ABIOMED INC
Form 10-K
May 24, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended March 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-09585

ABIOMED, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

(978) 646-1400

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:	Name of Each Exchange on Which Registered:
Common Stock, $.01 par value	The NASDAQ Stock Market LLC

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

None

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of the Form 10-K or any amendment to this Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	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 Exchange Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most

recently completed second fiscal quarter was $7,452,252,182. As of May 8, 2018, 44,477,837 shares of the registrant's common stock, $.01 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement for Abiomed, Inc.'s 2018 Annual Meeting of Stockholders, which is scheduled to be filed within 120 days after the end of Abiomed, Inc.'s fiscal year, are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) of this Form 10-K.

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NOTE REGARDING TRADEMARKS AND REGISTERED MARKS

ABIOMED, IMPELLA, IMPELLA 2.5, IMPELLA 5.0, IMPELLA LD, IMPELLA CP, IMPELLA RP, IMPELLA BTR, IMPELLA 5.5, and IMPELLA ECP are registered marks or trademarks of ABIOMED, Inc., and are registered in the U.S. and certain foreign countries. AB5000 and cVAD REGISTRY are trademarks of ABIOMED, Inc.

NOTE REGARDING COMPANY REFERENCES

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

PART I

ITEM 1. BUSINESS

Overview

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

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

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

In September 2017, we received FDA approval of a PMA for the Impella RP heart pump. The Impella RP heart pump is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥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 as stated in the indication.

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

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

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

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

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

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

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

Corporate Background

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

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

Our Existing Products

Impella 2.5®

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

The Impella 2.5 device received 510(k) clearance from the FDA in June 2008 for partial circulatory support for up to six hours. In March 2015, we received PMA approval from the FDA for the use of the Impella 2.5 device during elective and urgent high-risk PCI procedures. With this PMA approval, the Impella 2.5 device became the first FDA approved hemodynamic support device for use during high-risk PCI procedures. Under this first PMA, the Impella 2.5 is a temporary (up to six hours) ventricular support device indicated for use during high-risk PCI performed in elective

or urgent hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 device in these patients may prevent hemodynamic instability that may occur during planned temporary coronary occlusions and may reduce periprocedural and post-procedural adverse events. The product labeling allows for the clinical decision by physicians to leave the Impella 2.5 device in place beyond the intended duration of up to six hours should unforeseen circumstances arise.

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

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

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

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

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

Impella CP®

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

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

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

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

should unforeseen circumstances arise.

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

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

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

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

Impella 5.0® and Impella LD®

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

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

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

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

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

Impella RP®

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

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

In September 2017, we received FDA approval of a PMA for the Impella RP heart pump. This latest approval follows the prior FDA HDE received in January 2015 and adds the Impella RP heart pump to our platform of PMA approved devices. The Impella RP heart pump is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥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 as stated in the indication.

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

Our Product Pipeline

Impella 5.5™

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

Impella ECP™

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

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

Impella BTR™

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

Summary of Recent Financial Performance

For fiscal 2018, we recognized net income of $112.2 million, or $2.54 per basic share and $2.45 per diluted share, compared to $52.1 million, or $1.21 per basic share and $1.17 per diluted share for the prior fiscal year. For fiscal year

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

Our Markets

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

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

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

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

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

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

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

Research and Product Development

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

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

Sales, Clinical Support, Marketing and Field Service

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

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

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

Manufacturing

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

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

Intellectual Property

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

A substantial portion of our intellectual property rights relating to the Impella devices and other products under development, such as the Impella 5.5™, Impella ECP™, and Impella BTR™ devices, are in the form of trade secrets, rather than patents. We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants and other parties. We cannot assure you that our trade secrets will not become known to or be independently developed by our competitors.

We own or have rights to numerous U.S. and foreign patents. Our U.S. patents have expiration dates ranging from 2018 to 2035 and our foreign patents have expiration dates ranging from 2018 to 2032. We also own or have rights to certain pending U.S. and foreign patent applications. We believe patents will issue pursuant to such applications, but cannot guarantee it. Moreover, neither the timing of any issuance, the scope of protection, nor the actual issue date of these pending applications can be forecasted with precision. Where we have licensed patent rights from third parties, we could be required to pay royalties.

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

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

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

Competition

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

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

increasingly important for medical technology manufacturers.

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

Third-Party Reimbursement

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

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

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

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

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

In April 2018, CMS released a proposed set of hospital payment levels for patient discharges after October 1, 2018. The April 2018 Proposed Rule for the Inpatient Prospective Payment System, or IPPS, update includes ICD-10 coding and assignment of percutaneous Impella implantation to MS-DRG 215 for Other Heart Assist System Implant. The Proposed Rule also maintained bi-ventricular Impella support in MS-DRG 1-2 assignments, and Impella hospital transfer and support in MS-DRG 268-269 for the receiving hospital. Impella related procedures were previously

assigned to MS-DRG 216-221 for assistance in the catheterization lab only, and were reimbursed at a lower rate than MS-DRG 215 and MS-DRGs 1-2. A designated DRG 215 code will simplify coding and enable hospitals to receive payment in multiple settings and indications. The MS-DRG 215 proposed rate is lower than the previous year based on the CMS process to evaluate hospital charges, length of stay, patient comorbidities, taking into account hospital efficiencies over the prior year. The proposed rule for IPPS is open for public comment until June 2018. The final rulemaking may differ substantially from this proposal and will take effect October 1, 2018.

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

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

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

Government Regulation and Other Matters

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

United States Regulation

In the U.S., the FDA has responsibility for regulating medical devices under the authority of the Federal Food, Drug and Cosmetic Act, or 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 substantial delays that adversely affect the marketing and sale of our products. A number of our products are pending regulatory clearance or approval to begin commercial sales in various markets. Ultimately, the FDA may not authorize the commercial release of a medical device if it determines the device is not safe and effective or does not meet other standards for clearance or approval. Additionally, even if a product is cleared or approved, the FDA may require postmarket testing and surveillance programs to monitor the effects of these products once commercialized.

The FDA has the authority to halt the distribution of certain medical devices, detain or seize adulterated or misbranded medical devices, order the repair, replacement, or refund of the costs of such devices, or preclude the importation of devices that are or appear to be violative. The FDA also conducts inspections to determine compliance with the QSR

concerning the manufacturing and design of devices and medical device reporting regulations, recall regulations, clinical testing regulations, and other requirements. The FDA may withdraw product clearances or approvals due to failure to comply with regulatory standards, or the occurrence of unforeseen problems following initial approval, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. Additionally, the failure to comply with FDA or comparable regulatory standards or the discovery of previously unknown product problems could result in fines, delays, or suspensions of regulatory clearances or approvals, seizures, injunctions, recalls, refunds, civil money penalties, or criminal prosecution. Our compliance with applicable regulatory requirements is subject to continual review. Moreover, the FDA and several other U.S. agencies administer controls over the export of medical devices from the U.S. and the import of devices into the U.S., which could also subject us to sanctions for noncompliance.

Premarket Regulation

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

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

When clinical trials of a device are required in order to obtain FDA approval, the sponsor of the trial is generally required to file an IDE application before commencing the trials. The FDA reviews and must approve an IDE before a clinical study may begin in the U.S. In addition, the clinical study must be approved by an Institutional Review Board, or IRB, at each clinical site. The FDA, the IRB, or we may suspend a clinical trial at any time for various reasons, including if information emerges suggesting that the subjects are being exposed to an unacceptable health risk. All

clinical studies of investigational devices must be conducted in compliance with FDA requirements. Following the completion of a study, the data from the study must be collected, analyzed and presented in an appropriate submission to the FDA, either as a report submitted to the IDE file or in a marketing application such as a PMA.

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

Postmarket Regulation

The medical devices that we manufacture and distribute pursuant to regulatory clearances or approvals by the FDA and other countries' regulatory authorities are subject to continuing regulation by those agencies. The FDA reviews design, manufacturing, and distribution practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. Among other FDA requirements, we must comply with the FDA's good manufacturing practice regulations for medical devices, known as the QSR. These regulations govern the methods used in, and the facilities and controls used for, the design, testing, manufacture, packaging, labeling, storage, installation, and servicing of all finished medical devices intended for human use. We must also comply with Medical Device Reporting, or MDR requirements, which require us to report to the FDA any incident in any of our products that may have caused or contributed to a death or serious injury, including medical intervention to prevent a death or serious injury, or in which any of our products malfunctioned and, if such malfunction were to recur, would be likely to cause or contribute to a death or serious injury. Labeling, advertising, and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. The FDA's enforcement policy prohibits the marketing of approved medical devices for unapproved uses. We are subject to routine inspection by the FDA for compliance with the QSR and MDR requirements, as well as other applicable regulations. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, and require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also seek a judicial injunction enjoining certain violations of the FFDCA and imposing operating restrictions and assess civil or criminal fines and penalties against our officers, employees, or us. The FDA may also recommend criminal prosecution to the U.S. Department of Justice. Conduct giving rise to civil or criminal penalties may also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by our conduct. Regulatory authorities outside the U.S. enforce similar laws and regulations within their respective jurisdictions.

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. If the FDA or another regulatory agency determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion.

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

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

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

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

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

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

International Regulation

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

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

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

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

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

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

Health Care Initiatives

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

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

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

Health Care Reform

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

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

Other Regulations

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

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

Seasonality

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

Employees

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

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

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

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider these risks as well as the other information we include or incorporate by reference in this report, including our consolidated financial statements and the related notes. The risks and uncertainties we have described are not the only ones we face. If any of these risks materialize, the trading price of our common stock could fall and you could lose all or part of your investment.

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

Risks Related to Our Business

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

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

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

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

Competition from other companies offering circulatory care products is intense and subject to rapid technological change and evolving industry requirements and standards. We compete with companies that have substantially greater or broader financial, product development, sales and marketing resources and experience than we do. Our ability to compete effectively depends upon our ability to distinguish our company and our products from our competitors and their products. Factors affecting our competitive position include:

- the availability of other products and procedures that are technically equivalent or superior to our products, and which may be sold at lower prices;
- product performance and design;

- product safety;
- sales, marketing and distribution capabilities;
- comparable clinical outcomes;
- success and timing of new product development and introductions;
- physician and hospital acceptance of our products;

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

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

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

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

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. We have experienced significant growth in recent years in which we have expanded our operations and we have increased our employee headcount. This growth has placed significant demands on our management as well as our financial and operations resources. In order to achieve our business objectives, we will need to continue to grow. However, continued growth presents numerous challenges, including:

- developing our global sales, marketing and administrative infrastructure and capabilities;
- expanding manufacturing capacity, maintaining quality and increasing production;
- increasing our foreign and domestic regulatory compliance capabilities;
- implementing appropriate operational, financial and IT systems and internal controls;
- identifying, attracting and retaining qualified personnel, particularly experienced clinical staff; and
- hiring, training, managing and supervising our personnel worldwide.

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

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

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

- limitations inherent in first-generation devices, and our potential inability to develop successive improvements, including increases in service life and improvements in the ease of use of our products;
- introduction by other companies of new treatments, products and technologies that compete with our products;
-

timing and amount of reimbursement for these products, if any, by third-party payers;

- potential reluctance of clinicians and hospitals to obtain and support adequate training to use our products;
- cost of our products; and
- potential reluctance of physicians, patients, hospitals and society as a whole to accept medical devices that replace or assist the heart and risk of mechanical failure inherent in such devices.

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

Medical devices such as ours are extensively regulated by the FDA in the U.S. and by other federal, state, local and foreign authorities. Governmental regulations relate to the testing, development, manufacturing, labeling, design, sale, promotion, distribution, importing, exporting and shipping of our products. In the U.S., before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we must generally first receive PMA from the FDA. This process can be expensive and lengthy, and can entail significant expenses, primarily related to clinical trials. It generally takes between one to three years to receive approval, or even longer, from the time the PMA application is submitted to the FDA. Regulatory clearances or approvals, either foreign or domestic, may not be granted on a timely basis, if at all. If we are unable to obtain regulatory approvals or clearances for use of our products under development, or if the patient populations for which they are approved are not sufficiently broad, the commercial success of these products could be limited. The FDA may also limit the claims that we can make about our products. Any significant modifications to the design, materials, or intended use of those devices require FDA approval through PMA or HDE supplemental applications.

If we do not receive FDA approval for one or more of our products, we will be unable to market and sell those products in the U.S., which would have a material adverse effect on our operations and prospects.

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

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

The FDA, the U.S. Department of Justice, the Office of the Inspector General of Department of Health and Human Services, and other regulatory or enforcement agencies actively enforce regulations prohibiting the promotion of unapproved medical devices and the promotion of otherwise approved or cleared medical devices for unapproved uses. If any such agency determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products, such agencies could disagree and conclude that we have engaged in off-label promotion.

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

Off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

The use of our products outside their approved indications for use, or “off-label use,” may increase the risk of injury to patients. Clinicians may use our products for off-label uses, as the FDA does not restrict or regulate a clinician’s choice of treatment within the practice of medicine. Off-label use of our products may increase the risk of product liability

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

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

The regulatory approval process for new products and new indications for existing products often requires extensive clinical trials and procedures, including early clinical feasibility studies. Unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding such clinical data, could adversely affect both our ability to obtain necessary approvals and the market's view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these clinical trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. Failure to successfully complete these clinical trials or procedures in a timely and cost-effective manner could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures may be contradicted by subsequent clinical analysis. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be delayed, suspended, or terminated by us, the FDA, or other regulatory authorities at any time, if it is believed that the trial participants face unacceptable health risks or for numerous other reasons. The FDA may disagree with our interpretation of the data from our clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety and effectiveness of the product candidate. The FDA may also require additional pre-clinical studies or clinical trials which could further delay approval of our products.

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

The FDA and other regulatory agencies continue to review products even after they have received initial approval. If and when the FDA or another regulatory agency clears or approves our products under development, the manufacture and marketing of these products will be subject to continuing regulation, post-approval clinical studies, including compliance with the FDA's adverse event reporting requirements, prohibitions on promoting a product for unapproved uses, and Quality System Regulation, or QSR, requirements, which obligate manufacturers, including third-party and contract manufacturers, to adhere to stringent design, testing, control, documentation and other quality assurance procedures during the design and manufacture of a device.

Any modification to an FDA approved device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a supplemental PMA or HDE approval. The FDA requires each manufacturer to determine in the first instance whether a modification requires approval, but the FDA may review and potentially disagree with any such decision. Modifications of this type are common with new products. We anticipate that the first generation of each of our products will undergo a number of changes, refinements, enhancements and improvements over time. If the FDA requires us to seek approval for modification of a previously approved product for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval and we may be subject to significant regulatory fines or penalties, which could have a material adverse effect on our financial results and competitive position. We also cannot assure you that we will be successful in obtaining clearances or approvals for our modifications, if required. We and our third-party suppliers of product components are also subject to inspection and market surveillance by the FDA and other regulatory agencies for QSR and our regulatory other requirements, the interpretation of which can change. Compliance with QSR and similar legal requirements can be difficult and expensive. Enforcement actions resulting from failure to comply with government requirements could result in fines,

suspensions of approvals or clearances, recalls or seizure of products, operating restrictions or shutdown, and criminal prosecutions that could adversely affect the manufacture and marketing of our products. The FDA or another regulatory agency could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements, the occurrence of unanticipated safety problems 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.

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

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

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

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

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

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

In March 2010, the U.S. federal government enacted the Affordable Care Act, or ACA, which made changes to the manner in which many healthcare services are provided and paid for in the U.S. The ACA includes provisions that, among other things, reduce or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose increased taxes on certain companies and individuals. Results of the recent U.S. elections in 2016 have created a political environment in which substantial portions of the ACA could be repealed or revised. Recent tax reform legislation removes the financial penalty for individuals who do not have health insurance

effective in 2019. In addition, proposed changes in regulations would allow wider availability of health insurance that does not provide coverage for all of the essential health benefits required under the ACA. It remains unclear what other portions of the ACA may remain, or what any replacement or alternative programs may be created by any future legislation or regulation. Any such future actions may have significant impact on the reimbursement for healthcare services generally, including reducing significantly the number of Americans who have health insurance, which could lead our health care provider customers to be more cost conscious. Accordingly, our business and results of operations could therefore be adversely affected by any future federal or state healthcare reform legislation or regulation.

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

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

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

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

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

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

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

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

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

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

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

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

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

We are devoting most of our research and development and regulatory efforts, and significant financial resources, to the development of our Impella devices and product extensions of existing commercial products and new products. The development of new products and product extensions presents enormous challenges in a variety of areas, including blood compatible surfaces, blood compatible flow, manufacturing techniques, pumping mechanisms, physiological control, energy transfer, anatomical fit and surgical techniques. We may be unable to overcome all of these challenges, which could adversely affect our results of operations and prospects and limit our ability to bring new products to market.

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

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

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

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

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

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

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

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

inhibit our revenue growth.

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

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

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

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

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

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

Some of our suppliers may be the only source for a particular component, which makes us vulnerable to significant cost increases or shortage of supply. We have many foreign suppliers for some of our parts in which we are subject to currency exchange rate volatility. Some of our vendors are small in size and may have difficulty supplying the quantity and quality of materials required for our products as our business grows. Vendors that are the sole source of certain products may decide to limit or eliminate sales of certain components due to product liability or other concerns and we might not be able to find a suitable replacement for those products. Our inventory may run out before we find alternative suppliers and we might be forced to purchase substantial inventory, if available, to last until we are able to qualify an alternate supplier. If we cannot obtain a necessary component, we may need to find, test and obtain regulatory approval or clearance for a replacement component, produce the component ourselves or redesign the related product, which would cause significant delay and could increase our manufacturing costs. Any of these events could adversely impact our results of operations.

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

We are seeking to expand our international sales of our products by recruiting direct sales and support teams outside the U.S. Our international operations in Germany, Japan, France, Canada, the United Kingdom and Singapore are or will be subject to a number of risks, which may vary from the risks we experience in the U.S., including:

- the need to obtain regulatory approvals in foreign countries before our products may be sold or used;
- the need to procure reimbursement for our products in each foreign market;
    - the generally lower level of reimbursement available in foreign markets relative to the U.S.;
- the requirement to work with distributors or other partners to sell our products;
- longer sales cycles;
- limited protection of intellectual property rights;
- difficulty and delays in collecting accounts receivable;
- different income tax and sales tax environments;

- difficulty in supporting patients using our products;
- difficulty in attracting employees in foreign countries who want to work for a smaller U.S. based company;
- different payroll, employee benefits and statutory requirements;
- fluctuations in the values of foreign currencies; and
- political and economic instability.

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

We rely on distributors to sell our products in some international markets and poor performance by a distributor could reduce our sales and harm our business.

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

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

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

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

Our operating results may fluctuate unpredictably.

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

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

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

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

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

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

On December 22, 2017, the Tax Cuts and Jobs Act, or Tax Reform, was signed into law that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains

significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a rate of 21%, effective January 1, 2018, limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after fiscal 2018 and elimination of net operating loss carrybacks, revisions to the treatment for U.S. federal income tax purposes of foreign earnings, immediate deductions for certain new investments instead of deductions for depreciation

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

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

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

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

Our intellectual property rights are and will continue to be a critical component of our success. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, copyright, trade secret and domain name protection laws, as well as confidentiality agreements with our employees and others, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from using our proprietary technologies or from marketing products that are very similar or identical to ours.

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

Our business position also depends in part on our ability to maintain and defend our existing patents and obtain, maintain, and defend additional patents and other intellectual property rights. We intend to seek additional patents, but our pending and future patent applications may not result in issued patents or be granted on a timely basis. In addition, issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. The scope of our patent claims also may vary between countries, as individual countries have distinctive patent laws. We may be subject to challenges by third parties regarding our intellectual property, including, among others, claims regarding validity, enforceability, scope and effective term. Patent prosecution, related proceedings, and litigation in the U.S. and in other countries may be expensive, time consuming and ultimately unsuccessful. In addition, patents issued by foreign countries may afford less protection than is available under U.S. patent law and may not adequately protect our proprietary information. Our competitors may independently develop proprietary technologies and processes that are the same as or substantially equivalent to ours or design around our patents. Our competition may also hold or obtain intellectual property rights that would threaten our ability to develop or commercialize our product offerings. The expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect our business and our prospects.

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

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

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

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

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

The risk of product liability claims is heightened when we sell products that are intended to support a patient until the end of life. The finite life of our products, as well as complications associated with their use, could give rise to product liability claims whether or not the products have extended or improved the quality of a patient’s life. If we have to pay product liability claims in excess of our insurance coverage, our financial condition will be adversely affected.

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

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

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

We rely in part on information technology to store information, interface with customers, maintain financial accuracy, secure our data and accurately produce our financial statements. If our information technology systems do not

effectively and securely collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations would be materially impaired. Any such impairment could have a material adverse effect on our results of operations, financial condition and the timeliness with which we report our operating results.

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

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

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

We may pursue acquisitions to obtain complementary businesses, products or technologies. Any such acquisition may not produce the revenues, earnings or business synergies that we anticipate and an acquired business, product or technology might not perform as we expect. Our management could spend a significant amount of time, effort and money in identifying, pursuing and completing the acquisition. If we complete an acquisition, we may encounter significant difficulties and incur substantial expenses in integrating the operations and personnel of the acquired company into our operations. In particular, we may lose the services of key employees of the acquired company and we may make changes in management that impair the acquired company’s relationships with its legacy employees, vendors and customers. Additionally, we may acquire development-stage companies that are not yet profitable and which require continued investment, which could decrease our future earnings. We may assume significant liabilities in such a transaction.

Any of these outcomes could prevent us from realizing the anticipated benefits of an acquisition. To pay for an acquisition, we might use stock or cash. Alternatively, we might borrow money from a bank or other lender. If we use stock, our stockholders would experience dilution of their ownership interests. If we use cash or debt financing, our financial liquidity would be reduced.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

The market price of our common stock is volatile.

The market price of our common stock has fluctuated widely and may continue to do so. For example, from April 1, 2017 to March 31, 2018, the price of our stock ranged from a low of $117.37 per share to a high of $304.28 per share. Many factors could cause the market price of our common stock to rise and fall. Some of these factors are:

- variations in our quarterly results of operations;
- status of regulatory approvals for our products;
- introduction of new products by us or our competitors;
- acquisitions or strategic alliances involving us or our competitors;
- changes in healthcare policy or third-party reimbursement practices;
- changes in estimates of our performance or recommendations by securities analysts;
- the hiring or departure of key personnel;
- results of clinical trials of our products;
- notice of a recall or other safety issue that impacts the ability for customers to use our products;
- future sales of shares of common stock in the public market;
- the outcome of currently pending litigation and governmental investigations, or the initiation of additional litigation or government investigations against the company; and
- market conditions in the industry, particularly around reimbursement for our products and the economy as a whole.

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

The sale of additional shares of our common stock, the issuance of restricted stock units or the exercise of outstanding options to purchase our common stock, would dilute our stockholders' ownership interest.

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

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

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

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

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

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

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on our stockholders' investment will only occur if our stock price appreciates.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate offices are located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923. The locations and uses of our major properties as of March 31, 2018, are listed below:

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 and Administration
Aachen, Germany	(1)	Research and Development, Regulatory and Clinical Affairs, Manufacturing, Administration, Marketing, Distribution
Berlin, Germany	(2)	Research and Development
Tokyo, Japan	(2)	Administration, Regulatory and Clinical Affairs, Marketing, Distribution

(1) Owned properties

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

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

(2) Leased properties

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

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

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

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Price

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

	High	Low
Fiscal Year Ended March 31, 2018		
First Quarter	$ 147.45	$ 117.37
Second Quarter	171.00	139.55
Third Quarter	200.28	164.80
Fourth Quarter	304.28	188.05

	High	Low
Fiscal Year Ended March 31, 2017		
First Quarter	$ 109.66	$ 92.03
Second Quarter	131.16	108.77
Third Quarter	132.95	95.14
Fourth Quarter	126.04	103.53

Number of Stockholders

As of May 8, 2018, we had approximately 471 holders of record of our common stock and there were approximately 74,029 beneficial holders of our common stock. Many beneficial holders hold their stock through depositories, banks and brokers included as a single holder in the single "street" name of each respective depository, bank, or broker.

Dividends

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

Performance Graph

The following graph compares the yearly change in the cumulative total stockholder return for our last five full fiscal years, based upon the market price of our common stock, with the cumulative total return on a NASDAQ Composite Index (U.S. Companies) and a peer group, the NASDAQ Medical Equipment-SIC Code 3840-3849 Index, which is comprised of medical equipment companies, for that period. The performance graph assumes the investment of $100 on March 31, 2013 in our Common Stock, the NASDAQ Composite Index (U.S. Companies) and the peer group index, and the reinvestment of any and all dividends.

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

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

Transfer Agent

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

ITEM 6. SELECTED FINANCIAL DATA

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

SELECTED CONSOLIDATED FINANCIAL DATA

(In thousands, except per share data)

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

(1) The Tax Reform Act, among other items, reduces the U.S. federal statutory corporate income tax rate from 35% to 21% effective January 1, 2018. During the year ended March 31, 2018, the Company recorded tax expense adjustments for $21.4 million related to the revaluation of its deferred taxes due to a reduction of the U.S. federal statutory corporate income tax rate.

(2)

In the first quarter of fiscal 2018, the Company adopted ASU 2016-09 which requires that all excess tax benefits and tax deficiencies related share-based compensation arrangements be recognized as income tax benefit or expense, instead of in stockholders' equity as previous guidance required. The income tax benefit for the year ended March 31, 2018 included excess tax benefits of $31.0 million. These recognized excess tax benefits resulted from restricted stock units that vested or stock options that were exercised during the year ended March 31, 2018.

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

(4) This reflects a $35.1 million reclassification of current deferred tax assets to long-term deferred tax assets on the March 31, 2015 consolidated balance sheet due to the adoption of ASU No. 2015-17, Income Taxes (Topic 740)—Balance Sheet Classification of Deferred Taxes. This reclassification did not impact working capital at March 31, 2014 due to the full valuation allowance on deferred tax assets for those years.

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

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

Overview

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

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

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

In September 2017, we received FDA approval of a PMA for the Impella RP heart pump. The Impella RP heart pump is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥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 February 2018, we received two expanded PMA approvals from the FDA for our Impella heart pumps. The first expanded approval is for use of Impella 2.5, CP, 5.0 and LD heart pumps on patients with cardiogenic shock associated with cardiomyopathy, including peripartum and postpartum cardiomyopathy. The second expanded PMA approval is for use of the Impella 2.5 and Impella CP heart pumps during elective and high-risk PCI procedures. This expanded PMA approval confirms Impella support as appropriate in patients with severe coronary artery disease,

complex anatomy and extensive comorbidities, with or without depressed ejection fraction.

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

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

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

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

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

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

Summary of Recent Financial Performance

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

Critical Accounting Policies and Estimates

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

Revenue Recognition

We recognize revenue when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectability is reasonably assured.

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

Maintenance and service support contract revenues are included in revenue and are recognized ratably over the service contract term. Revenue is recognized as it is earned in limited instances where we rent console medical devices to

customers on a month-to-month basis or for a longer specified period of time. Other service revenues are recognized as the services are performed.

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

Income Taxes

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

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

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

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

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

Recent Accounting Pronouncements

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

Results of Operations

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

	Fiscal Years Ended March 31,		
	2018	2017	2016
Revenue	100.0 %	100.0 %	100.0 %

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

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

Revenue

Our revenue is comprised of the following:

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

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

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

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

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

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

Costs and Expenses

Cost of Revenue

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

Research and Development Expenses

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

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

Selling, General and Administrative Expenses

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

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

Income Tax Provision

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

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

Net Income

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

Fiscal Years Ended March 31, 2017 and March 31, 2016 ("fiscal 2017" and "fiscal 2016")

Revenue

Our revenue is comprised of the following:

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

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

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

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

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

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

Costs and Expenses

Cost of Revenue

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

Research and Development Expenses

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

Selling, General and Administrative Expenses

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

Income Tax Provision

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

Net Income

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

Liquidity and Capital Resources

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

A summary of our cash flow activities is as follows:

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

Cash Provided by Operating Activities

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

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

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

revenues, a $11.5 million increase in inventory as we build up inventory safety stock to support growing demand for our Impella devices, a $7.4 million increase in accounts payable and accrued expenses due to increase in operating expenses.

Cash Used in Investing Activities

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

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

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

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

Cash Provided by Financing Activities

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

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

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

Operating Capital and Liquidity Requirements

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

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

funded our operations through product sales and the sale of equity securities.

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

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

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

Contractual Obligations and Commercial Commitments

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

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

(1) See Note 11 to our consolidated financial statements entitled "Commitments and Contingencies—Leases" for disclosures related to our operating lease obligations.

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

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

Investment and Interest Rate Risk

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

Currency Exchange Rates

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

Concentrations of Risk

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

Other Investment Risk

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of March 31, 2018. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of March 31, 2018, these disclosure controls and procedures were effective to provide reasonable assurance that material information required to be disclosed by us, including our consolidated subsidiaries, in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Evaluation of Changes in Internal Control over Financial Reporting

During the fourth quarter of our fiscal year ended March 31, 2018, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we assessed the effectiveness of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment under the framework in Internal Control—Integrated Framework (2013), our management concluded that our internal control over financial reporting was effective as of March 31, 2018.

Important Considerations

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

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

Deloitte & Touche LLP, an independent registered public accounting firm that audited our financial statements for the fiscal year ended March 31, 2018, included in this annual report, has issued an attestation report on the effectiveness of our internal control over financial reporting. This report is set forth below:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of

ABIOMED, Inc.

Opinion on Internal Control over Financial Reporting

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

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

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance

with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts

May 24, 2018

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTOR, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

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

ITEM 11. EXECUTIVE COMPENSATION

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

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

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

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

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

(1) The financial statements from our Annual Report for our fiscal year ending March 31, 2018 are attached hereto.

(2) Consolidated financial statement schedule

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

(3) Exhibits

EXHIBIT INDEX

		Filed with	Incorporated by Reference		
Exhibit		this Form			Exhibit
No.	Description	10-K	Form	Filing Date	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	Restated By-Laws, as amended.		10-K (File No.	May 27, 2004	3.2

		001-09585)		
3.3*	Certificate of Designations of Series A Junior Participating Preferred Stock—filed as Exhibit 3.3 to the 1997 Registration Statement.	S-3	September 29, 1997	3.3
3.4	Amendment to the Company's Restated Certificate of Incorporation to increase the authorized shares of common stock from 25,000,000 to 100,000,000.	8-K (File No. 001-09585)	March 21, 2007	3.4
4.1[P]	Specimen Certificate of common stock.	S-1	June 5, 1987	4.1
10.1*[P]	Form of Indemnification Agreement for Directors and Officers.	S-1	June 5, 1987	10.13
10.2*	Amendment to 1992 Combination Stock Option Plan.	10-Q (File No. 001-09585)	October 14, 1997	10.2
10.3*	1988 Employee Stock Purchase Plan, as amended.	10-Q (File No. 001-09585)	February 8, 2005	10.11
10.4*	1989 Non-Qualified Stock Option Plan for Non-Employee Directors.	10-Q (File No. 001-09585)	October 27, 1995	10.1

Exhibit No.	Description	Filed with this Form	Incorporated by Reference		
		10-K	Form	Filing Date	Exhibit No.
10.5*	1998 Equity Incentive Plan.		10-Q/A (File No. 001-09585)	January 8, 1999	10
10.6*	2000 Stock Incentive Plan Agreement, as amended.		Sch. 14A (File No. 001-09585)	July 15, 2005	Appendix A
10.7*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Directors.		10-Q (File No. 001-09585)	February 9, 2006	10.16
10.8*	Form of Abiomed, Inc. Non-Statutory Stock Option Agreement for the 2000 Stock Incentive Plan for Employees or Consultants.		10-Q (File No. 001-09585)	February 9, 2006	10.17
10.9*	Fourth Amended and Restated 2008 Stock Incentive Plan.		10-K (File No. 001-09585)	May 28, 2015	10.9
10.10*	Form of Non-Statutory Stock Option Agreement for Employees and Consultants under 2008 Stock Incentive Plan.		8-K (File No. 001-09585)	August 18, 2008	10.1
10.11*	Form of Non-Statutory Stock Option Agreement for Non-Employee Directors under 2008 Stock Incentive Plan.		8-K (File No. 001-09585)	August 18, 2008	10.2
10.12*	Form of Restricted Stock Agreement under 2008 Stock Incentive Plan.		8-K (File No. 001-09585)	August 18, 2008	10.3
10.13*	2015 Omnibus Incentive Plan.		Sch. 14A (File No. 001-09585)	July 2, 2015	Appendix A
10.14*	Form of TSR Award (Performance and Time-Based RSU).		10-Q (File No. 001-09585)	August 6, 2015	10.4
10.15*	TSR Award Agreement (Performance- and Time-Based RSU) of Michael R. Minogue dated November 14, 2016.		10-Q (File No. 001-09585)	February 3, 2017	10.1

10.16*	Form of Employee Time-Based RSU Agreement under the 2015 Omnibus Incentive Plan.	10-K (File No. 001-09585)	May 25, 2017	10.16
10.17*	Form of Non-Employee Director Time-Based RSU Agreement under the 2015 Omnibus Incentive Plan.	10-Q (File No. 001-09585)	February 5, 2016	10.4
10.18*	Form of Field Employee Time-Based Option Agreement under the 2015 Omnibus Incentive Plan.	10-K (File No. 001-09585)	May 25, 2017	10.18
10.19*	Form of Performance-Based RSU Agreement under the 2015 Omnibus Incentive Plan.	10-K (File No. 001-09585)	May 25, 2017	10.19
10.20*	Form of Non-Employee Director Time-Based Option Agreement.	10-Q (File No. 001-09585)	February 5, 2016	10.7
10.21*	Employment Agreement of Michael R. Minogue dated April 5, 2004 (including Change in Control Agreement).	10-Q (File No. 001-09585)	August 9, 2004	10.10
10.22*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008.	10-Q (File No. 001-09585)	February 9, 2009	10.3
10.23*	Amendment to Employment Agreement with Michael R. Minogue dated December 31, 2008.	10-Q (File No. 001-09585)	February 9, 2009	10.4
10.24*	Inducement stock option granted to Michael R. Minogue dated April 5, 2004.	10-Q (File No. 001-09585)	August 9, 2004	10.11

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

		001-09585)		
10.35	Purchase and Sale Agreement dated as of December 9, 2015 between Abiomed, Inc. and Thibeault Nominee Trust.	10-Q (File No. 001-09585)	February 5, 2016	10.1
10.36	First Amendment to Purchase and Sale Agreement dated as of January 19, 2016 between Abiomed, Inc. and Thibeault Nominee Trust.	10-Q (File No. 001-09585)	February 5, 2016	10.2
10.37	Lease Agreement dated August 12, 2016 between Abiomed, Inc. and Leo C. Thibeault, Jr., Trustee of the Thibeault Nominee Trust.	10-Q (File No. 001-09585)	November 4, 2016	10.1
10.38	Purchase and Sale Agreement dated as of December 16, 2016 between Abiomed, Inc. and gewoge AG and Thibeault Nominee Trust for the facility located in Aachen, Germany	10-K (File No. 001-09585)	May 25, 2017	10.42
10.39*	Form of Employee Time-Based Option Agreement under the 2015 Omnibus Incentive Plan.	10-K (File No. 001-09585)	May 25, 2017	10.43

Exhibit No.	Description	Filed with this Form 10-K	Incorporated by Reference Form	Filing Date	Exhibit No.
10.40	Notice of Exercise of Option to Buy, dated September 12, 2017.		10-Q (File No. 001-09585)	November 2, 2017	10.1
10.41	Lease agreement for additional space in Danvers, Massachusetts dated February 2, 2017		10-Q (File No. 001-09585)	February 6, 2018	10.1
10.42	Lease agreement amendment for additional space in Danvers, Massachusetts dated December 14, 2017		10-Q (File No. 001-09585)	February 6, 2018	10.2
10.43*	Offer letter with Todd A. Trapp dated March 30, 2018	X			
10.44*	Change of Control Severance Agreement between Abiomed, Inc. and Todd Trapp dated April 6, 2018	X			
10.45	Lease Agreement for Additional Space in Danvers, Massachusetts dated March 2, 2018	X			
11.1	Statement regarding computation of Per Share Earnings (see Note 2, Notes to Consolidated Financial Statements).	X			
21.1	Subsidiaries of the Registrant.	X			
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm.	X			
31.1	Rule 13a—14(a)/15d—14(a) certification of principal executive officer.	X			
31.2	Rule 13a—14(a)/15d—14(a) certification of principal accounting officer.	X			
32.1	Section 1350 certification.	X			
101		X			

	The following financial information from the ABIOMED, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of March 31, 2018 and 2017; (ii) Consolidated Statements of Operations for the fiscal years ended March 31, 2018, 2017 and 2016; (iii) Consolidated Statements of Comprehensive Income for the fiscal years ended March 31, 2018, 2017 and 2016; (iv) Consolidated Statements of Stockholders' Equity for the fiscal years ended March 2018, 2017 and 2016; (v) Consolidated Statements of Cash Flows for the fiscal years ended March 31, 2018, 2017 and 2016; and (vi) Notes to Consolidated Financial Statements.

*Management contract or compensatory plan.
PExhibit filed by paper

Item 16.Form 10-K Summary.

None.

SIGNATURES

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

ABIOMED, Inc.

Dated: May 24, 2018 By /s/ TODD A. TRAPP
Todd A. Trapp
Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

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

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

/s/ CHRIS D. VAN GORDER	Director	May 24, 2018
Chris D. Van Gorder		

ABIOMED, INC.

Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of

ABIOMED, Inc.

Opinion on the Financial Statements

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

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

Change in Accounting Principle

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

Basis for Opinion

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

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts

May 24, 2018

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

ABIOMED, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(in thousands, except share data)

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

Total stockholders' equity	689,524	452,071
Total liabilities and stockholders' equity	$786,375	$550,414

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

ABIOMED, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(in thousands, except per share data)

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

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

ABIOMED, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Income

(in thousands)

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

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, March 31, 2015	41,335,773	$ 413	1,282,944	$ (19,347)	$ 465,046	$ (137,222)	$ (17,330)	$ 291,560
Restricted stock units issued	507,471	5	-	-	(5)	-	-	-
Stock options exercised	829,385	8	-	-	9,763	-	-	9,771
Stock issued under employee stock purchase plan	16,772	-	-	-	1,135	-	-	