137	90,138	65,104	28,666
Other income (expense):					
Investment income, net	8,166	3,688	1,554	395	196
Other income (expense), net (1)	30,382	(388)	(349)	339	(97)
	38,548	3,300	1,205	734	99
Income before income taxes	263,360	160,437	91,343	65,838	28,765
Income tax provision (benefit) (2)(3)(4)	4,344	48,267	39,227	27,691	(84,923)
Net income	$ 259,016	$ 112,170	$ 52,116	$ 38,147	$ 113,688
Basic net income per share	$ 5.77	$ 2.54	$ 1.21	$ 0.90	$ 2.80
Basic weighted average shares outstanding	44,911	44,153	43,238	42,204	40,632
Diluted net income per share	$ 5.61	$ 2.45	$ 1.17	$ 0.85	$ 2.65
Diluted weighted average shares outstanding	46,151	45,849	44,658	44,895	42,858
Balance Sheet Data:					
Cash, cash equivalents, short and long term marketable securities	$ 513,416	$ 399,751	$ 277,091	$ 213,053	$ 145,954
Working capital (5)	571,199	409,589	257,341	241,851	145,720
Total assets	1,054,346	786,375	550,414	423,931	338,367
Stockholders' equity	936,890	689,524	452,071	368,775	291,560

(1) In fiscal 2019, the Company invested $25.0 million in Shockwave Medical, a medical device company. The fair value of this investment as of March 31, 2019 was $56.2 million and the Company recognized a gain of $31.2 million in Other income.

(2) The Tax Reform Act, among other items, reduced 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.

(3) In 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 provision for the years ended March 31, 2019 and 2018 included excess tax benefits of $69.3 million and $31.0 million, respectively. These recognized excess tax benefits resulted from restricted stock units that vested or stock options that were exercised during the years ended March 31, 2019 and 2018.

(4) Income tax benefit for the year ended March 31, 2015 was impacted by the release of the $101.5 million valuation allowance on certain deferred tax assets.

(5) 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."

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

You should read the following discussion and analysis of our financial condition and results of operations together with our "Selected Financial Data" and the consolidated financial statements and the related notes included elsewhere in "Financial Statements and Supplementary Data." Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should read "Part I, Item 1.A Risk Factors" in this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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. We expect that all of our product and service revenue in the near future will be from our Impella devices.

Our Impella 2.5, Impella 5.0, Impella LD, Impella CP and Impella RP devices have FDA, CE Mark and Health Canada approval, which allows us to market these devices in the U.S., European Union and Canada. Our Impella 2.5, Impella 5.0 and Impella CP devices have regulatory approval from the MHLW. We expect to continue to make additional PMA supplement submissions for our Impella portfolio of devices for additional indications.

In July 2017, we received approval from the MHLW for reimbursement for the Impella 2.5 and 5.0 heart pumps in Japan. Reimbursement in Japan for the Impella 2.5 and 5.0 is equivalent to our average Impella sales price in the U.S. We continue to focus on our controlled commercial launch of Impella devices in Japan.

In September 2017, we received a PMA from the FDA 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 m², 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.

In February 2018, we received two expanded PMAs from the FDA for our Impella heart pumps. The first expanded approval is for use of Impella 2.5, Impella CP, Impella 5.0 and Impella LD heart pumps on patients with cardiogenic shock associated with cardiomyopathy, including peripartum and postpartum cardiomyopathy. The second expanded PMA is for use of the Impella 2.5 and Impella CP heart pumps during elective and high-risk PCI procedures. This expanded PMA 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 our Impella CP SmartAssist™ platform. The SmartAssist platform includes optical sensor technology for improved positioning, the use of algorithms that enable improved native heart assessment during the weaning process and cloud-based technology that enables secure, real-time, remote viewing of the Impella console for physicians and hospital staff from anywhere with internet connectivity. The platform is intended to provide enhanced monitoring capability, reduce setup time and improve ease of use for physicians. The SmartAssist platform is also approved under CE Mark in the European Union and other countries that require a CE Mark approval. We have begun a controlled roll-out of the SmartAssist platform at certain hospital sites.

In November 2018, we announced the results of our FDA-approved prospective multi-center feasibility study, "STEMI Door to Unloading with Impella CP system in acute myocardial infarction" (STEMI DTU). The trial focused 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, enrolled 50 patients at 10 sites. 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 initiates a cardio-protective effect at the myocardial cell level, which may alleviate myocardial damage caused by reperfusion injury at the time of revascularization. The intent of this study was to 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.

In April 2019, the FDA approved the initiation of the STEMI DTU pivotal randomized controlled trial. The prospective, multi-center, two-arm trial plans to enroll 668 patients undergoing treatment for a STEMI heart attack. Half the patients will be randomized to receive delayed reperfusion after 30 minutes of left ventricular unloading with the Impella CP. The other half will receive immediate reperfusion, the current standard of care. The trial will test the hypothesis that unloading the left ventricle for 30 minutes prior to reperfusion will reduce myocardial damage from a heart attack and lead to a reduction in future heart failure related events. We expect this trial to begin in October 2019 and we estimate that it will take three to four years to complete enrollment. The trial allows for an adaptive design, which permits adjustments to the study sample size after an interim analysis.

In January 2019, we proactively sent physicians who use Impella RP post-approval study data that provides additional evidence of the benefits of following proper protocols for placement of Impella RP such as early placement and following proper inclusion and exclusion criteria when selecting patients for Impella RP. In February 2019, the FDA released a letter to health care providers on the Impella RP heart pump reiterating to physicians to follow proper protocols for the use of Impella RP. In March 2019, we presented survival data from the 18-month post-approval study of 42 Impella RP patients at the American College of Cardiology's Annual Scientific Session. This interim post-approval study data showed an improved survival rate for cardiogenic shock patients who followed the Recover Right protocol, which are patients who met the inclusion and exclusion criteria of the Recover Right FDA PMA trial, when compared to salvage patients outside the Recover Right protocol (>48 hours in cardiogenic shock from right side failure). In May 2019, the FDA issued an update to its February 2019 letter to inform the health care community of these interim post-approval study results which validated that the Impella RP heart pump is safe and effective for the treatment of right heart failure. The data showed a 64% survival rate and 90% heart recovery for the subgroup of PAS patients who met the enrollment criteria of Impella RP's premarket clinical studies. Impella RP is the most studied right-sided device and the only percutaneous technology with FDA approval designating it as safe and effective for right heart support.

In March 2019, we received PMDA approval from MHLW for our Impella CP heart pump in Japan. We expect to start selling the Impella CP heart pump as an additional product offering in Japan later in calendar year 2019.

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 in "Note 2. Basis of Preparation and Summary of Significant Accounting Policies" to our consolidated financial statements in this report.

Revenue Recognition

Effective April 1, 2018 we adopted ASU 2014-09 (“Topic 606”), “Revenue from Contracts with Customers”. For a discussion on the impact of this accounting policy adoption, including key accounting policy elections, see “Note 3. Revenue Recognition” to our consolidated financial statements in this report.

Revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration we expect to receive in exchange for transferring products or services to a customer.

Product revenue is generally recognized when the customer obtains control of our product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract.

Service revenue is generally recognized over time as the services are rendered to the customer based on the extent of progress towards completion of the performance obligation. We recognize service revenue over the term of the service contract. Services are expected to be transferred to the customer throughout the term of the contract and we believe recognizing revenue ratably over the term of the contract best depicts the transfer of value to the customer. Revenue generated from preventative maintenance calls is recognized at a point in time when the services are provided to the customer.

Revenue from the sale of products and services are evidenced by either a contract with the customer or a valid purchase order or an invoice which includes all relevant terms of sale. We perform a review of each specific customer's credit worthiness and ability to pay prior to acceptance as a customer. Further, we perform periodic reviews of customers' creditworthiness.

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 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. Basis of Preparation and Summary of Significant Accounting Policies” to our consolidated financial statements in this report.

Results of Operations for the Fiscal Years Ended March 31, 2019 and March 31, 2018 ("fiscal 2019" and "fiscal 2018")

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,	
	2019	2018
Revenue	100.0 %	100.0 %
Costs and expenses as a percentage of total revenue:		
Cost of revenue	16.8	16.6
Research and development	12.2	12.7
Selling, general and administrative	41.8	44.2
Total costs and expenses	70.8	73.5
Income from operations	29.2	26.5
Other income and income tax provision	(4.5)	7.6
Net income as a percentage of total revenue	33.7 %	18.9 %

Revenue

The following table disaggregates the Company's revenue by products and services:

	Fiscal Years Ended March 31,	
	2019	2018
	(in $000's)	
Impella product revenue	$ 741,699	$ 570,870
Service and other revenue	27,733	22,879
Total revenue	$ 769,432	$ 593,749

The following table disaggregates the Company's revenue by geographical location:

	Fiscal Years Ended March 31,	
	2019	2018
	(in $000's)	
U.S. revenue	$ 665,082	$ 526,685
International revenue	104,350	67,064
Total revenue	$ 769,432	$ 593,749

Impella product revenue encompasses Impella 2.5, Impella CP, Impella 5.0, Impella LD, Impella RP and Impella AIC console sales. Service and other revenue represents revenue earned on service maintenance contracts and preventative maintenance calls.

Total revenue for fiscal 2019 increased $175.7 million, or 30%, to $769.4 million from $593.7 million for fiscal 2018. Impella product revenue for fiscal 2019 increased by $170.8 million, or 30%, to $741.7 million from $570.9 million for fiscal 2018. Most of the increase in Impella product revenue was from increased 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 higher utilization in Germany and our controlled launch of Impella 2.5 and Impella 5.0 in Japan.

Service and other revenue for fiscal 2019 increased by $4.8 million, or 21%, to $27.7 million from $22.9 million for fiscal 2018. The increase in service and other revenue was primarily due to an increase in preventative maintenance service contracts. We expect growth for service and other revenue to be slower than our Impella product revenue in the near future as most of our U.S. customers have service contracts with three-year terms.

Costs and Expenses

Cost of Revenue

Cost of revenue for fiscal 2019 increased by $31.0 million, or 31%, to $129.6 million from $98.6 million for fiscal 2018. Gross margin was 83% for each of fiscal 2019 and fiscal 2018. The increase in cost of product revenue was related to higher demand for our Impella devices and higher production volume and costs to support growing demand for our Impella devices. There was a minimal difference in gross margin as the increased investment in manufacturing capacity was at a pace consistent with our revenue growth.

Research and Development Expenses

Research and development expenses for fiscal 2019 increased by $18.2 million, or 24%, to $93.5 million from $75.3 million for fiscal 2018. The increase in research and development expenses was primarily due to product development initiatives relating to our existing products, such as optical sensor technology, the development of Impella 5.5™ and Impella ECP™ devices and related product accessories, increased clinical spending primarily related to our cVAD Study and our continued focus on quality and regulatory 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 Study and launch the STEMI pivotal study 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 2019 increased by $58.9 million, or 22%, to $321.6 million from $262.7 million for fiscal 2018. 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 12. Commitment and Contingencies – Contingencies" to our consolidated financial statements in this report.

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 plan to increase our marketing, service and training investments as a result of recent PMAs 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 expect to have sizable stock-based compensation expense in the future. We also expect to continue to incur significant legal expenses in the foreseeable future related to ongoing patent litigation and other legal matters discussed in "Note 12. Commitment and Contingencies – Contingencies" to our consolidated financial statements in this report.

Other Income

Other income increased by $35.2 million, to $38.5 million for fiscal 2019, compared to $3.3 million for fiscal 2018. This increase was primarily due to the recognition of a $31.2 million gain from our investment in Shockwave Medical.

Income Tax Provision

The income tax provision decreased by $44.0 million, or 91%, to $4.3 million for fiscal 2019, compared to $48.3 million for fiscal 2018. Our effective income tax rate was 1.6% in fiscal 2019, and 30.1% in fiscal 2018. The decrease in the income tax provision and the effective tax rate for fiscal 2019 were primarily driven by $69.3 million in excess tax benefits in fiscal 2019, compared to $31.0 million in fiscal 2018. These excess tax benefits are related to the adoption of the new accounting standard for stock-based compensation on April 1, 2017, which requires restricted stock units that vested or stock options that were exercised during the year to be recorded in the statement of operations. The decrease in income tax provision was also due to the impact of the enactment of the Tax Reform Act, which resulted in a decrease in the federal statutory income tax rate applied of 21% in fiscal 2019 from a blended rate of 31.5% in fiscal 2018.

Net Income

In fiscal 2019, we recognized net income of $259.0 million, or $5.77 per basic share and $5.61 per diluted share. Net income in fiscal 2019 included excess tax benefits related to stock-based awards of $69.3 million, or $1.54 per basic share and $1.50 per diluted share, and a $23.6 million gain, net of tax, related to our investment in Shockwave Medical.

In fiscal 2018, we recognized net income of $112.2 million, or $2.54 per basic share and $2.45 per diluted share. Net income in fiscal 2018 included excess tax benefits related to stock-based awards of $31.0 million, or $0.70 per basic share and $0.68 per diluted share, and income tax expense of $21.4 million, or $0.48 per basic share and $0.47 per diluted share due to the effect of implementing the Tax Reform Act.

The increase in our net income for fiscal 2019 was also driven primarily by higher Impella product revenue due to greater utilization of our Impella devices in the U.S., Germany and Japan.

Results of Operations for the Fiscal Years Ended March 31, 2018 and March 31, 2017

For a comparison of our results of operations for the fiscal years ended March 31, 2018 and March 31, 2017, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our annual report on Form 10-K for the fiscal year ended March 31, 2018, filed with the SEC on May 24, 2018.

Liquidity and Capital Resources

At March 31, 2019, our total cash, cash equivalents, and short and long-term marketable securities totaled $513.4 million, an increase of $113.6 million compared to $399.8 million at March 31, 2018. The increase in our cash, cash equivalents, and short and long-term marketable securities was primarily due to positive cash flows from operations, offset by cash used for investments in property, equipment and other investments, and cash used for financing activities related to equity activity.

A summary of our cash flow activities is as follows:

	For the Year Ended March 31,	
	2019	2018
Net cash provided by operating activities	$ 252,197	$ 192,546
Net cash used for investing activities	(116,455)	(180,762)
Net cash used for financing activities	(55,775)	(9,137)
Effect of exchange rate changes on cash	(1,921)	1,288
Net increase in cash and cash equivalents	$ 78,046	$ 3,935

For a discussion of our liquidity and capital resources as of and our cash flow activities for the fiscal year ended March 31, 2017, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our annual report on Form 10-K for the fiscal year ended March 31, 2018, filed with the SEC on May 24, 2018.

Cash Provided by Operating Activities

For the year ended March 31, 2019, cash provided by operating activities consisted of net income of $259.0 million as discussed above, adjusted for non-cash items of $32.0 million less cash used in working capital of $38.8 million. Adjustments for non-cash items consisted primarily of $54.5 million of stock-based compensation expense, a change in fair value of our investments in medical technology companies of $30.2 million, a $7.7 million change in our deferred tax provision, $14.1 million of depreciation and amortization expense, $4.3 million in inventory and other write-downs and a change in fair value of contingent consideration of $0.9 million. The decrease in cash from changes in working capital included a $22.0 million increase in accounts receivable associated with higher revenues and a $37.2 million increase in inventory to support growing demand for our Impella devices offset by a $21.4 million increase in accounts payable and accrued expenses and a $1.5 million increase in deferred revenue.

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.

Cash Used for Investing Activities

For the year ended March 31, 2019, net cash used for investing activities included $29.7 million in purchases (net of maturities) of marketable securities and other and $44.0 million for the purchase of property and equipment mostly related to the continued expansion of manufacturing capacity, investments in enhancing information systems, and construction and renovation of office space and research and development facilities in Danvers and Aachen. We also made $42.7 million of investments in medical technology companies and intangible assets during fiscal 2019.

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, the continued expansion of manufacturing capacity, office space and research and development facilities in Danvers and Aachen, and investments in information systems. We also made $6.4 million of investments in medical technology companies during fiscal 2018.

Capital expenditures for fiscal 2020 are estimated to range from $50 million to $60 million, including additional capital expenditures for manufacturing capacity expansions in our Danvers and Aachen facilities, additional office space, building and leasehold improvements and information systems development projects.

Cash Used for Financing Activities

For the year ended March 31, 2019, net cash used for financing activities included $71.8 million in payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards offset by $12.9 million in proceeds from the exercise of stock options and $3.1 million in proceeds from the issuance of stock under the employee stock purchase plan.

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.

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 infrastructures, increase our manufacturing capacity, pay for 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, cover legal expenses related to ongoing patent litigation and other legal matters, cover payments in lieu of issuance of common stock for payroll withholding taxes upon vesting of certain equity awards and 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, our ability to maintain or reduce the length of the selling cycle for our products, our 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, 2019, we had no long-term debt outstanding.

Marketable securities at March 31, 2019 consisted of $392.4 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 $25.2 million and $13.3 million at March 31, 2019 and March 31, 2018, 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.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements or guarantees of third-party obligations during the periods presented. An "off-balance sheet arrangement" generally entails a transaction, agreement or other contractual arrangement to which an entity unconsolidated with us, is a party under which we have any obligation arising under a guarantee contract, derivative instrument or variable interest or a retained or contingent interest in assets transferred to such entity or similar arrangement that serves as credit, liquidity or market risk support for such assets.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at March 31, 2019 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

	Maturities of Payments Due (in $000's)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease commitments (1)	$ 14,274	3,398	4,712	2,876	3,288
Contractual obligations (2)	1,253	624	629	—	—
Total obligations	$ 15,527	4,022	5,341	2,876	3,288

(1) See "Note 12 Commitments and Contingencies – Commitments – Leases" to our consolidated financial statements in this report for disclosures related to our operating lease obligations.

(2) Contractual obligations represent future cash commitments under agreements with third parties, primarily for marketing and advertising arrangements.

ITEM 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES 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 marketable securities 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, corporate debt securities and commercial paper. The market value of our investments may decline if current market interest rates rise. Marketable securities as of March 31, 2019 consisted of $392.4 million. If market interest rates were to increase immediately and uniformly by 10% from levels as of March 31, 2019, we believe the decline in fair market value of our investment portfolio would be immaterial. Our marketable securities are recorded at fair value, and gains or losses from these securities are recognized as they occur. Any such declines would only result in a realized loss if we choose or are forced to sell the investments before their respective scheduled maturities, which we currently do not anticipate.

Foreign Currency Exchange Rate Risk

We have foreign currency exposure to exchange rate fluctuations and particularly with respect to the Euro, British pound sterling, Japanese yen, Singapore dollar and Australian 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 as of March 31, 2019, the result would have been a reduction of stockholders' equity of approximately $17.6 million.

Credit Risk

In the normal course of business, we provide credit to our 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 2019, we had no customers that represented 10% or more of our total revenue 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 medical device companies that focus on heart failure and heart pump technologies. We monitor any events or changes in circumstances that may have a significant effect on the fair value of our other investments, either due to impairment or based on observable price changes, and make any necessary adjustments. 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. In fiscal 2019, we invested $25.0 million in medical device company Shockwave Medical. The fair value of this investment as of March 31, 2019 was $56.2 million and we recognized a gain of $31.2 million in Other income. The aggregate carrying amount of our other investments was $80.8 million and $12.6 million at March 31, 2019 and 2018, respectively, and is classified within other assets on our consolidated balance sheets.

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 report.

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) and Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of March 31, 2019. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2019, 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, 2019, 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) and Rule 15d-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, 2019.

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, 2019, included in this 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, 2019, 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, 2019, 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, 2019, of the Company and our report dated May 23, 2019, 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 23, 2019

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

Not applicable.

PART III

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

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

ITEM 11. *EXECUTIVE COMPENSATION*

The information required by Item 11 is incorporated by reference herein from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this report.

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

The information required by Item 12 is incorporated by reference herein from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this report.

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

The information required by Item 13 is incorporated by reference herein from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this report.

ITEM 14. *PRINCIPAL ACCOUNTING FEES AND SERVICES*

The information required by Item 14 is incorporated by reference herein from our definitive proxy statement which will be filed no later than 120 days after the close of the fiscal year covered by this report.

PART IV

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

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

(1) The following financial statements are attached hereto.

(2) Consolidated financial statement schedule

Information is contained within "Note 5. 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		
			Form	Filing Date	Exhibit No.
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 Entwicklungsgellschaft 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	Amended & Restated By-Laws, as Amended and Restated February 5, 2019	X			
3.3*	Certificate of Designations of Series A Junior Participating Preferred Stock		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[P]	Specimen Certificate of common stock		S-1	June 5, 1987	4.1
4.2	Description of Common Stock	X			
10.1*[P]	Form – Indemnification Agreement for Directors and Officers		S-1	June 5, 1987	10.13
10.2*	Form – Employment, Nondisclosure and Non-Competition Agreement		10-K (File No. 001-09585)	May 24, 2018	10.28
10.3*	Form – TSR Award Agreement (Performance- and Time-Based RSU)		10-Q (File No. 001-09585)	August 6, 2015	10.4
10.4*	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

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
10.5*	Form – Change of Control Agreement		8-K (File No. 001-09585)	August 18, 2008	10.4
10.6*	1988 Employee Stock Purchase Plan, as Amended and Restated February 5, 2019	X			
10.7*	Second Amended & Restated 2015 Omnibus Incentive Plan		Sch. 14A (File No. 001-09585)	June 22, 2018	Appendix A
10.8*	Form – Time-Based RSU Agreement (Employee) under the 2015 Omnibus Incentive Plan		10-K (File No. 001-09585)	May 25, 2017	10.16
10.9*	Form –Time-Based RSU Agreement (Non-Employee Director) under the 2015 Omnibus Incentive Plan		10-Q (File No. 001-09585)	February 5, 2016	10.4
10.10*	Form – Time-Based RSU Agreement (Field Employee) under the 2015 Omnibus Incentive Plan		10-K (File No. 001-09585)	May 25, 2017	10.18
10.11*	Form – Performance-Based RSU Agreement (Employee) under the 2015 Omnibus Incentive Plan		10-K (File No. 001-09585)	May 25, 2017	10.19
10.12*	Form – Time-Based Stock Option Agreement (Employee) under the 2015 Omnibus Incentive Plan		10-K (File No. 001-09585)	May 25, 2017	10.43
10.13*	Form – Time-Based Stock Option Agreement (Non-Employee Director) under the 2015 Omnibus Incentive Plan		10-Q (File No. 001-09585)	February 5, 2016	10.7
10.14*	Employment Agreement – Michael R. Minogue dated April 5, 2004 (including Change in Control Agreement)		10-Q (File No. 001-09585)	August 9, 2004	10.10
10.15*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008		10-Q (File No. 001-09585)	February 9, 2009	10.3
10.16*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008		10-Q (File No. 001-09585)	February 9, 2009	10.4
10.17*	Offer letter with David Weber dated April 23, 2007		10-Q (File No. 001-09585)	August 9, 2007	10.1
10.18*	Offer letter with Todd A. Trapp dated March 30, 2018		10-K (File No. 001-09585)	May 24, 2018	10.43
10.19*	Change of Control Severance Agreement between ABIOMED, Inc. and Todd Trapp dated April 6, 2018		10-K (File No. 001-09585)	May 24, 2018	10.44
10.20	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
10.21	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

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
10.22	Notice of Exercise of Option to Buy, dated September 12, 2017, Relating to Purchase and Sale Agreement between ABIOMED, Inc. and Thibeault Nominee Trust		10-Q (File No. 001-09585)	November 2, 2017	10.1
10.23	Lease agreement dated February 2, 2017 for property located at 24-42 Cherry Hill Drive, Danvers, Massachusetts		10-Q (File No. 001-09585)	February 6, 2018	10.1
10.24	Lease amendment – first amendment dated December 14, 2017, for property located at 24-42 Cherry Hill Drive, Danvers, Massachusetts		10-Q (File No. 001-09585)	February 6, 2018	10.2
10.25	Lease amendment – second amendment dated March 2, 2018, for property located at 24-42 Cherry Hill Drive, Danvers, Massachusetts		10-K (File No. 001-09585)	May 24, 2018	10.45
10.26	Lease amendment – fourth amendment dated July 23, 2018, for property located at 24-42 Cherry Hill Drive, Danvers, Massachusetts		10-Q (File No. 001-09585)	August 8, 2018	10.1
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, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of March 31, 2019 and 2018; (ii) Consolidated Statements of Operations for the fiscal years ended March 31, 2019, 2018 and 2017; (iii) Consolidated Statements of Comprehensive Income for the fiscal years ended March 31, 2019, 2018 and 2017; (iv) Consolidated Statements of Stockholders' Equity for the fiscal years ended March 2019, 2018 and 2017; (v) Consolidated Statements of Cash Flows for the fiscal years ended March 31, 2019, 2018 and 2017; and (vi) Notes to Consolidated Financial Statements.	X			

* Management contract or compensatory plan, contract or arrangement.

P Exhibit filed by paper

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 23, 2019

By /s/ TODD A. TRAPP
Todd A. Trapp
Vice President, Chief Financial Officer
(Principal Financial Officer and Principal 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
/s/ MICHAEL R. MINOGUE **Michael R. Minogue**	Chairman, Director, President and Chief Executive Officer (Principal Executive Officer)	May 23, 2019
/s/ TODD A. TRAPP **Todd A. Trapp**	Vice President, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 23, 2019
/s/ DOROTHY E. PUHY **Dorothy E. Puhy**	Director	May 23, 2019
/s/ JEANNINE M. RIVET **Jeannine M. Rivet**	Director	May 23, 2019
/s/ ERIC A. ROSE, M.D. **Eric A. Rose, M.D.**	Director	May 23, 2019
/s/ MARTIN P. SUTTER **Martin P. Sutter**	Director	May 23, 2019
/s/ PAUL G. THOMAS **Paul G. Thomas**	Director	May 23, 2019
/s/ CHRIS D. VAN GORDER **Chris D. Van Gorder**	Director	May 23, 2019

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2019, 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, 2019, 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 23, 2019, 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 23, 2019

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, 2019	March 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 121,021	$ 42,975
Short-term marketable securities	370,677	319,274
Accounts receivable, net	90,809	70,010
Inventories	80,942	50,204
Prepaid expenses and other current assets	13,748	11,808
Total current assets	677,197	494,271
Long-term marketable securities	21,718	37,502
Property and equipment, net	145,005	117,167
Goodwill	32,601	35,808
In-process research and development	15,208	16,705
Long-term deferred tax assets, net	77,502	70,746
Other assets	85,115	14,176
Total assets	$ 1,054,346	$ 786,375
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 32,185	$ 23,565
Accrued expenses and other liabilities	57,420	46,147
Deferred revenue	16,393	14,970
Total current liabilities	105,998	84,682
Other long-term liabilities	1,061	776
Contingent consideration	9,575	10,490
Long-term deferred tax liabilities	822	903
Total liabilities	117,456	96,851
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Class B Preferred Stock, $.01 par value	—	—
Authorized - 1,000,000 shares; Issued and outstanding - none		
Common stock, $.01 par value	451	444
Authorized - 100,000,000 shares; Issued - 47,026,226 shares at March 31, 2019 and 46,100,649 shares at March 31, 2018;		
Outstanding - 45,122,985 shares at March 31, 2019 and 44,375,337 shares at March 31, 2018		
Additional paid in capital	690,507	619,905
Retained earnings	399,473	140,457
Treasury stock at cost - 1,903,241 shares at March 31, 2019 and 1,725,312 shares at March 31, 2018	(138,852)	(67,078)
Accumulated other comprehensive loss	(14,689)	(4,204)
Total stockholders' equity	936,890	689,524
Total liabilities and stockholders' equity	$ 1,054,346	$ 786,375

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,		
	2019	2018	2017
Revenue	$ 769,432	$ 593,749	$ 445,304
Costs and expenses:			
Cost of revenue	129,567	98,581	70,627
Research and development	93,503	75,297	66,386
Selling, general and administrative	321,550	262,734	218,153
	544,620	436,612	355,166
Income from operations	224,812	157,137	90,138
Other income:			
Investment income, net	8,166	3,688	1,554
Other income (expense), net	30,382	(388)	(349)
	38,548	3,300	1,205
Income before income taxes	263,360	160,437	91,343
Income tax provision	4,344	48,267	39,227
Net income	$ 259,016	$ 112,170	$ 52,116
Basic net income per share	$ 5.77	$ 2.54	$ 1.21
Basic weighted average shares outstanding	44,911	44,153	43,238
Diluted net income per share	$ 5.61	$ 2.45	$ 1.17
Diluted weighted average shares outstanding	46,151	45,849	44,658

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,		
	2019	2018	2017
Net income	$ 259,016	$ 112,170	$ 52,116
Other comprehensive (loss) income:			
Foreign currency translation (loss) gain	(11,431)	16,862	(5,855)
Net unrealized gain (loss) on marketable securities	946	(460)	(211)
Other comprehensive (loss) income	(10,485)	16,402	(6,066)
Comprehensive income	$ 248,531	$ 128,572	$ 46,050

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					
	Number of shares	Par value	Number of shares	Amount	Additional Paid in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance, April 1, 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 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	—	—	—	—	—	—	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
Restricted stock units issued	427,431	4	—	—	(4)	—	—	—
Stock options exercised	485,363	5	—	—	12,944	—	—	12,949
Stock issued under employee stock purchase plan	12,467	—	—	—	3,052	—	—	3,052
Stock issued to directors	316	—	—	—	116	—	—	116
Return of common stock to pay withholding taxes on restricted stock	(177,929)	(2)	177,929	(71,774)	—	—	—	(71,776)
Stock compensation expense	—	—	—	—	54,494	—	—	54,494
Other comprehensive loss	—	—	—	—	—	—	(10,485)	(10,485)
Net income	—	—	—	—	—	259,016	—	259,016
Balance, March 31, 2019	45,122,985	$ 451	1,903,241	$ (138,852)	$ 690,507	$ 399,473	$ (14,689)	$ 936,890

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,		
	2019	2018	2017
Operating activities:			
Net income	$ 259,016	$ 112,170	$ 52,116
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	14,121	11,005	6,202
Bad debt expense	720	38	159
Stock-based compensation	54,494	40,353	32,866
Write-down of inventory and other	4,252	3,946	3,085
Accretion on marketable securities	(2,744)	—	—
Change in fair value of other investments	(30,161)	—	—
Excess tax benefit from stock-based awards	—	—	(12,038)
Deferred tax provision	(7,745)	42,624	25,803
Change in fair value of contingent consideration	(915)	1,337	1,590
Changes in assets and liabilities:			
Accounts receivable	(22,023)	(15,289)	(11,550)
Inventories	(37,181)	(15,686)	(12,284)
Prepaid expenses and other assets	(2,527)	(4,466)	(2,366)
Accounts payable	7,976	4,412	7,565
Accrued expenses and other liabilities	13,406	7,722	22,223
Deferred revenue	1,508	4,380	1,745
Net cash provided by operating activities	252,197	192,546	115,116
Investing activities:			
Purchases of marketable securities	(361,602)	(325,408)	(278,501)
Proceeds from the sale and maturity of marketable securities and other	331,886	206,909	205,482
Purchases of other investments and intangible assets	(42,735)	(6,400)	(2,899)
Purchases of property and equipment	(44,004)	(55,863)	(50,415)
Net cash used for investing activities	(116,455)	(180,762)	(126,333)
Financing activities:			
Proceeds from the exercise of stock options	12,949	9,303	10,660
Excess tax benefit from stock-based awards	—	—	12,038
Taxes paid related to net share settlement upon vesting of stock awards	(71,776)	(20,317)	(20,105)
Proceeds from the issuance of stock under employee stock purchase plan	3,052	2,394	1,720
Principal payments on capital lease obligation	—	(517)	(446)
Net cash (used for) provided by financing activities	(55,775)	(9,137)	3,867
Effect of exchange rate changes on cash	(1,921)	1,288	(1,841)
Net increase in cash and cash equivalents	78,046	3,935	(9,191)
Cash and cash equivalents at beginning of year	42,975	39,040	48,231
Cash and cash equivalents at end of year	$ 121,021	$ 42,975	$ 39,040
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 5,290	$ 4,641	$ 1,405
Cash paid for interest on capital lease obligation	—	302	354
Supplemental disclosure of non-cash investing and financing activities:			
Property and equipment under capital lease obligation	—	—	16,784
Property and equipment in accounts payable and accrued expenses	4,787	3,338	5,692

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

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 cardiac surgeons for patients who are in need of hemodynamic support prophylactically or emergently before, during or after angioplasty or heart surgery procedures.

Note 2. Basis of Preparation and Summary of Significant Accounting Policies

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, and Regulation S-X. The information presented reflects 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 U.S. 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 an original 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.

The Company's marketable securities, consisting of U.S. Treasuries, U.S. Government Agency, and corporate debt securities, and commercial paper, 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. 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, 2019, 2018 or 2017. No individual customer had an accounts receivable balance greater than 10% of total accounts receivable at March 31, 2019 and 2018.

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.

Effective April 1, 2019, the Company will adopt ASU 2016-02, "Leases." This new guidance requires the Company's lease commitments to be recognized as operating lease liabilities and right-of-use assets, which will increase total assets and total liabilities that the Company will report on its consolidated balance sheet in future periods.

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. 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.

In applying the goodwill impairment test, the Company first assesses 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 the Company's 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 more likely than not that the fair value of a reporting unit is less than its carrying value, then performing a two-step impairment test is necessary.

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.

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 estimates for certain payroll costs, such as bonuses and commissions; contract service fees, such as amounts due to clinical research organizations and 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. 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

On April 1, 2018 the Company adopted ASU 2014-09 ("Topic 606"), "Revenue from Contracts with Customers". For a discussion on the impact of this accounting policy adoption, including key accounting policies and elections, see "Note 3. Revenue Recognition."

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, 2019, 2018 and 2017.

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, 2019, 2018 and 2017 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 stock awards and shares to be purchased under the Company's employee stock purchase plan. For the fiscal years ended March 31, 2019, 2018 and 2017, the Company's basic and diluted net income per share were as follows (figures in tables are in thousands, except per share data):

	Fiscal Years Ended March 31,		
Basic Net Income Per Share	**2019**	**2018**	**2017**
Net income	$ 259,016	$ 112,170	$ 52,116
Weighted average shares - basic	44,911	44,153	43,238
Net income per share - basic	$ 5.77	$ 2.54	$ 1.21

	Fiscal Years Ended March 31,		
Diluted Net Income Per Share	**2019**	**2018**	**2017**
Net income	$ 259,016	$ 112,170	$ 52,116
Weighted average shares - basic	44,911	44,153	43,238
Effect of dilutive securities	1,240	1,696	1,420
Weighted average shares - diluted	46,151	45,849	44,658
Net income per share - diluted	$ 5.61	$ 2.45	$ 1.17

For the fiscal years ended March 31, 2019, 2018 and 2017, approximately 64,000, 155,000 and 24,000 shares of common stock underlying outstanding securities 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 in fiscal 2018 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 11. Income Taxes" for further information related to the Tax Reform Act 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.

Recently Adopted Accounting Pronouncements

Effective April 1, 2018, the Company adopted the Financial Accounting Standards Board ("FASB") standard update ASU 2014-09 ("Topic 606"), "Revenue from Contracts with Customers," which provides a principles-based, five-step approach to measure and recognize revenue from contracts with customers. The adoption did not have a material impact on the Company's consolidated financial statements as of the adoption date, or for the year ended March 31, 2019. Additional information and disclosures required by this new standard are contained in "Note 3. Revenue Recognition."

Effective April 1, 2018, the Company adopted the FASB standard update ASU 2016-01, "Recognition and Measurement of Financial Assets and Financial Liabilities," which requires certain financial assets and equity investments to be measured at fair value with changes in fair value recognized in the statement of operations. The adoption of this guidance did not have a material impact on the Company's consolidated statement of operations, cash flows, and balance sheet as of the adoption date or for the year ended March 31, 2019. Additional information and disclosures required by this new standard are contained in "Note 8. Goodwill, In-Process Research and Development, and Other Assets."

On June 20, 2018, the FASB issued ASU 2018-07, "Compensation – Stock Compensation ("Topic 718"): Improvements to Nonemployee Share-Based Payment Accounting," which simplifies the accounting for share-based payments granted to nonemployees for goods and services. ASU 2018-07 eliminated the previous guidance for accounting for share-based payments to nonemployees and expanded Topic 718 to include share-based payments transactions to nonemployees. ASU 2018-07 is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The adoption of ASU 2018-07 required a modified retrospective transition approach, with a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year. The Company early adopted ASU 2018-07 in the first quarter of fiscal 2019. The adoption of this guidance did not have a material impact on the Company's consolidated statements of operations, cash flows, and balance sheet as of the adoption date or for the year ended March 31, 2019.

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:

Description of Change:	Impact of Change Upon Adoption on April 1, 2017 and for the Year Ended March 31, 2018:	Adoption Method:
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, 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.

	Common Stock		Treasury Stock					
	Number of shares	Par value	Number of shares	Amount	Additional Paid in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
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					1,835	75,246		77,081
Balance, April 1, 2017	43,673,286	$ 437	1,575,995	$(46,763)	$ 567,797	$ 28,287	$ (20,606)	$ 529,152

Recently Issued Accounting Pronouncements Not Yet Effective

In February 2016, the FASB issued ASU 2016-02, "Leases." The new guidance significantly impacts lessee accounting and financial statement disclosures. Specifically, this guidance requires lessees to identify arrangements that should be accounted for as leases. Under this guidance, for lease arrangements exceeding a one-year term, a right-of-use asset and lease obligation is recorded by the lessee for all leases on the balance sheet, whether operating or financing, while the statement of operations includes lease expense for operating leases and amortization and interest expense for financing leases. The lease obligation amount recorded on the balance sheet at the date of adoption of this guidance must be calculated using the applicable incremental borrowing rate at the date of adoption. Leases with a term of one year or less will be accounted for similar to existing guidance for operating leases. The Company has evaluated its lease arrangements to determine the impact of ASU 2016-02 on its consolidated financial statements as well as updating processes and controls in order to adopt the new standard. This evaluation included a review of the Company's existing leasing arrangements on its facilities and a review of existing contracts with its suppliers, vendors, and customers to determine if these agreements contained embedded leases. Based on the results of this evaluation, the adoption of this standard will not have a material impact to the Company's consolidated financial statements. Lease commitments will be recognized as operating lease liabilities and right-of-use assets upon adoption, which will increase total assets and total liabilities that the Company reports on its consolidated balance sheet. The Company also anticipates changes to its disclosures to comply with the new disclosure requirements. In addition, the Company is implementing necessary changes to its lease accounting policies and controls. ASU 2016-02 must be adopted using a modified retrospective approach for all leases existing at, or entered into after the date of initial adoption, with an option to elect to use certain transition relief. ASU 2016-02 will become effective for the Company upon adoption on April 1, 2019.

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments-Credit Losses (Topic 326)." This new guidance will require financial instruments to be measured at amortized cost, and accounts receivables to be presented at the net amount expected to be collected. The new model requires an entity to estimate credit losses based on historical information, current information, and reasonable and supportable forecasts, including estimates of prepayments. ASU 2016-13 is effective for annual reporting periods beginning after December 31, 2019. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements. ASU 2016-13 will become effective for the Company in fiscal 2021.

In January 2017, the FASB issued ASU 2017-04, "Intangibles - Goodwill and Other (Topic 350)." The new guidance simplifies the accounting for goodwill impairment by removing Step 2 of the goodwill impairment test, which required companies to estimate the implied fair value of goodwill and recognize an impairment charge by the amount in which the carrying value exceeds the implied fair value. Under the new guidance, if the carrying value of a reporting unit exceeds its fair value, a goodwill impairment charge will be recorded, even if the difference is attributable to the fair value of other assets in the reporting unit. ASU 2017-04 is effective for annual reporting periods beginning after December 15, 2019. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements. ASU 2017-04 will become effective for the Company in fiscal 2021.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820)." which modifies the disclosure requirements on fair value measurements. The Company has investments accounted for and disclosed under Topic 820 and will modify disclosures as applicable to conform with the new guidance. ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019 and early adoption is permitted. The Company does not expect the adoption of this standard and the required disclosure changes to have a material impact on its consolidated financial statements. ASU 2018-13 will become effective for the Company in fiscal 2021.

Note 3. Revenue Recognition

Adoption of Topic 606, "Revenue from Contracts with Customers"

The Company adopted Topic 606 on April 1, 2018, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for fiscal year 2019 reflect the application of Topic 606 guidance while the reported results for fiscal year 2018 were prepared under the guidance of ASC 605, "Revenue Recognition." The adoption of Topic 606 did not have a material impact on the timing or amount of revenue recognized upon adoption and there was no cumulative prior period adjustment recorded to the opening balance of retained earnings upon adoption. Accordingly, the adoption of Topic 606 did not have a material impact on the Company's consolidated balance sheet, statement of operations, stockholders' equity or cash flows as of the adoption date or for the year ended March 31, 2019.

The Company has made the following accounting policy elections and elected to use certain practical expedients, as permitted by the FASB, in applying Topic 606: (1) the Company accounts for amounts collected from customers for sales and other taxes, net of related amounts remitted to tax authorities; (2) the Company does not adjust the promised amount of consideration for the effects of a significant financing component because, at contract inception, the Company expects the period between the time when the Company transfers a promised good or service to the customer and the time when the customer pays for that good or service will be one year or less; (3) the Company expenses costs to obtain a contract as they are incurred if the expected period of benefit, and therefore the

amortization period, is one year or less; (4) the Company accounts for shipping and handling activities that occur after control transfers to the customer as a fulfillment cost rather than an additional promised service and these fulfillment costs are recorded as selling, general and administrative expenses; (5) the Company does not assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer; and (6) the Company does not disclose the transaction price allocated to unsatisfied performance obligations when the original expected contract duration is one year or less.

The Company generates revenue primarily from the sale of Impella 2.5, Impella CP, Impella 5.0, Impella LD, Impella RP and Impella AIC products. The Company also earns revenue from preventative maintenance service contracts and maintenance calls.

The Company determines revenue recognition through the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligation in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligation in the contract
- Recognition of revenue when, or as, a performance obligation is satisfied

Identification of contracts and performance obligations

The Company accounts for a contract with a customer when there is an approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of the consideration is probable. The Company's performance obligations consist mainly of transferring control of products and services identified in the contracts, purchase orders or invoices. For each contract, the Company considers the obligation to transfer products and services to the customer, each of which are distinct, to be performance obligations.

Transaction price and allocation to performance obligations

Transaction prices of products or services are typically based on contracted rates with customers and there is only variable consideration in limited instances. To the extent that the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method or the most likely amount, depending on the circumstances, to which the Company expects to be entitled. An expected value method may be an appropriate estimate of the amount of variable consideration if an entity has a large number of contracts with similar characteristics whereas the most likely amount method may be an appropriate estimate of the amount of variable consideration if the contract has only two possible outcomes. Variable consideration is included in the transaction price if, in the Company’s judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company’s anticipated performance and all information (historical, current and forecasted) that is reasonably available. Sales and other taxes collected on behalf of third parties are excluded from revenue.

The Company does not provide for rights of return to customers on product sales and, therefore, does not record a provision for returns. Customers typically have a limited time frame to notify the Company of any defective or non-conforming products. The Company’s limited warranty provision is accounted for using the cost accrual method and is recognized as expense when products are sold and is not considered a separate performance obligation.

If a contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately.

Revenue Recognition

Revenue is recognized when, or as, obligations under the terms of a contract are satisfied, which occurs when control of the promised products or services is transferred to customers. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer.

Product revenue is generally recognized when the customer obtains control of the Company’s product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract.

Service revenue is generally recognized over time as the services are rendered to the customer based on the extent of progress towards completion of the performance obligation. The Company recognizes service revenue over the term of the service contract. Services are expected to be transferred to the customer throughout the term of the contract and the Company believes recognizing revenue ratably over the term of the contract best depicts the transfer of value to the customer. Revenue generated from preventative maintenance calls is recognized at a point in time when the services are provided to the customer.

Revenue from the sale of products and services are evidenced by either a contract with the customer or a valid purchase order and an invoice which includes all relevant terms of sale and shipment of product or service provided has been incurred. The Company performs a review of each specific customer's credit worthiness and ability to pay prior to acceptance as a customer. Further, the Company performs periodic reviews of its customers' creditworthiness prospectively.

Disaggregation of Revenue

The Company generally sells its Impella products and services through a direct sales force in the U.S. and Germany and through direct sales and distribution agreements in other international markets outside (e.g., in Europe, Japan, Canada, Latin America, Asia-Pacific). Revenue is disaggregated from contracts between product revenue and service and other revenue and by geography, which the Company believes best depicts how the nature, amount, timing, and uncertainty of revenues and cash flows are affected by economic factors.

The following table disaggregates the Company’s revenue by products and services:

	Fiscal Years Ended March 31,		
	2019	2018	2017
		(in $000's)	
Impella product revenue	$ 741,699	$ 570,870	$ 423,694
Service and other revenue	27,733	22,879	21,610
Total revenue	$ 769,432	$ 593,749	$ 445,304

The following table disaggregates the Company’s revenue by geographical location:

	Fiscal Years Ended March 31,		
	2019	2018	2017
		(in $000's)	
U.S. revenue	$ 665,082	$ 526,685	$ 405,781
International revenue	104,350	67,064	39,523
Total revenue	$ 769,432	$ 593,749	$ 445,304

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts or rebates that are offered within contracts between the Company and its customers relating to the Company’s sales of its products. These reserves are based on the amounts earned or are expected to be claimed on the related sales and are classified as a liability. Where appropriate, these estimates take into consideration relevant factors such as the Company’s historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. These reserves reflect the Company’s best estimates of the amount of consideration to which it is entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ from the Company’s estimates. If actual results in the future vary from the Company’s estimates, the Company adjusts these estimates, which would affect revenue and earnings in the period such variances become known.

Rebates and Discounts

The Company provides certain customers with rebates and discounts that are defined in the Company's contract arrangements with customers and are recorded as a reduction of revenue in the period the related product revenue is recognized, resulting in a reduction to revenue and the establishment of a liability, which are all included in accrued expenses in the accompanying consolidated balance sheets. Rebates normally result from performance-based offers that are primarily based on attaining contractually specified sales volumes as well as product usage. Discounts are normally from early payment incentives. The Company estimates the amount of rebates and discounts based on an estimate of the third-party's sales and the respective rebate or discount defined in the customer contractual arrangement.

The following table summarizes product revenue rebates and discounts for the year ended March 31, 2019 (in thousands):

	Rebates and Discounts
Balance at March 31, 2018	$ 1,405
Credits related to prior period balance	(759)
Provision related to current period revenue	2,180
Credits related to current period revenue	(1,294)
Balance at March 31, 2019	$ 1,532

Contract Balances

The timing of revenue recognition, billings and cash collections results in accounts receivables and deferred revenue on the consolidated balance sheet. A receivable is recognized in the period the Company's right to the consideration from the customer is unconditional. The change in the accounts receivable balances relate to the timing of revenue recognition, billings and cash collections. The Company generally does not have any performance obligations with a term of more than one year.

Payment terms vary by contract type and type of customer and generally range from 30 to 60 days for direct sales customers. Payment terms with certain international distributors can be up to 90 days. The Company's contracts with customers do not typically include extended payment terms.

Deferred Revenue

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, deferred revenue is recorded. Deferred revenue is recognized as revenue after control of the products or services is transferred to the customer and all revenue recognition criteria have been met.

The Company's deferred revenue balance was $16.4 million and $15.0 million as of March 31, 2019 and March 31, 2018, respectively, and it was due to the timing of product shipment and completion of recognizing revenue when the customer obtains control of the product, and additional preventative maintenance service contracts and the subsequent recognition of the contract ratably over the term of the service contract. During the year ended March 31, 2019, the Company recognized $14.9 of revenue that was included in the deferred revenue balance as of March 31, 2018.

Costs to Obtain or Fulfill a Customer Contract

The Company has certain costs to obtain and fulfill a customer contract, such as commissions and shipping costs. The Company recognizes the incremental costs of obtaining contracts as an expense when incurred if the amortization period of the assets that the Company otherwise would have recognized is one year or less. The Company accounts for shipping and handling activities related to contracts with customers as costs to fulfill the promise to transfer the associated products. These costs are included in Selling, general, and administrative expenses.

Note 4. Cash Equivalents, Marketable Securities and Fair Value Measurements

The Company's cash equivalents and marketable securities at March 31, 2019 and 2018 are classified on the balance sheet as follows:

	March 31, 2019	March 31, 2018
	(in $000's)	
Cash equivalents	$ 80,089	$ 22,595
Short-term marketable securities	370,677	319,274
Long-term marketable securities	21,718	37,502
	$ 472,484	$ 379,371

The Company's cash equivalents and marketable securities at March 31, 2019 and 2018 are invested in the following:

March 31, 2019:	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in $000's)			
Money market funds	$ 60,089	$ —	$ —	$ 60,089
Repurchase agreements	20,000	—	—	20,000
Short-term U.S. Treasury mutual fund securities	58,786	13	(12)	58,787
Short-term government-backed securities	126,336	60	(15)	126,381
Short-term corporate debt securities	128,626	97	(9)	128,714
Short-term commercial paper	56,780	16	(1)	56,795
Long-term corporate debt securities	21,529	189	—	21,718
	$ 472,146	$ 375	$ (37)	$ 472,484

March 31, 2018:	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in $000's)			
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
	$ 380,183	$ 7	$ (819)	$ 379,371

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, 2019 and 2018:

	Level 1	Level 2	Level 3	Total
March 31, 2019:		**(in $000's)**		
Assets				
Money market funds	$ 60,089	$ —	$ —	$ 60,089
Repurchase agreements	—	20,000	—	20,000
Short-term U.S. Treasury mutual fund securities	—	58,787	—	58,787
Short-term government-backed securities	—	126,381	—	126,381
Short-term corporate debt securities	—	128,714	—	128,714
Short-term commercial paper	—	56,795	—	56,795
Long-term corporate debt securities	—	21,718	—	21,718
Investment in Shockwave Medical (see Note 8)	56,195	—	—	56,195
Liabilities				
Contingent consideration	—	—	9,575	9,575

	Level 1	Level 2	Level 3	Total
March 31, 2018:		**(in $000's)**		
Assets				
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
Liabilities				
Contingent consideration	—	—	10,490	10,490

The Company has determined that the estimated fair value of its money market funds and its investment in medical device company Shockwave are reported as Level 1 financial assets as they are valued at quoted market prices in active markets. The investment in Shockwave is classified within other assets in the consolidated balance sheet and is further discussed in "Note 8. Goodwill, In-Process Research & Development and Other Assets."

The Company has determined that the estimated fair value of its repurchase agreements, U.S. Treasury mutual fund securities, government-backed securities, corporate debt securities and commercial paper are reported as Level 2 financial assets as they are based on model-driven valuations in which all significant inputs are observable, or can be derived from or corroborated by observable market data for substantially the full term of the asset.

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 and AIS 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, 2019, 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 the Company's 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, 2019 (in $000's)	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Clinical and regulatory milestone	$ 5,371	Probability weighted income approach	Projected fiscal year of milestone payments	2020 to 2023
			Discount rate	3.8% to 4.0%
			Probability of occurrence	Probability adjusted level of 40% for the base case scenario and 15% to 40% for various downside and upside scenarios
Revenue-based milestone	4,204	Monte Carlo simulation model	Projected fiscal year of milestone payments	2025 to 2035
			Discount rate	17%
			Expected volatility for forecasted revenues	50%
			Probability of payment (risk-neutral)	70.1%
	$ 9,575			

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, 2019, 2018 and 2017:

	Fiscal Years Ended March 31,		
	2019	2018	2017
	(in $000's)		
Level 3 liabilities, beginning balance	$ 10,490	$ 9,153	$ 7,563
Additions	—	—	—
Payments	—	—	—
Change in fair value	(915)	1,337	1,590
Level 3 liabilities, ending balance	$ 9,575	$ 10,490	$ 9,153

The change in fair value of the contingent consideration was primarily due to estimates related to development timelines and the passage of time on the fair value measurement of milestones. 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.

Note 5. Accounts Receivable

The components of accounts receivable are as follows:

	March 31, 2019	March 31, 2018
	(in $000's)	
Trade receivables	$ 91,849	$ 70,330
Allowance for doubtful accounts	(1,040)	(320)
	$ 90,809	$ 70,010

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

	Fiscal Years Ended March 31,		
	2019	2018	2017
		(in $000's)	
Balance at beginning of year	$ 320	$ 282	$ 124
Additions	720	38	159
Write-offs	—	—	(1)
Balance at end of year	$ 1,040	$ 320	$ 282

Note 6. Inventories

The components of inventories are as follows:

	March 31, 2019	March 31, 2018
	(in $000's)	
Raw materials and supplies	$ 24,468	$ 16,481
Work-in-progress	35,195	23,179
Finished goods	21,279	10,544
	$ 80,942	$ 50,204

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 7. Property and Equipment

The components of property and equipment are as follows:

	March 31, 2019	March 31, 2018
	(in $000's)	
Land	$ 7,262	$ 7,680
Building and building improvements	86,705	63,700
Leasehold improvements	2,190	2,905
Machinery and equipment	59,146	42,787
Furniture and fixtures	11,456	8,104
Construction in progress	17,946	19,850
Total cost	184,705	145,026
Less accumulated depreciation	(39,700)	(27,859)
	$ 145,005	$ 117,167

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.

Depreciation expense related to property and equipment was $13.9 million, $11.0 million, and $6.2 million for the fiscal years ending March 31, 2019, 2018 and 2017, respectively.

Note 8. Goodwill, In-Process Research & Development and Other Assets

Goodwill

The carrying amount of goodwill at March 31, 2019 and 2018 was $32.6 million and $35.8 million, respectively, and has been recorded in connection with the Company's acquisition of Impella Cardiosystems AG, in May 2005 and ECP and AIS in July 2014. The goodwill activity is as follows:

	(in $000's)
Balance at March 31, 2017	$ 31,045
Foreign currency translation impact	4,763
Balance at March 31, 2018	$ 35,808
Foreign currency translation impact	(3,207)
Balance at March 31, 2019	$ 32,601

The Company has no accumulated impairment losses on goodwill. The Company performed a qualitative assessment during the annual impairment review for fiscal 2019 as of October 31, 2018 and concluded that it is more likely than not that the fair value of the Company's single reporting unit is not less than its carrying amount. Therefore, the two-step goodwill impairment test for the reporting unit was not necessary in fiscal 2019.

In-Process Research & Development

The carrying amount of IPR&D assets at March 31, 2019 and 2018 was $15.2 million and $16.7 million, respectively, and was recorded in conjunction with the Company's acquisition of ECP and AIS, in July 2014. The estimated fair value of IPR&D assets at the acquisition date 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 an original discount rate of 21 % 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, 2019 and 2018 are as follows:

	(in $000's)
Balance at March 31, 2017	$ 14,482
Foreign currency translation impact	2,223
Balance at March 31, 2018	$ 16,705
Foreign currency translation impact	(1,497)
Balance at March 31, 2019	$ 15,208

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 value. The Company performed its annual impairment review for fiscal 2019 as of October 31, 2018 and concluded that it was more likely than not that the fair value of the IPR&D assets is not less than its carrying value.

Other Assets

Other Investments

The Company periodically makes investments in 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 $80.8 million and $12.6 million at March 31, 2019 and 2018, respectively, and is classified within other assets in the consolidated balance sheets. During the years ended March 31, 2019 and 2018 the Company made investments of $39.9 million and $6.4 million, respectively, in medical device companies.

The carrying value of the Company's portfolio of other investments and the change in the balance for fiscal years ended March 31, 2019, 2018 and 2017 are as follows:

	Fiscal Years Ended March 31,		
	2019	2018	2017
	(in $000's)		
Beginning Balance	$ 12,649	$ 7,249	$ 4,350
Additions	39,935	6,400	2,899
Disposals	(1,966)	—	—
Change in fair value, net	30,161	(1,000)	—
Ending Balance	$ 80,779	$ 12,649	$ 7,249

On April 1, 2018, the Company adopted ASU 2016-01. This guidance requires equity investments to be measured at fair value with changes in fair value recognized in net income. For investments that do not have readily determinable market values, the Company has elected to measure these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment.

The Company monitors any events or changes in circumstances that may have a significant effect on the fair value of investments, either due to impairment or based on observable price changes, and makes any necessary adjustments. In fiscal 2019, the Company invested $25.0 million in medical device company Shockwave Medical. The fair value of this investment as of March 31, 2019 was $56.2 million and the Company recognized a gain of $31.2 million in Other income. Also included in Other income is an impairment loss of $1.0 million relating to the Company's disposal of an investment in a private medical device company. No other adjustments have been made to the fair value of the Company's investments in medical device companies in fiscal 2019.

Other Intangible Assets

During fiscal 2019, the Company made payments totaling $2.8 million to license manufacturing rights to certain technology from third parties. These intangible assets are classified with other assets in the Company's consolidated balance sheet and are amortized over their useful life of 15 years.

Amortization expense related to intangibles assets was $0.2 million for the fiscal year ended March 31, 2019. There was no amortization expense for the years ended March 31, 2018 and 2017.

Note 9. 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 10. 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, 2019 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 Amended and Restated Omnibus 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, 2019, a total of approximately 3,895,000 shares were available for future issuance under the 2015 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, 2019, 2018 and 2017:

	Fiscal Years Ended March 31,		
	2019	2018	2017
		(in $000's)	
Cost of revenue	$ 2,643	$ 1,721	$ 1,061
Research and development	9,312	5,895	6,050
Selling, general and administrative	42,539	32,737	25,755
	$ 54,494	$ 40,353	$ 32,866

The components of stock-based compensation for the fiscal years ended March 31, 2019, 2018 and 2017 were as follows:

	Fiscal Years Ended March 31,		
	2019	2018	2017
		(in $000's)	
Restricted stock units	$ 45,998	$ 34,559	$ 26,570
Stock options	7,445	5,202	5,829
Employee stock purchase plan	1,051	592	467
	$ 54,494	$ 40,353	$ 32,866

Stock Options

The following table summarized stock option activity for the fiscal year ended March 31, 2019:

	Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at beginning of period	1,282	$ 46.81	5.31	$ 313,158
Granted	81	379.90		
Exercised	(485)	26.68		
Cancelled and expired	(25)	138.68		
Outstanding at end of period	853	$ 87.14	5.57	$ 176,629
Exercisable at end of period	623	$ 40.72	4.58	$ 152,598

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, 2019 was approximately $12.2 million and the weighted-average period over which this cost will be recognized is 1.9 years.

The aggregate intrinsic value of options exercised for fiscal years 2019, 2018 and 2017 was $174.0 million, $66.4 million and $74.8 million, respectively. The total cash received as a result of employee stock option exercises during the fiscal years ended March 31, 2019, 2018 and 2017 was approximately $12.9 million, $9.3 million and $10.7 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, 2019, 2018 and 2017 was as follows:

	Fiscal Years Ended March 31,		
	2019	2018	2017
Valuation assumptions:			
Weighted average grant-date fair value	$ 141.47	$ 52.34	$ 42.40
Risk-free interest rate	2.91%	1.87%	1.41%
Expected option life (years)	4.04	4.07	4.14
Expected volatility	42.8%	43.5%	48.9%

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.

Restricted Stock Units

The following table summarizes restricted stock unit activity for the fiscal year ended March 31, 2019:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value (per share)
Restricted stock units at beginning of period	880	$ 109.01
Granted	195	376.95
Vested	(427)	103.54
Forfeited	(28)	189.05
Restricted stock units at end of period	620	$ 193.53

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, 2019 was $44.0 million and the weighted-average period over which this cost will be recognized is 1.9 years.

The weighted average grant-date fair value for restricted stock units granted during the fiscal years ended March 31, 2019, 2018 and 2017 was $376.95, $137.40 and $97.43 per share, respectively. The total fair value of restricted stock units vested in fiscal years 2019, 2018 and 2017 was $171.3 million, $51.0 million and $51.3 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, 2019 was $17.8 million and the weighted-average period over which this cost will be recognized is 1.9 years.

Performance-Based Awards

In May 2018, performance-based awards of restricted stock units for the potential issuance of 114,000 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 2019 such that the remaining outstanding 77,000 shares of common stock as of March 31, 2019 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 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 97,000 shares of common stock as of March 31, 2019 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 38,000 shares of common stock as of March 31, 2019 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 140,765 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. One-half of the market-based restricted stock units earned vested in June 2018 and the remaining restricted stock units will vest in June 2019 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. One-half of the restricted stock units vested in June 2018 based on performance criteria described above and the remaining half of the restricted stock units will vest in June 2019.

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 11. Income Taxes

In December 2017, the Tax Cuts and Jobs Act ("Tax Reform Act"), was signed into law. The Tax Reform Act makes broad and complex changes to the U.S. tax code that were effective January 1, 2018. The Tax Reform Act included significant changes in tax laws, including, but not limited to, (1) reducing the U.S. federal corporate tax rate from 35% to 21%; (2) requiring companies to pay a one-time transition tax on certain unrepatriated earnings on foreign subsidiaries, if applicable; (3) adding a new provision designed to tax global intangible low-taxed income ("GILTI"); and (4) imposing additional limitation on the deductibility of executive compensation and certain employee fringe benefits. ASC 740, "Income Taxes," 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.

As a result of the Tax Reform Act, the Company's U.S. federal statutory corporate income tax rate of 21% was applied in the computation of the income tax provision for the year ended March 31, 2019, a 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, and the pre-enactment rate of 35% was applied in the computation of the income tax provision for the year ended March 31, 2017. 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. As a result of the reduction in the federal statutory tax rate, the Company evaluated its ability to utilize its foreign tax credits carryforward. The Company has concluded that it will be able to use these foreign tax credits within the carryforward period.

The Company provisionally remeasured its net deferred tax assets due to the lower U.S. federal statutory corporate tax rate and recorded an income tax expense adjustment of $21.4 million during the year ended March 31, 2018. Guidance issued by the SEC, provided a measurement period of one year from the enactment date to finalize the accounting for effects of the Tax Reform Act, and no adjustments were made to the Company's provisional estimate of the impacts of the Tax Reform Act during the year ended March 31, 2019. The Tax Reform Act allows for a 100% deduction for the potential repatriation of foreign subsidiary earnings with minimal U.S. income tax consequences other than the one-time transition tax. Since most of the Company's cash and cash equivalents held by foreign subsidiaries are disregarded entities for domestic tax purposes, any repatriation of such funds to the U.S. would likely have a nominal tax impact. In addition, the Company has elected to treat GILTI tax as a period expense and provide for the tax in the year that the tax is incurred. The GILTI regime resulted in additional federal income tax expense of $0.5 million during the year ended March 31, 2019.

The Company's income tax provision was $4.3 million, $48.3 million and $39.2 million for the fiscal years ended March 31, 2019, 2018 and 2017, respectively. The Company's effective tax rate was 1.6%, 30.1% and 43.0% for the fiscal years ended March 31, 2019, 2018 and 2017, respectively.

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 $69.3 million and $31.0 million as an income tax benefit for fiscal years ended March 31, 2019 and 2018, respectively. 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 units that vest or stock options that are exercised, and the fair value assigned to such stock-based awards under U.S. GAAP.

The components of the Company's income tax provision for the fiscal years ended March 31, 2019, 2018 and 2017 are as follows:

	Fiscal Years Ended March 31,		
	2019	2018	2017
	(in $000's)		
Income before provision for income taxes:			
United States	$ 223,340	$ 134,006	$ 78,172
Foreign	40,020	26,431	13,170
Income before income taxes	263,360	160,437	91,342
Current tax expense:			
Federal	—	752	7,313
State	564	1,491	5,045
Foreign	11,525	3,400	1,066
	12,089	5,643	13,424
Deferred tax (benefit) expense:			
Federal	(7,153)	38,848	23,008
State	(1,503)	(1,014)	(349)
Foreign	911	4,790	3,144
	(7,745)	42,624	25,803
Total income tax provision	$ 4,344	$ 48,267	$ 39,227

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

	March 31, 2019	March 31, 2018
	(in $000's)	
Deferred tax assets		
Net operating loss and tax credit carryforwards	$ 62,835	$ 48,724
Stock-based compensation	15,488	13,271
Nondeductible reserves and accruals	9,739	8,290
Foreign net operating loss carryforwards	7,360	9,598
Deferred revenue	3,677	3,770
Depreciation and amortization	485	826
Other, net	128	822
	$ 99,712	$ 85,301
Deferred tax liabilities		
Goodwill	(7,136)	(6,787)
In-process research and development	(4,593)	(5,045)
Depreciation	(2,175)	(1,011)
Basis differences on other investments	(7,146)	—
Domestic deferred tax liability on foreign net operating loss carryforwards	(680)	(963)
	(21,730)	(13,806)
Net deferred tax assets	77,982	71,495
Valuation allowance	(1,302)	(1,652)
Net deferred tax assets	$ 76,680	$ 69,843
Reported as:		
Long-term deferred tax assets, net	$ 77,502	$ 70,746
Long-term deferred tax liabilities	(822)	(903)
Net deferred tax assets	$ 76,680	$ 69,843

The significant differences between the statutory and effective income tax rate for the years ended March 31, 2019, 2018, and 2017 consist of the following items:

	Fiscal Years Ended March 31,		
	2019	2018	2017
Statutory income tax rate	21.0 %	31.5 %	35.0 %
Increase (decrease) resulting from:			
Excess tax benefits from stock-based awards	(24.1)	(17.2)	0.2
Foreign taxes	4.1	2.2	2.0
Permanent differences	1.8	2.4	3.3
Credits	(1.5)	(4.9)	(3.3)
State taxes, net	0.1	2.0	3.8
Change in valuation allowance	(0.4)	0.5	0.2
Effect of the Tax Reform Act on net deferred tax assets	—	13.0	—
Rate differential on foreign operations	0.2	—	0.1
Other	0.4	0.6	1.7
Effective tax rate	1.6 %	30.1 %	43.0 %

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, 2019 and 2018, respectively, the Company maintained a valuation allowance of $1.3 million and $1.7 million for deferred tax assets primarily related to net 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, 2019 and 2018.

Changes in the valuation allowance for deferred tax assets during the fiscal years ended March 31, 2019, 2018 and 2017 were as follows:

	Fiscal Years Ended March 31,		
	2019	2018	2017
	(in $000's)		
Balance at beginning of year	$ 1,652	$ 2,468	$ 2,418
Increases	—	325	50
Decreases	(350)	(1,141)	—
Balance at end of year	$ 1,302	$ 1,652	$ 2,468

As of March 31, 2019, the Company had NOLs of approximately $116.6 million, which expire in varying years from fiscal 2029 through fiscal 2034. NOLs generated during fiscal 2019 and prospectively are no longer subject to expiration. Federal NOL of $42.2 million, generated during the year ended March 31, 2019, primarily due to excess tax benefits, can be carried forward indefinitely. At March 31, 2019, the Company had foreign NOLs of approximately $2.8 million, primarily in France, which do not expire. As of March 31, 2019, the Company had foreign tax credits of $9.8 million which expire in varying years from fiscal 2022 through fiscal 2028. In addition, at March 31, 2019, the Company had federal and state research and development credit carryforwards of approximately $19.0 million and $10.1 million, respectively, which expire in varying years from fiscal 2020 through fiscal 2039.

As of March 31, 2019 and 2018, the Company has no material uncertain tax positions, and no interest and penalties on uncertain tax positions were recognized during the years ended March 31, 2019, 2018 and 2017, 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. During fiscal 2019, the Company closed an income tax audit in Germany, which covered fiscal years 2012 through 2015. The Company also closed an Internal Revenue Service ("IRS") audit during fiscal 2019 relating to its fiscal year 2016 tax return. These audits did not materially impact our financial statements. All other tax years remain subject to examination by the IRS, state and foreign tax authorities.

Note 12. Commitments and Contingencies

Commitments

Leases

Future minimum lease payments under non-cancelable leases as of March 31, 2019 are approximately as follows:

	Operating Leases
Fiscal Years Ended March 31,	(in $000s)
2020	$ 3,398
2021	2,712
2022	2,000
2023	1,462
2024	1,414
Thereafter	3,288
Total minimum lease payments	$ 14,274

In February 2017, the Company entered into a lease agreement for 21,603 square feet of office space in Danvers, Massachusetts expiring 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 for which rent began on June 1, 2018. In March 2018, the Company entered into a second amendment to the lease to add an additional 11,269 square feet of space. In July 2018 the Company entered into an amendment to lease an additional 23,864 square feet of space from October 1, 2018 through September 30, 2027. With this most recent amendment, the Company has leased 63,343 square feet in total at this location as of October 1, 2018. The Company also has a right of first offer to purchase the property from January 1, 2018 through August 31, 2035. The annual rent expense for this lease is estimated to be $0.9 million.

In September 2016, the Company entered into a lease agreement for an office in Berlin, Germany which commenced in May 2017 and expires in March 2025. The annual rent expense for the lease is estimated to be $0.2 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.

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.

Thoratec Matters

Thoratec Corporation ("Thoratec"), a subsidiary of Abbott Laboratories, has challenged a number of Company-owned patents in Europe in connection with the launch of Thoratec's HeartMate PHP medical device ("PHP") in Europe. The Company has counterclaimed for infringement in the Dusseldorf Regional Court in Germany. The infringement action has been stayed until resolution of invalidity proceedings at the German Federal Court of Justice. These actions relate solely to Thoratec's ability to manufacture and sell its PHP product in Europe and have no impact on the Company's ability to manufacture or sell its Impella® line of medical devices.

Maquet Matters

In December 2015, the Company received a letter from Maquet Cardiovascular LLC ("Maquet"), a subsidiary of Getinge AB, asserting that the Company's Impella devices infringe certain claims with guidewire, lumen, rotor, purge and sensor features, which were in two Maquet patents and one pending patent application (which has since issued as a third patent) in the U.S. and elsewhere, and attaching a draft litigation complaint. The letter encouraged the Company to take a license from Maquet. In May 2016, the Company filed suit in U.S. District Court for the District of Massachusetts ("D. Mass." or "the Court") against Maquet, seeking a declaratory judgment that the Company's Impella devices do not infringe Maquet's cited patent rights. The three Maquet patents will expire in September 2020, December 2020 and October 2021.

In August 2016, Maquet sent a letter to the Company identifying four new Maquet U.S. continuation patent filings with claims that Maquet alleges are infringed by the Company's Impella devices. The four U.S. continuation applications have been issued as patents of Maquet and 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 July 21, 2017, the Court granted a motion to add three of the four additional continuation patents to the 2016 Action. On April 24 and 25, 2018, the Court conducted a Markman hearing on claim interpretation. On September 7, 2018, the judge issued a Memorandum and Order on Claim Construction, where he interpreted the disputed claim terms in the case. A hearing was held on November 2, 2018 to re-hear arguments on one of the terms. Maquet filed a motion for reconsideration of a disputed claim term. That motion was denied on May 22, 2019. Discovery remains ongoing and no schedule has yet been set for the remainder of the case. On November 22, 2017, Maquet filed a second action in D. Mass (the "2017 Action") alleging that the Company's Impella 2.5, Impella CP, and Impella 5.0 heart pumps infringe certain claims of the fourth additional U.S. continuation patent mentioned above (the seventh patent overall). Discovery in the 2017 Action is ongoing and no schedule has yet been set for the remainder of the case.

In the 2016 Action and 2017 Action, Maquet seeks injunctive relief and monetary damages in the form of a reasonable royalty, with three times the amount for alleged willful infringement. In its responses to the Company's counterclaims, Maquet admits that its current commercially available products do not embody the claims of the asserted patents.

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 7th patent. 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. The first and second cases are in discovery stages.

In a series of letters during January and February 2019, Maquet informed the Company of seven new divisional patent applications filed from the patents in the 2016 Action and 2017 Action and having claims that Maquet alleges would be infringed by the Impella products if the new applications were to issue as patents. The first of the seven new applications has issued and has been added to the 2017 Action. Any patents arising from the seven new applications will expire in September 2020.

Following March 31, 2019, five of the six remaining new divisional patent applications of Maquet issued as patents or received indication from the U.S. Patent and Trademark Office that they will issue as patents. One of these patents has already been added to the 2017 Action and the parties have agreed to add the other new patents in due course.

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 reasonably estimate a possible loss or range of possible losses at this stage of each of the legal proceedings, including the significant number of legal and factual issues still to be resolved in the Maquet and Thoratec patent disputes.

Note 13. Accrued Expenses

Accrued expenses consisted of the following:

	March 31, 2019	March 31, 2018
	(in $000's)	
Employee compensation	$ 32,926	$ 30,330
Sales and income taxes	12,262	4,562
Research and development	3,309	3,162
Marketing	1,707	2,305
Professional, legal and accounting fees	2,757	1,870
Warranty	1,272	1,081
Other	3,187	2,837
	$ 57,420	$ 46,147

Employee compensation consists primarily of accrued bonuses, accrued commissions and accrued employee benefits at March 31, 2019 and 2018.

Note 14. 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 14%, 11% and 9% of total revenue during the fiscal years ended March 31, 2019, 2018 and 2017, respectively. As of March 31, 2019 and 2018, most of the Company's long-lived assets are located in the U.S. except for $43.4 million and $35.5 million at March 31, 2019 and 2018, respectively, which are located primarily in Germany.

Note 15. 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, 2019 and 2018:

	Fiscal Year Ended March 31, 2019				
	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Total Year
			(in $000's)		
Revenue	$ 180,010	$ 181,778	$ 200,563	$ 207,081	$ 769,432
Cost of revenue	30,850	29,846	34,023	34,848	129,567
Other operating expenses	102,412	101,612	104,185	106,844	415,053
Other income, net (1)	1,739	1,513	2,155	33,141	38,548
Income before income taxes	48,487	51,833	64,510	98,530	263,360
Income tax provision (benefit) (2)	(41,579)	1,706	19,648	24,569	4,344
Net income	$ 90,066	$ 50,127	$ 44,862	$ 73,961	$ 259,016
Basic net income per share	$ 2.02	$ 1.11	$ 1.00	$ 1.64	$ 5.77
Diluted net income per share	$ 1.95	$ 1.09	$ 0.97	$ 1.60	$ 5.61

	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 (benefit) (2)(3)	(3,582)	7,981	32,208	11,660	48,267
Net income	$ 37,374	$ 24,503	$ 13,446	$ 36,847	$ 112,170
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) In fiscal 2019, the Company invested $25.0 million in medical device company Shockwave Medical. The fair value of this investment as of March 31, 2019 was $56.2 million and the Company recognized a gain of $31.2 million in Other income.

(2) 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.

(3) 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 provision for the years ended March 31, 2019 and 2018 included excess tax benefits of $69.3 million and $31.0 million, respectively. These recognized excess tax benefits resulted from restricted stock units that vested or stock options that were exercised during the years ended March 31, 2019 and 2018.

OFFICES

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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 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, 2019. Readers are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this annual report. Except as required by law 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.
Senior Vice President and Chief Operating Officer

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

TODD A. TRAPP
Vice President and Chief Financial Officer

ANDREW J. GREENFIELD
Vice President and Chief Commercial Officer

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

THORSTEN SIESS, PH.D.
Vice President and Chief Technology Officer

SETH BILAZARIAN, M.D.
Vice President and Chief Medical Officer

MARC A. BEGAN
Vice President, General Counsel and Secretary

BOARD OF DIRECTORS

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

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

JEANNINE M. RIVET
Former 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
Chief Executive Officer and Founder, Prominex

CHRISTOPHER D. VAN GORDER, FACHE
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.

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